Study on the monitoring of the implementation of Directive 2006/52/EC as regards the use of nitrites by industry in different categories of meat products

Final report

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Title	Study on the monitoring of the implementation of Directive 2006/52/EC as regards the use of nitrites by industry in different categories of meat products
Conducted for	European Commission, Directorate-General for Health and Food Safety
By	Food Chain Evaluation Consortium (Civic Consulting - Agra CEAS Consulting - Arcadia International - Van Dijk Management Consultants)
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ABSTRACT

The study on the monitoring of the implementation of Directive 2006/52/EC as regards the use of nitrites by industry in different categories of meat products led by Civic Consulting of the Food Chain Evaluation Consortium aimed to collect technological data about the need for nitrites and information on the use of nitrites in different types of meat products and meat preparations in the EU in view of exploring the possibility of reviewing the current maximum levels of nitrites as authorised in the legislation. Based on data collected through a literature review, a survey and an expert workshop conducted for this study, results indicate that there is a possibility to review the current maximum levels of nitrites authorised. This conclusion is consistent with the lower levels currently authorised in Denmark, as well as the previous experience in countries such as Finland or Germany, where stricter maximum levels were applied in the past.

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LIST OF ABBREVIATIONS

ADI	Acceptable Daily Intake
AVEC	Association of Poultry Processors and Poultry Trade in the EU
CLITRAVI	Liaison Center for the Meat Processing Industry in the EU
DG SANTE	Directorate General for Health and Food Safety
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
IARC	International Agency for Research on Cancer
IBC	International Butchers' Confederation
IMTA	International Meat Trade Association
MS	Member State(s)
ppm	Parts per million (10^{-6} or equivalent to mg/kg)
TOR	Terms of Reference
WHO	World Health Organization

1. EXECUTIVE SUMMARY

The European Commission has launched a study on the monitoring of the implementation of Directive 2006/52/EC as regards the use of nitrites by industry in different categories of meat products. The purpose of the study was to collect technological data about the need for nitrites and information on the use of nitrites in different types of meat products and meat preparations in the EU. This specific purpose relates to the wider aim of clarifying the real technological need for nitrites in order to explore the possibility of reviewing the current maximum levels of nitrites as established by relevant EU legislation. The study was led by Civic Consulting of the Food Chain Evaluation Consortium.

To examine the technological need for nitrites, the use of nitrites by meat producers and possible alternatives to the use of nitrites, the study followed three methodological steps:

- Survey within the EU meat industry about the use and use levels of nitrite in the different categories of meat products and preparations;
- Literature research on the use of nitrites in meat and the effect on colour, taste and preservation, including protection against Clostridium botulinum, and the possible formation of nitrosamines; and
- Workshop with a panel of experts in meat technology with specific experience on the use of nitrite and its effect on colour, taste and preservation.

Through these methodological tools, the study gathered information on the following key issues: the use and use levels of nitrites in meat products and preparations in the EU; the effect of nitrite on meat colour, taste, and preservation; the formation of nitrosamines; and possible alternatives to the use of nitrites. Finally, using the evidence collected on these issues, the study examined possibility to review the current maximum levels of nitrites authorised in the EU legislation.

1.1. The use and use levels of nitrites in meat products and preparations

Concerning the levels of nitrites currently used in the EU, results of our survey of meat business operators, their organisations and other stakeholders show that for many categories of meat products and preparations, the typical levels used by producers vary widely: for the same product category, e.g. non-heat treated processed meat derived from minced red meat, reported typical use levels ranged between 15.6 mg/kg and 180 mg/kg of added nitrite, the latter value being significantly above the limit of 150 mg/kg provided in the legislation. According to the experts in the workshop panel, two key reasons can serve to explain this wide variation in reported use levels for non-traditional products and preparations. On one hand, producers may use excessive amounts of nitrite due to a lack of awareness of the legal limits. On the other hand, the results point to the unwillingness of some producers to use lower amounts than provided in traditional recipes or in the legislation. By contrast, country differences are not considered to be relevant in explaining the diverging levels of nitrites used.

The conclusions arising from these findings are threefold: Firstly, there is a need for raising awareness of producers concerning the maximum amounts of nitrites authorised in the EU, which should be coupled with a better enforcement of the legislation. This double objective could be achieved by providing both producers and inspectors with guidance and tools to allow them to calculate and monitor the use levels of nitrites. Moreover, producers could be required to report the levels used in their production processes and to provide recipes and other documentation, such as amounts and concentrations of curing salt purchased/used in a specified production period, to ensure better enforcement. A simpler categorisation of products, based on technological processes, could also contribute to a better alignment of practices with the legal provisions.

Secondly, it can be concluded that at least to some extent, producers may use the legislation as a benchmark for the amount of nitrites they add to their meat products and preparations. This conclusion is supported by the results of the EC's 2013 desk study, which found that for otherwise identical products, companies adapted their use levels depending on whether the product was intended to be delivered to the Danish market for example, or to other EU countries. Thus, in an effort to remain "on the safe side", producers may be hesitant to deviate from the legal limits or from traditional recipes that do not take into account improvements in hygiene practices.

Finally, evidence from producers typically using nitrite levels at the lower end of the distribution suggests that there is scope for reducing the amount of nitrites used. This conclusion is based on the practical experience of producers as observed through survey results, but it is also confirmed to a certain extent by examining the findings concerning the effect of nitrite on meat colour, taste and preservation.

1.2. **The effect of nitrite on meat colour, taste and preservation**

Results from the study relating to the technological need for nitrites confirm that nitrites have an important role in current production processes for achieving the typical cured colour and flavour and for ensuring microbiological safety. For colouring purposes, results of the expert panel suggest that levels between 55 to 70 mg/kg of nitrites added is sufficient for colour formation in non-traditional meat products and preparations, with 80 mg/kg of added nitrite a meaningful point of reference for ensuring colour stability. For traditional products, 20 to 30 mg/kg of residual nitrite is according to the panel an appropriate range to ensure colour stability in most traditional meat products (with 40 to 50 mg/kg suggested for some traditional products). Similarly, a range between 50 to 80 mg/kg of added nitrite provides meaningful guidance for safeguarding taste-related aspects in non-traditional products and preparations. For traditional products, values between 30 to 50 mg/kg of residual nitrite are considered by the panel to suffice for flavouring purposes.

Concerning the minimum level of nitrite required to ensure microbiological safety, most members of the expert panel that had an opinion regarding this aspect agreed that the range of 80 to 100 mg/kg of nitrite added would be reasonably safe for a majority of products when used in combination with other hurdles. However, the panel also emphasised that it is not possible to reach a firm conclusion for all products and all situations, acknowledging that microbiological safety is dependent upon a large number of factors. The panel concluded that a reduction of maximum levels to 100 mg/kg of added nitrite would be sufficient for a majority of products without significant effects on colour, flavour and microbiological safety (which would have to be demonstrated, e.g. by reference to countries in which such limits are or were in place, or other evidence). For some products, a higher concentration of nitrite would be required, e.g. for fermented products. It is notable that several countries in the past have applied even stricter maximum levels, and nitrite-free processed meat products are on the market in various countries. Abolishing the use of nitrites in meat products and preparations – while not supported by the panel – would be technically feasible if the production processes underwent technological changes. The panel found that without the presence of nitrites, microbiological safety can be ensured if a correct combination of key parameters such as water activity, pH, storage temperature, and shelf life are achieved. The panel also underlined the importance of packaging for ensuring the microbiological safety of meat products. Abolishing nitrites would primarily affect traditional products, for which production processes would need to change so that the product would not remain the same.

1.3. The formation of nitrosamines

Although curing salt containing nitrite has been historically used for preservation purposes and for inducing the desired flavour and colour of cured meat, since the 1970s there has been concern about the formation of nitrosamines resulting from the use of nitrite in meat production. Acknowledging that the use of nitrites in meat may lead to the formation of nitrosamines, the EU legislation in place seeks to find a balance between the need for microbiological safety and the risk of nitrosamine formation.

While the link between ingoing amounts of nitrite and nitrosamine formation has not been established, previous studies have suggested the correlation is positive, though not necessarily linear. On the other hand, results from the literature review and expert workshop conducted for this study suggest that there is strong evidence of the link between the consumption of processed meat, endogeneous nitrosamine formation and an increased risk of colorectoral cancer.

Three potential routes for nitrosamine formation in meat products have been documented: in the course of the production process (in situ), during the subsequent preparation of meat products at home, as well as in the gastro-intestinal tract (in vivo) following consumption. Although the extent to which nitrosamines are formed in the gastro-intestinal tract is difficult to detect, results of the survey and of the expert workshop suggest that in vivo nitrosamine formation and nitrosamines formed during the preparation of products at home are likely to be more relevant routes than nitrosamines formed in the production process. Moreover, several factors that increase the risk of nitrosamine formation were identified in the expert workshop and literature review: these include the intense heating of meat products (e.g. through frying, baking or barbecuing) and the presence of black pepper.

As a result, the study has identified several measures that can be taken to reduce the risk of nitrosamine formation in meat products and preparations. In addition to avoiding intense heat treatment and the use of pepper, measures that can be taken by producers discussed in the literature and expert workshop include following good production practices and adding compounds that can scavenge the reactive nitrogen species, such as ascorbate. According to the expert panel, consumers can also decrease their exposure to nitrosamines by cleaning their pans and barbecue grills after cooking meat. Finally, a reduction in the use of nitrites has been suggested in the literature as a way of decreasing exposure to nitrosamines.

1.4. Possible alternatives to the use of nitrites

Given the risk of nitrosamine formation related to the use of nitrites in meat products and preparations, in the 1970s and 1980s pressure mounted to reduce nitrate and/or nitrite addition to meat products and even to eliminate them completely.[1] As a result, past and ongoing research has sought to find alternatives for achieving protection against microbiological activity and for inducing the desired colour and flavour in meat

[1] European Food Safety Authority (EFSA), "Opinion of the Scientific Panel on Biological Hazards on the Effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products", The EFSA Journal, Vol. 14, 2003, pp. 1–31.

products. In some countries, the meat industry has attempted to reduce the levels of nitrites used by replacing them with various natural substances or other additives.

In the workshop discussion concerning possible alternatives to nitrites, a number of experts provided insight concerning meat products that are produced in their Member State without the addition of nitrites. For instance, in Germany several such products exist, which also do not contain organic sources of nitrate such as fermented celery extract. These products have a shorter shelf-life and tend to be vacuum-packed. In the Netherlands, products without nitrites have been on the market for ten years, without incurring problems related to microbiological safety. Other companies in this country produce organic products with 60 or 80 mg/kg of nitrite added, whose safety is ensured through a shorter shelf life and a lower storage temperature. A member of the expert panel clarified that the production of Parma-type dry-cured ham, which does not involve the use of nitrite, uses a specific technology based on refrigeration at a low temperature until water activity (a_w) reaches a value of 0.96, followed by a long maturation period. A combination of these factors ensures that the product is safe.

The literature reviewed in the course of this study identified a number of alternatives for achieving the technological uses of nitrites. These included e.g. organic acids such as lactate and diacetate (for preservation), fermented red rice and plant extracts (for colour and taste). Moreover, in the course of the expert workshop, a number of existing additives were discussed that aim to achieve microbiological safety (e.g. nisin, ethyl lauroyl arginate and essential oils) or that are added for colouring and flavouring purposes (e.g. lycopene, tomato paste, phytochemicals), although but none were found by the panel to produce adequate results.

In addition, results from the survey, literature research, and expert workshop have suggested that there is currently no single alternative that can fulfill all three technological needs (colour, flavour, microbiological safety). The panel concluded that while there is no adequate replacement for nitrite that would allow for the production of the products currently on the market, existing alternatives might be helpful in reducing the amount of ingoing nitrite.

1.5. **The possibility to review the current maximum levels of nitrites used**

Taken together, these conclusions indicate that there is a possibility to review the current maximum levels of nitrites authorised in the legislation. This conclusion is consistent with the lower levels authorised in Denmark, as well as the previous experience in countries such as Finland or Germany, where stricter maximum levels were applied in the past. If a review of maximum levels were to take place in the EU, the results of the study suggest that it would be beneficial to base new maximum levels on a simpler categorisation of meat products and preparations, preferably related to the technological processes used. Moreover, a revised limit could be introduced that would apply for most products, with a process put in place for industry to identify products for which a higher limit needs to apply due to safety considerations. Assuming that a review of the maximum levels would aim to reduce exposure to nitrite, a key suggestion related to the need for regulating nitrite (NO_3) and nitrate (NO_2) together in order to avoid producers reducing nitrite levels while simultaneously increasing nitrate levels to compensate the reduction.

2. INTRODUCTION

This final report presents the results of the ad-hoc study on the monitoring of the implementation of Directive 2006/52/EC as regards the use of nitrites by industry in different categories of meat products for the Directorate General for Health and Food Safety (DG SANTE) of the European Commission. The study was led by Civic Consulting of the Food Chain Evaluation Consortium (FCEC).

The report is structured as follows:

- Section 3 presents the objectives and the scope of the study;
- Section 4 provides the background to the study, including a description of the current legislation in place and an overview of the key issues related to the use of nitrites in meat products and preparations;
- Section 5 describes the methodological approach of the study, outlining each of the Tasks carried out;
- Section 6 presents the results of the study concerning the general use of nitrites in meat, as well as the levels of nitrites used in the different categories of meat products and preparations in the EU;
- Section 7 provides the results of the study regarding the effects of nitrite on meat colour, taste and preservation;
- Section 8 presents the study results related to the formation of nitrosamines arising from the use of nitrites in meat;
- Section 9 discusses results concerning the alternatives to nitrites which are currently in development, testing, or use;
- Section 10 provides the results from the survey and expert workshop related to the possibility of reviewing the current maximum level of nitrites authorised in the legislation and concludes on this overarching question taking into account the evidence collected throughout the study; and
- The Annexes contain a complete list of the literature reviewed under Task 2, the survey questionnaire used for Task 3, data tables presenting survey results, and the summary notes from the expert workshop carried out in the context of this study.

3. OBJECTIVES AND SCOPE OF THE STUDY

3.1. Purpose and objectives of the study

According to the Terms of Reference (TOR), the purpose of the study was to collect technological data about the need for nitrites and information on the use of nitrites in different types of meat products and meat preparations in the EU. This specific purpose relates to the wider aim of clarifying the real technological need for nitrites in order to explore the possibility of reviewing the current maximum levels of nitrites as established by relevant EU legislation.

3.2. Geographical coverage and time period

The study focused on the current use and use levels of nitrite in the meat industry, as well as on the current technological needs and effects on colour, taste and preservation, including for the protection against Clostridium botulinum. The study covered the 28 EU Member States, though some literature reviewed relates also to third countries.

3.3. Scope

In addition to outlining the specific and operational objectives of the study, as well as its legal basis and general context, the TOR define the four methodological steps that have been followed in the implementation of the study.

These are as follows:

- A survey within the EU meat industry about the use and use levels of nitrite in the different categories of meat products/preparations;
- Literature research on the use of nitrites in meat and the effect on colour, taste and preservation, including protection against Clostridium botulinum, and the possible formation of nitrosamines;
- The organisation of a workshop with a panel of experts (maximum 15 experts) in meat technology with specific experience on the use of nitrite and its effect on colour, taste and preservation, representing the variety of meat products/preparations on the EU market; and
- A report on the possibility to review the current maximum levels, taking into account the conclusions of the first three points.

These methodological steps are described in greater detail under Section 5.

4. BACKGROUND TO THE STUDY

4.1. The EU legislative framework for nitrites

Food additives have been regulated in the European Union for many years under the Framework Directive 89/107/EEC and by a series of subsequent directives and regulations. Indicative levels of nitrites and residual amounts allowed were originally established in Directive 95/2/EC on food additives other than colours and sweeteners. The 1995 directive was then amended with Directive 2006/52/EC, which, with the exception of certain products, replaced "indicative ingoing amounts" with maximum amounts of nitrite that may be added during the manufacturing process. The new directive distinguished between sterilised meat products, and non-sterilised meat products, providing a new maximum limit for the former (100 mg/kg and 150 mg/kg respectively). Furthermore, Directive 2006/52/EC differentiated between various traditional products and curing methods, providing maximum levels permitted in these products. Due to the large number of varieties of curing products and manufacturing methods, the directive specifies that the category limits apply also to "similar products."

In 2006, a series of reforms were launched by the European Commission with the aim of modernising legislation on food additives, flavourings and enzymes. In 2008, existing legislation was consolidated into four simplified regulations, collectively known as the Food Improvement Agent Package (FIAP), guaranteeing the free movement of food while ensuring a high level of consumer protection and greater freedom of choice between different foodstuffs. As part of the legislative package, Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 sets out the conditions for the approval of additives and harmonising standards across Member States for their use, and repeals the previous directives on food additives. Annex II of Regulation 1333/2008 contains a list of authorised additives, including nitrites and their maximum authorised levels to be added to meat products and traditional meat preparations. As indicated in the Terms of Reference, this regulation constitutes the legal basis of this study. A series of regulations amended Annex II of Regulation 1333/2008, including Commission Regulation (EU) 1129/2011 (EC), applicable as of June 2013. It provides the current legal basis for the maximum levels of nitrite allowed, adding new traditional products to the meat categories previously established by Directive 2006/52/EC. The most recent legislation related to the use of nitrites is Commission Regulation (EU) No 601/2014, which also amends Annex II of Regulation 1333/2008 by expanding the list of products for which nitrites are authorised to certain meat preparations. This Regulation also acknowledges that meat preparations may be either processed or unprocessed.

Regulation 1333/2008 also introduces the principle that food additives should be kept under continuous observation. In this context, all currently authorised food additives are subject to a re-evaluation by EFSA in accordance with Commission Regulation (EU) No 257/2010 that sets up a programme for the re-evaluation of approved food additives. EFSA has scheduled to examine the safety of nitrites in the framework of this re-evaluation.

4.2. **The use of nitrites in meat**

4.2.1. *Preservation and microbiological safety*

Meat and meat products are extremely perishable foodstuffs due to the high level of moisture contained within them, the favourable level of pH for microbial activity, and the richness of proteins, peptides and amino acids.[2] Unless proper preservation and storage is applied, microbial activity and proliferation is largely inevitable. A micro-organism occasionally found in meat is *Clostridium botulinum*, a harmful anaerobic bacterium that is widely present in the environment (soil, river and sea water).

The toxins produced by C. botulinum are responsible for causing botulism, a disease with a mortality rate of 5 to 10 percent of cases. According to the World Health Organization (WHO), these toxins are amongst the most lethal substances known, capable of blocking nerve functions and leading to respiratory and muscular paralysis. Foodborne botulism occurs through the ingestion of improperly processed food, particularly of vegetables, fish, and meat, in which C. botulinum has multiplied and produced the toxin. Prevention of the disease is thus primarily achieved through careful food preservation and hygiene, particularly using measures that prevent bacterial growth and toxin production.[3] One such method is the addition of nitrites to certain food products during the manufacturing process. These are used in the form of sodium nitrite and potassium nitrite (labelled as E250 and E249 respectively). The antimicrobial property of nitrites, when combined with a number of other factors, limits the risk of botulism by preventing the growth of bacterial spores of C. botulinum.

According to the European Food Safety Authority (EFSA), it has generally been recognized since the 1970s that the level of nitrites needed to prevent botulism is based on product-specific factors and therefore must be determined individually for each class of products. These factors include salt and pH levels, heat treatment, spore and iron levels in the meat, as well as the presence of other additives and the nature of competing flora.[4] Therefore, depending on the products and curing methods used, different amounts of nitrites are added during the manufacturing process, and various maximum levels are authorized in the relevant legislation. The main categories of products and curing methods are described below.

4.2.2. *Curing of meat using nitrites*

The term “cured meat products” refers to products to which curing salts (usually sodium chloride) and nitrites or nitrates have been added.[5] Although historically, salt was used to preserve fish and meat products, over time it became clear that potassium nitrite was responsible for the preservative effects. Current manufacturing processes use sodium nitrite, potassium nitrite, and nitrates to achieve this effect,

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[2] European Food Safety Authority (EFSA), “Opinion of the Scientific Panel on Biological Hazards on the Effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products,” *The EFSA Journal*, Vol. 14, 2003, pp. 1–31.
[3] World Health Organization (WHO), “Botulism,” 2013. http://www.who.int/mediacentre/factsheets/fs270/en/.
[4] Sindelar, Jeffrey J, and Andrew L Milkowski, “Sodium Nitrite in Processed Meat and Poultry Meats: A Review of Curing and Examining the Risk/Benefit of Its Use,” *American Meat Science Association White Paper Series*, Vol. 3, 2011.
[5] European Food Safety Authority (EFSA), “Opinion of the Scientific Panel on Biological Hazards on the Effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products,” *The EFSA Journal*, Vol. 14, 2003, p.1.

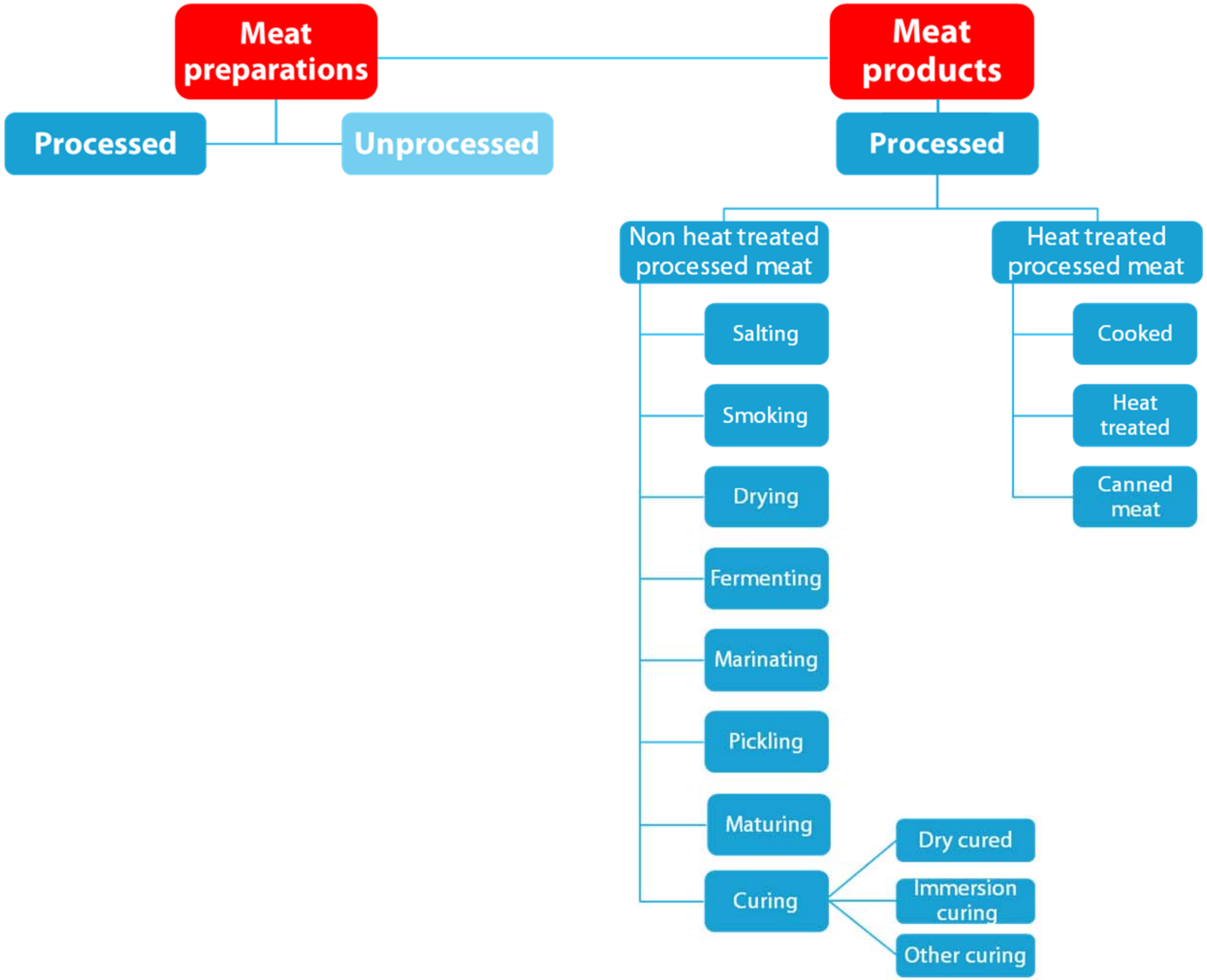
though the latter is used less frequently, and reserved mainly for products such as dry sausages and dry cured hams.[6]

A key distinction to be made in studying the microbiological safety of meat is between non-proteolytic strains of C. botulinum and proteolytic strains of the bacterium. Non-proteolytic strains are significantly sensitive to heat, and thus spores of C. botulinum can be effectively inactivated by heating the meat at 90°C for at least 10 minutes (as used for the manufacture of refrigerated, processed foods of extended durability, such as canned meats). After this treatment, no health risk is considered to remain. Proteolytic strains, however, are more resistant to such treatment, and therefore a higher temperature is needed to destruct the spores. In some products, the use of a so-called "botulinum cook" requiring three minutes of heating at 121°C is not viable due to resulting undesirable changes in the appearance and flavour of the meat. Therefore, a range of alternative and combined curing methods are used for different products.[7] The figure below presents the various categories of meat products according to the processing method used.

[6] Ibidem.

[7] European Food Safety Authority (EFSA), "Opinion of the Scientific Panel on Biological Hazards on the Effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products," *The EFSA Journal*, Vol. 14, 2003, p. 19.

Figure 1: Categories of meat products and preparations



Source: Civic Consulting on the basis of Guidance document describing the food categories in part E of Annex II to Regulation (EC) No 1333/2008.

Research shows that for meats that are cooked as part of the curing process, levels of 50 to 100 mg of sodium nitrite added per kilogram of meat are sufficient to prevent the growth and toxin production of C. botulinum.[8] However, many types of products exist that are cured using processes that do not (or do not solely) involve cooking. The most recent European legislation regulating the maximum levels of nitrites to be used in meat products identifies six categories of meat products in which nitrites may be used:

- Non heat treated processed meat;
- Heat treated processed meat;
- Traditional immersion cured products;
- Traditional dry cured products;
- Other traditionally cured products;
- Meat preparations.[9]

In the legislation, *non heat treated processed meat* (1) refers to products that are processed through curing, salting, smoking, drying, fermenting, marinating, pickling or maturing in order to preserve and extend the shelf life of meats.[10]

Heat-treated processed meats (2) includes products that are cooked, heat-treated (including sterilised) and canned meat cuts.[11]

Traditional immersion cured products (3) refers to meat products that are cured by immersion in a curing solution containing nitrites and/or nitrates, salt, and other components. This category includes products with a curing time ranging between three and 21 days. Additional processes may include injections of curing solution into the products, pre-cooking, smoking, and time allowed for stabilisation and maturation, depending on the product. Examples of meat products found in this category include cured tongue, bacon, Wiltshire ham and bacon, and similar products. A complete list is provided at the end of this background section.

Traditional dry cured products (4) are prepared using a dry curing process, involving the dry application of a curing mixture containing nitrites and/or nitrates, salt, and other components to the surface of the meat. The process is followed by a period of stabilisation or maturation. Dry curing can take between four and 15 days, depending on the product. Products prepared according to this method include dry cured ham and dry cured bacon.

Other traditionally cured products (5) may include a combination of immersion and dry cured processes, processes where nitrite and/or nitrate is included in a compound product, or where the curing solution is injected into the product prior to cooking. This category covers a variety of products such as jellied veal and brisket.

Meat preparations (6) refers to an exhaustive list of traditional goods produced in various Member States and to which nitrites may be added. These are: *lomo de cerdo adobado, pincho moruno, careta de cerdo adobada, Costilla de cerdo adobada, Kasseler, Bräte,*

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[8] Ibidem.
[9] European Commission, "Annex II to Regulation 1333/2008 of the European Parliament and of the Council of 16 December 2008 on Food Additives," *Official Journal of the European Union*, 2008 (OJ L354, 31.12.2008, p.16)
[10] European Commission, *Guidance Document Describing the Food Categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives*, 2013. http://ec.europa.eu/food/food/fAEF/additives/docs/guidance_1333-2008_descriptors_annex2_20131218_en.pdf.
[11] Ibidem.

Surfleisch, toorvorst, šašlõkk, ahjupraad, kiełbasa surowa biała, kiełbasa surowa metka, and *tatar wołowy (danie tatarskie).*

4.2.3. *Technological uses*

In addition to their use for preservation and bacterial growth prevention, nitrites are added to meat products for their effect on colour and taste. In particular, nitrite is known for "fixing" the desirable and characteristic shaded pink or red colour of meat. It is used both for inducing and maintaining the colour throughout an extended shelf-life. Though some studies have shown that relatively small quantities of nitrite are necessary to induce a cured colour, others have reported that significantly higher concentrations of the substance are required to maintain colour and prevent rapid fading, especially for products with a longer shelf-life period.[12] The effect of nitrite on meat occurs when the nitrite ion is transformed into nitric oxide, which reacts with myoglobin to produce the characteristic colour.[13]

Nitrites are also used in the food industry for their enhancing effect on meat flavour. Although the chemical reactions associated with nitrites as a flavouring agent are less well documented, sensory analyses and comparisons between nitrosated samples and nitrite-free samples consistently show that consumers perceive a distinction between the two. Meat products to which nitrites have been added are reported to contain a stronger and more typical flavour, and are ranked higher in terms of consumer taste. The use of nitrites contributes to the delay of lipid oxidation, thus preventing the development of a rancid taste.[14]

4.3. **Possible formation of nitrosamines**

Despite the sensorial benefits of using nitrites in meat products and the substantial increase in microbiology safety the substance provides, the use of nitrites in meat has raised controversy in the past decades. In particular, there was concern in the 1970s and 1980s over occasional findings of endogenously formed N-nitroso compounds with the potential to yield nitrosamines, which are carcinogenic.[15] Nitrite – and nitrate, when it is reduced to nitrite in foods and endogenously – can form the potentially carcinogenic N-nitroso compounds when it is ingested in the following process: nitrite is acidified to form nitrous acid; following dimerization and dehydration, it forms nitrous anhydride, which then reacts with amines to form nitrosamines. The process, which requires an acidic environment in the first step of the reaction, occurs mainly in the stomach.[16] In addition to the endogenous (*in vivo*) process of nitrosamine formation described above, research has shown that N-nitroso compounds may also be formed *in situ*; i.e. in the course of the production process.[17] This occurs when nitrite reacts with secondary or tertiary amines in the meat, which have undergone a transformation due to enzymatic

[12] Sindelar, Jeffrey J, and Andrew L Milkowski, "Sodium Nitrite in Processed Meat and Poultry Meats: A Review of Curing and Examining the Risk/Benefit of Its Use," *American Meat Science Association White Paper Series*, Vol. 3, 2011. p.2

[13] World Health Organization International Agency for Research on Cancer, "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans," Vol. 94, 2010. p. 66

[14] Sindelar, Jeffrey J, and Andrew L Milkowski, "Sodium Nitrite in Processed Meat and Poultry Meats: A Review of Curing and Examining the Risk/Benefit of Its Use," *American Meat Science Association White Paper Series*, Vol. 3, 2011. p. 4.

[15] European Food Safety Authority (EFSA), "Opinion of the Scientific Panel on Biological Hazards on the Effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products," *The EFSA Journal*, Vol. 14, 2003, p.12.

[16] World Health Organization International Agency for Research on Cancer, "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans," Vol. 94, 2010. p. 275.

[17] Debeuckelaere, Wim, *Les nitrosamines dans les aliments dans cinq pays de l'Union europeenne*, 1999. p.10

and bacterial activity. The presence of nitrosamines in meat products tends to increase in concentration with time, temperature and acidity.[18]

Thus, the main sources of N-nitroso compounds have been found to be nitrite-preserved meat products.[19] In particular, cured products that are heated or fried before consumption – such as bacon – are a major source of dietary exposure to nitrosamines.[20] This concern is already reflected in the 1990 and 1995 opinions of the Scientific Committee on Food (SCF),[21] which recommends limiting exposure to preformed nitrosamines in food by lowering the amount of nitrites added to food.

In 2006, the International Agency for Research on Cancer (IARC) conducted a review of the carcinogenic nature of nitrites. The 2010 IARC monograph summarising the results of this review found that although "there is limited evidence in humans for the carcinogenicity of nitrite in food", "ingested nitrate or nitrite under conditions that result in endogenous nitrosation is probably carcinogenic to humans […]".[22] The subsequent EU legislation (Annex II of Regulation 1333/2008 as amended by Regulation 1129/2011) establishing the limits of nitrites to be used in meat products is consistent with this position, specifying that the use of nitrites in meat may lead to the formation of nitrosamines. Therefore, the legislation seeks to find a balance between the need for microbiological safety and the risk of nitrosamine formation. It also reaffirms the need to discuss the possibility of reducing current maximum levels of the use of nitrites and to further simplify the rules for the traditionally manufactured products.

More recently, in October 2015, a Working Group of 22 experts from 10 countries convened by the IARC Monographs Programme classified processed meat as carcinogenic to humans (Group 1). The classification was said to be based on sufficient evidence in humans that the consumption of processed meat causes colorectal cancer. Moreover, the Working Group noted that a positive association with the consumption of processed meat was found for stomach cancer. According to a summary of the evaluation, "Meat processing, such as curing and smoking, can result in formation of carcinogenic chemicals, including N-nitroso-compounds (NOC) and polycyclic aromatic hydrocarbons (PAH)."[23]

4.4. **Current maximum levels on the use of nitrites in meat products**

4.4.1. *Input levels vs. residual amounts*

It should be reminded that the limits of nitrite use in non heat treated processed meats and heat treated processed meats as specified in Annex II of Regulation 1333/2008 refer to maximum amounts that may be added during the manufacturing process. This is in line with EFSA's 2003 opinion, which argues that "the ingoing amount of nitrite, rather than the residual amount, contributes to the inhibitory activity against C. botulinum," and that therefore, "control of nitrite in cured meat products should be via the input levels

[18] U.S. Department of Health and Human Services, National Toxicology Program, "Report on Carcinogens," Ed. 13, 2013.
[19] World Health Organization International Agency for Research on Cancer, "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans," Vol. 94, 2010, p. 72.
[20] Adler-Nissen, Jens, Maria Helbo Ekgreen, and Jorgen Risum, *Practical Use of Nitrite and Basis for Dosage in the Manufacture of Meat Products*, 2014.
[21] Along with four other scientific committees giving the European Commission advice on food safety, the Scientific Committee on Food (SCF), established in 1974, was transferred to the European Food Safety Authority (EFSA) in 2003.
[22] World Health Organization International Agency for Research on Cancer, "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans," Vol. 94, 2010, p.325.
[23] World Health Organization International Agency for Research on Cancer, "Carcinogenicity of Consumption of Red and Processed Meat", Lancet Oncology, Vol. 2045, No. 15, 2015, pp. 1–2.

rather than the residual amounts."[24] However, for most of the traditional cured products, maximum residual limits are given and these apply to the residual nitrite levels as measured at the end of the production process. According to Annex II of Regulation (EC) No 1333/2008, the specification of residual levels is exceptionally permitted for traditionally manufactured meat products on the condition that those products are adequately specified and identified. Moreover, the maximum residual levels should not result in intake levels above the ADI established in 1990.

4.4.2. *Danish national provisions*

Under Article 114(4) of the Treaty on the Functioning of the European Union, Member States are permitted to maintain national provisions following the adoption of a harmonisation measure by the European Parliament and Council, by the Council or by the Commission, subject to the Commission's approval. In light of this, Denmark notified the Commission in 2007 that it would request to maintain its national provisions, which set a maximum limit of nitrites below those established in Annex II of Regulation 1333/2008 for most product categories. The Member State justified this request claiming its own legislation would ensure a higher level of protection of health and human life than the limits provided by EU legislation.

Denmark was granted the right to maintain its national provisions in Commission Decision 2008/448/EC, which found that this would not constitute an obstacle to the functioning of the internal market. The 2008 Commission Decision provided authorisation for the Danish national provisions up to 2010, after which a second Decision (2010/561/EU) further prolonged the approval. The divergence between Danish and European nitrites standards had already been brought to light in previous years. Indeed, while implementing Directive 95/2/EC in 1996, Denmark had informed the Commission about the more stringent levels fixed in its own legislation, and requested to keep its national provisions in place. In 1999, the Commission rejected Denmark's request in the 1999/830/EC Decision, which was ultimately annulled after Denmark challenged the decision in the European Court of Justice.

As a result of these arrangements concerning Denmark's national provisions, the maximum levels that apply to meat products marketed in Denmark are generally lower than in the remainder of the EU.[25] For instance, while bacon in the EU may contain 175 mg/kg of residual nitrite, in Denmark, this maximum is set at 150 mg/kg. It should be noted that while EU legislation uses both maximum residual amounts and maximum added amounts, Danish provisions concern only maximum added amounts, which makes comparisons between the two provisions more difficult. None of the maximum limits on products accounted for in the Danish provisions exceed 150 mg/kg.

The table below presents the current maximum levels of nitrites applicable to the EU.

[24] European Food Safety Authority (EFSA), "Opinion of the Scientific Panel on Biological Hazards on the Effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products," *The EFSA Journal*, Vol. 14, 2003, p. 27.

[25] European Commission, "Commission Decision 2008/448/EC," Official Journal of the European Union, 2008, pp. 98–107.

Table 1: Current maximum limits on use of nitrites in meat products as permitted by EU legislation

Food category	Restrictions/exceptions	Maximum level (mg/kg)
Non heat treated processed meat	N/A	150[a]
Heat treated processed meat	Except sterilised meat products	150[a][d]
	Only sterilised meat products	100[a][c][d]
Traditional immersion cured products	Only Wiltshire bacon and similar products	175[b]
	Only Wiltshire ham and similar products	100[b]
	Only Entremeada, entrecosto, chispe, orelheira e cabeca (salgados), toucinho fumado and similar products	175[b]
	Only cured tongue	50[b]
	Only kylmâsavustettu poronliha/kallrökt renkött	150[a]
	Only bacon, filet de bacon and similar products	150[a]
	Only rohschinken, nassgepökelt and similar products	50[b]
Traditional dry cured products	Only dry cured bacon and similar products	175[b]
	Only dry cured ham and similar products	100[b]
	Only presunto, presunto da pa and paio do lombo and similar products	100[b]
	Only rohschinken, trockengepökelt and similar products	50[b]
Other traditionally cured products	Only rohschinken, trocken-/nasgepökelt and similar products	50[b]
	Only jellied veal and brisket	50[b]
	Only vysočina, selský salám, turistický trvanlivý salám, poličan, herkules, lovecký salám, dunjaská klobása, paprikás and similar products	180[a]
Meat preparations	Only lomo de cerdo adobado, pincho moruno, careta de cerdo adobada, Costilla de cerdo adobada, Kasseler, Bräte, Surfleisch, toorvorst, šašlõkk, ahjupraad, kiełbasa surowa biała, kiełbasa surowa metka, and tatar wołowy (danie tatarskie)	150[a]

Notes: (a) Maximum added amount; (b) Maximum residual amount, residue level at the end of the production process; (c): Fo-value 3 is equivalent to 3 minutes heating at 121 °C (reduction of the bacterial load of one billion spores in each 1 000 cans to one spore in a thousand cans); (d) Nitrates may be present in some heat-treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment. Source: Compiled by Civic Consulting, using data from Commission Regulation (EU) No 1129/2011 and Commission Regulation (EU) No 601/2014.

In the following table the categories are altered to converge with those used by the Danish maximum levels, where possible.

Table 2: Maximum amounts of nitrite as permitted by EU legislation and Danish legislation

EU product category	Maximum ingoing amount (EU, mg/kg)	Maximum residual amount (EU, mg/kg)	Danish product category	Maximum ingoing amount (DK, mg/kg)
Sterilised meat products				
Sterilised meat products	100		Helkonserverede produkter	100
Traditional pickle cured products				
Wiltshire bacon		175	Wiltshire bacon og udskæringer heraf	
Various Iberian bacon types		175		
Wiltshire ham		100		
Rohschinken, nassgepökelt		50	Spegeskinker	
Traditional dry cured products				
Dry cured bacon		175		
Dry cured ham		100		
Various Iberian dry cured hams		100		
Rohschinken, trochengepökelt		50	Spegeskinker	150
Other traditional cured products				
Rohschinken, trocken/nassgepökelt		50	Ikke-varmebehandlede kødprodukter fremstillet af hele kødstykker samt udskivede stykker heraf	60
Jellied veal and brisket		50	Varmebehandlede do Rullepølse Leverpostej, kødboller Halvkonserverede produkter – hele kødstykker	60 100 0 150
Various Central European sausages	180		Ikke-varmebehandlede kødprodukter fremstillet af findelt kød samt udskivede stykker af produkterne Fermenterede spegepølser Varmebehandlede kødprodukter fremstillet af findelt kød samt udskivede stykker af produkterne	60 100 60

			Halvkonserverede produkter findelt kød	150
Meat preparations				
Only lomo de cerdo adobado, pincho moruno, careta de cerdo adobada, Costilla de cerdo adobada, Kasseler, Bräte, Surfleisch, toorvorst, šašlõkk, ahjupraad, kiełbasa surowa biała, kiełbasa surowa metka, and tatar wołowy (danie tatarskie)	150			

Source: Compiled by Civic Consulting using data from Adler-Nissen, Jens, Maria Helbo Ekgreen, and Jorgen Risum, Practical Use of Nitrite and Basis for Dosage in the Manufacture of Meat Products, 2014.

4.5. Revision of maximum levels

Following Denmark's 2007 request and the two consecutive approvals by the Commission, EFSA was asked to urgently assess the data provided by the Danish authorities in order to determine whether it (or any other recent scientific developments) provided scientific evidence for a revision for the maximum limits on nitrites in food as adopted in Directive 2006/52/EC. In its scientific opinion adopted on 11 March 2010, the EFSA Panel on Food Additives and Nutrient Sources concluded that the data provided by the Danish authorities does not provide a basis to revise the current ADI (Acceptable Daily Intake) levels for nitrite. In addition, the Panel concluded that exposure to preformed nitrosamines in food should be minimised using appropriate technological practices such as the lowering of nitrate and nitrite levels added to food to the minimum required to achieve the necessary preservative effect and to ensure microbiology safety. The Panel added that the evaluation of the technological need for maximum use levels of nitrite was outside its scope.

Considering the Danish national provisions, the 2011 EFSA opinion, and the affirmation included in Annex II to Regulation 1333/2008 maintaining that "the Commission will consult Member States, the stakeholders and the Authority to discuss the possibility to reduce the current maximum limits in all meat products (…)", this study seeks further explore this possibility, in particular by attempting to further clarify the technological need for nitrites in the meat industry.

5. METHODOLOGY

5.1. Task 1: Inception

In the inception phase, we started up the study by implementing the workplan discussed in the kick-off meeting into our dedicated project management software. We carried out an initial review of relevant literature to support the study team in preparing the exploratory interviews and drafting of the inception report. A kick-off meeting was held with DG SANTE on 28 January 2015 in order to agree upon the details of the work to be conducted and the planning of the study. The overall methodological approach was confirmed as described in the offer, with some changes made to the timeline and workshop agenda. It was decided that the interim report would be submitted following the completion of Tasks 2 and 3 and would serve as a basis for the expert workshop (Task 4).

As a result of the kick-off meeting, a list of stakeholders to be consulted through the survey (Task 3) was agreed between the FCEC and DG SANTE. In parallel, we started the interview process for this study through a round of exploratory interviews with key stakeholders, considering suggestions for interviewees made by the Commission during the kick-off meeting. The table below presents the list of exploratory interviews conducted in this round.

Table 3: List of exploratory interviews

Name of interviewee(s)	Organisation	Date of interview
Dirk Dobbelaere **Linda Jensen** **Guido Bresseleers**	Liaison Center for the Meat Processing Industry (CLITRAVI)	13 February 2015
Hubert Paelinck	Katholieke Universteit Leuven	26 February 2015
Cees Vermeeren	Association of Poultry Processors and Poultry Trade (AVEC)	27 February 2015

These interviews allowed us to gain a preliminary overview of the use, use levels and technological needs for nitrites in industry, to initiate contact with key stakeholders and to discuss the categorisation of meat products and preparations. An initial categorisation of meat products and preparations was also discussed with stakeholders and experts during the exploratory interviews. In parallel, the Commission elaborated a refined and simplified version of the categories, that was communicated to Civic Consulting. Using this simplified categorisation and the results of the exploratory interviews, we prepared a consolidated categorisation of meat products and preparations which was approved during the inception meeting and subsequently used in the survey questionnaire (see Task 3 below).

5.2. Task 2: Literature research

The relevant literature (in English and French) was identified through search engines and specialised databases and journals. The exploratory interviews conducted in Task 1 and the experts contacted for participation in the workshop (Task 3) also helped to identify the key literature relevant to this study. After identifying the relevant literature, it was collected and tagged in Mendeley (a software for literature review and indexing), according to a list of tags provided in the inception report.

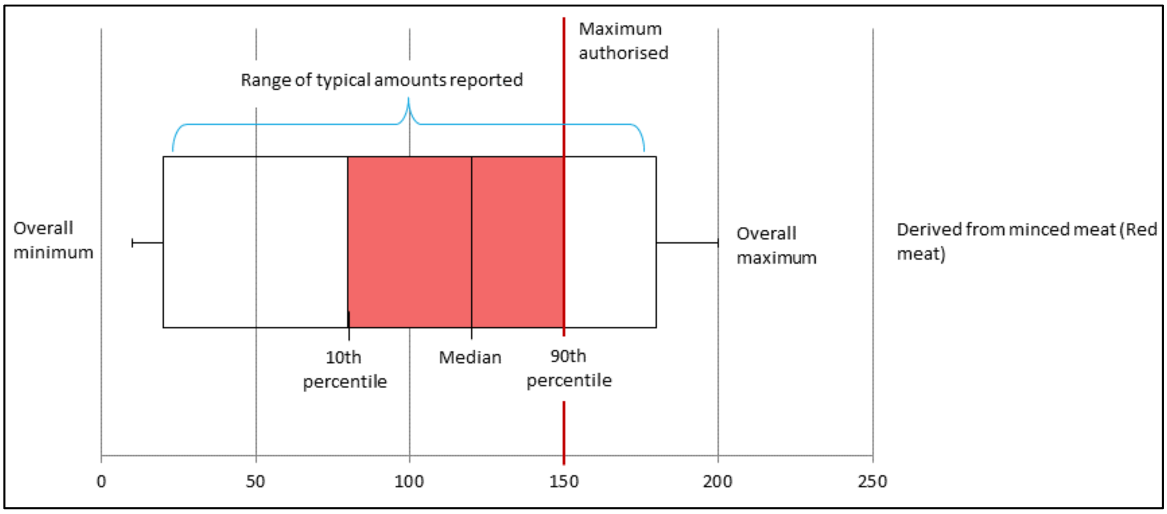
Following collection, the literature was reviewed, and key information and abstracts, where available, were synthesized in the summary tables included in this report. A full list of literature reviewed is provided in the Annex.

5.3. Task 3: Survey of meat business operators, their organisations and other stakeholders

The survey questionnaire was developed in the inception phase on the basis of the kick-off meeting and exploratory interviews, also considering information gathered through the literature research (Task 2). The final survey questionnaire is provided in the Annex to this report. After being approved by the Commission and tested with selected stakeholders, the survey was implemented on an online platform (Qualtrics). The survey link was distributed to relevant EU level organisations of food business operators and meat producers/processors (e.g. CLITRAVI, AVEC, IMTA, IBC), their member organisations, and research institutes/individual experts. In parallel, EU-level organisations were asked to forward the survey link to their member organisations, who in turn passed on the link to their member companies. The survey was launched on 20 April 2015 and remained open for seven weeks, closing on 8 June 2015. Several reminders were sent to participants throughout this period. A total of 108 respondents contributed to the survey, including participants across all stakeholder groups: organisations of food business operators/meat producers or processors (10 respondents); individual meat producers/processors (83 respondents); and respondents from research institutes/universities (nine respondents).[26] Six respondents also selected the stakeholder category "Other".

Survey results were then synthesised and analysed with respect to the objective of the study. For this purpose, we have created box plots illustrating the key statistics of the survey responses. Data tables presenting individual responses provided by survey participants were also compiled for each relevant sub-category of product types examined. The following figure provides an example of a box plot.

Figure 2: Example of boxplot depicting use levels of nitrite in non-heat treated processed meat



Source: Civic Consulting.

[26] In some cases, stakeholder categories provided by respondents were re-coded where they were reported incorrectly. For example, a company operating in the U.K. who erroneously selected "Organisation of food business operators/meat producers or processors" appears as a "Company" in the survey results presented in this report.

As shown above, the box plots constructed for this report provide the maximum authorised for the relevant product category, represented by the red vertical line. It shows the overall minimum and overall maximum as reported and the range of typical amounts reported. Inside the box, the tenth percentile, 90th percentile, and median (i.e. the middle value of the data set) are provided. While the total length of the box represents the range of typical amounts reported, the length of the coloured box indicates the typical values reported by the middle 80 percent of respondents. In the figure above, the 90th percentile coincides with the maximum authorised (150 mg/kg).

5.4. Task 4: Workshop

The results of Task 2 (Literature research) and Task 3 (Survey) presented in the interim report served as a basis for the discussions in the expert workshop, which took place on 8 September in Brussels. 14 external experts attended the workshop, as well as the research team from Civic Consulting, experts from EFSA and Commission staff.

All external experts received a formal invitation including details about the aims of the workshop and the agenda. The FCEC also provided its support in coordinating arrangements concerning travel and accommodation for workshop participants. The table below presents the list of external experts that attended the workshop on 8 September 2015.

Table 4: Members of the expert panel

Name	Organisation	Specialisation	Meat products covered in publications/research
Prof. Hubert Paelinck	KU Leuven, Subdivision Technology and Quality of Animal Products	Meat technology, food microbiology, nitrites, N-Nitrosamines	Heated meat products, cooked meat products, cured meat products
Prof. Jorge Ruiz Carrascal	University of Copenhagen, Department of Food Science	Meat technology, food microbiology and food additives, nitrites in meat	Dry-cured meat products
Prof. Eero Puolanne	University of Helsinki (Professor Emeritus)	Meat technology, use of nitrites in meat	Dry fermented sausages, cooked meat products, and other meat products
Prof. Jens Adler-Nissen	Technical University of Denmark, Division of Industrial Food Research	Meat technology, meat product manufacture, use of nitrites in meat	Various types of meat products (incl. e.g. dry-cured ham)
Dr José Angel Pérez Alvarez	Miguel Hernandez University, AgroFood Technology Department	Meat technology, use of nitrites in meat, meat and meat products colour	Various types of meat products, incl. cooked and dry-cured meat products
Theo Verkleij	Netherlands Organisation for applied Scientific Research (TNO)	Meat technology, use of nitrites in meat and meat products	Cured, cooked, fermented and dry cured organic meat products
Monica Berga-	Stazione Sperimentale	Meat technology, nitrites	Cooked meat products

maschi	per l'Industria delle Conserve Alimentari	in meat	
Dr Monika Gibis	University of Hohenheim, Institute of Food Science and Biotechnology, Department of Food Physics and Meat Science	Meat science and technology, meat and cancer, use of nitrite and alternatives to nitrite	Various types of meat products, processed meat incl. bacon, emulsified/dried sausages, canned sausages
Dr Régine Talon	French National Institute for Agricultural Research (INRA), Microbiology Research Unit	Food microbiology	Various types of meat products incl. fermented meat products
Prof. Mike Peck	Institute of Food Research in Norwich	Physiology and molecular biology, including Clostridium botulinum	Various types of meat products, incl. red meat
Dr Gunter Kuhnle	University of Reading	Human nutrition, nutritional biochemistry, meat and cancer, natural alternatives to nitrites	Red meat, processed meat
Prof. Dr Stefaan De Smet	Ghent University, Department of Animal Production	Animal science, food science, use of nitrites in meat	Red meat, poultry, processed meat
Dr Karolina Wojciak	Department of Meat Technology and Food Quality, University of Life Sciences Lublin	Meat science and technology, preservation,	Various types of meat products, incl. fermented sausage, organic products
Dr Ilse Fraeye	KU Leuven, Subdivision Technology and Quality of Animal Products	Food technology	Various types of meat products, incl. cooked meat products and dry fermented sausages

The workshop was divided into five main sessions, reflecting the key topics discussed in the sections included in this report. One of the five sessions served to conclude the discussions of the workshop and to provide an indicative response to the possibility of reviewing the current maximum levels of nitrite in meat products and preparations.

After prior approval of the workshop participants, the discussions were recorded electronically and a summary of conclusions reached at the meeting was prepared, highlighting the key results of each workshop session, and indicating areas where agreement was reached between experts, and where disagreement occurred. The summary of the workshop was circulated to the experts in order to verify their accuracy. The summary notes are provided in Annex 6 of this report.

5.5. Task 5: Synthesis and analysis

Following the expert workshop, we proceeded with adjoining the conclusions from the workshop to the results of the survey and of the literature review already presented in the interim report. We also conducted a final round of literature review, based on additional suggestions for relevant articles provided by the experts following the workshop. The results of this final round of literature research have been presented in the relevant sections of this report. Finally, based on evidence generated throughout the study using the three main methodological tools (literature research, surveys and expert workshop), we have drafted a conclusion on the possibility to review the current maximum levels. We have also identified and rendered explicit remaining gaps or limitations.

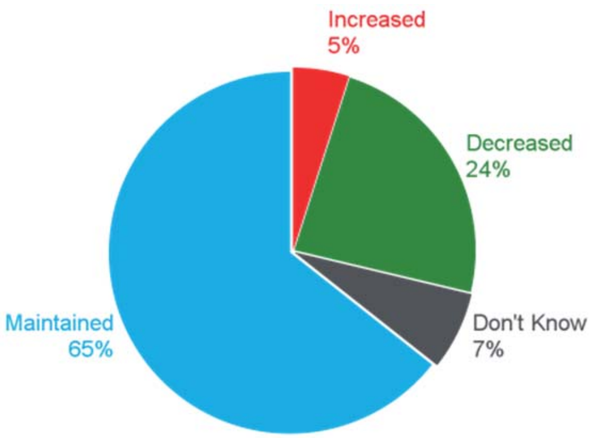
6. THE USE AND USE LEVELS OF NITRITES IN MEAT PRODUCTS AND PREPARATIONS

This section examines the study results concerning the use and use levels of nitrites in meat products and preparations. We first present the survey results for the general use of nitrites by producers, before providing detailed survey results for each of the categories listed in Table 1 in Section 4.4.1 above. We then present results from the literature research and expert workshop.

6.1. Survey results on the general use of nitrites in meat products and preparations

To obtain insight on the current usage of nitrites in the meat industry, our survey asked respondents whether their company or member companies had increased, maintained, or decreased the amount of nitrites used in meat products/preparations in recent years. The answer to this question is illustrated in the figure below:

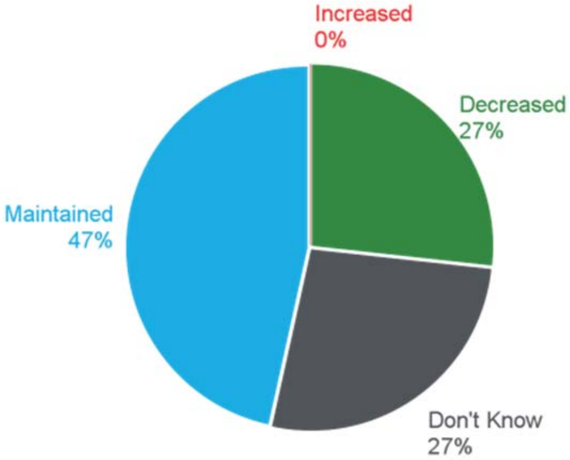
Figure 3: "In recent years, has your company/have your member companies increased, maintained, or decreased the amounts of nitrites used in meat products/preparations?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=85. This question was asked to meat producers/processors and their organisations.

As the figure shows, a majority (65%) of producers/processors and their organisations reported that they have maintained the amount of nitrites in meat products and preparations, with almost one quarter (24%) of respondents affirming that they have reduced the amount of nitrites used. A small minority (5%) reported that the amount of nitrites used in meat products/preparations has increased in recent years, with the remaining respondents (7%) selecting "Don't know". The result is largely consistent with the responses provided by experts from research institutes/universities, as the figure below illustrates.

Figure 4: "In recent years, have meat producers/processors in your country increased, maintained, or decreased the amounts of nitrites used in meat products/preparations?"

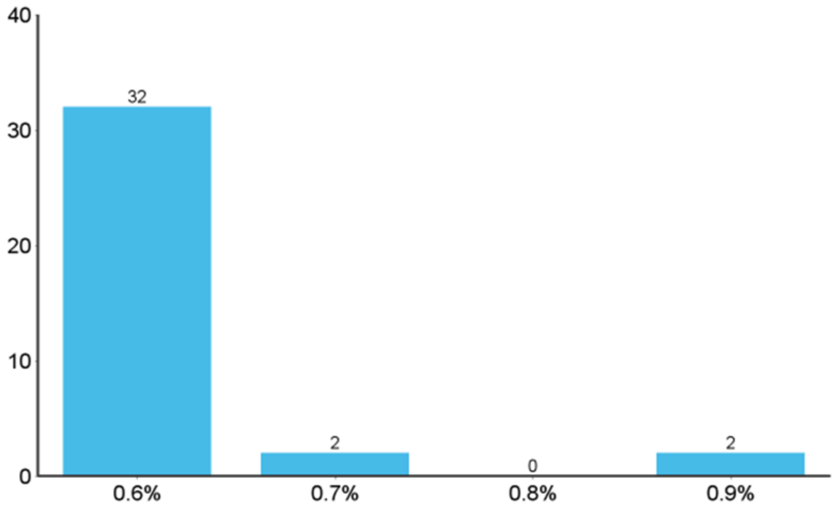


Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=15. This question was asked to respondents from research institutes/universities and other stakeholders.

As shown in the figure above, none of the experts that responded to our survey considered that meat producers/processors in their country have increased the amounts of nitrites used in meat products/preparations in recent years. Just over one quarter (27%) of experts considered that the meat industry in their country had decreased the amounts of nitrites used, with 47% stating that the amounts of nitrites used have been maintained and a further 27% responding "Don't know".

Producers, processors, and their organisations were also asked to indicate the amount of nitrites presents in the nitrite salt used for curing meat products and preparations. The answer to this survey question is illustrated in the figure below:

Figure 5: "What is the amount of nitrites present in the nitrite salt used by your company/members for the curing of meat products/preparations?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=36. This question was asked to meat producers/processors and their organisations.

As the figure illustrates, most industry stakeholders reported using curing salt with 0.6% of nitrites, with two respondents selecting 0.7% and two others reporting 0.9%.

However, a large number of respondents did not select one of the four options and provided only comments concerning the nitrite salt used by their company/members. In these comments, respondents mainly explained that various levels of nitrites are used according to different products, or provided additional details concerning the curing salt mixtures used by their company. A full list of comments provided by survey respondents is included in the Annex to this report.

To examine the extent to which producers and processors currently use nitrites in meat products and preparations in greater detail, the survey asked respondents to indicate the minimum, typical, and maximum levels of nitrites used in different product categories and sub-categories. For each main category of meat products or preparations, a box plot is used to illustrate the reported amount of nitrites used in the production process or the residual amount present in the final product (depending on whether the legislation provides a maximum amount added or a maximum residual amount).

In addition to the box plots, data tables present the values for the overall minimum, overall maximum and median of typical amounts reported for each sub-category. Additional data tables present the detailed answers provided by individual respondents, which form the basis for the summary figure and overview tables.

6.2. Survey results on the use of nitrites in meat preparations and non-traditional meat products

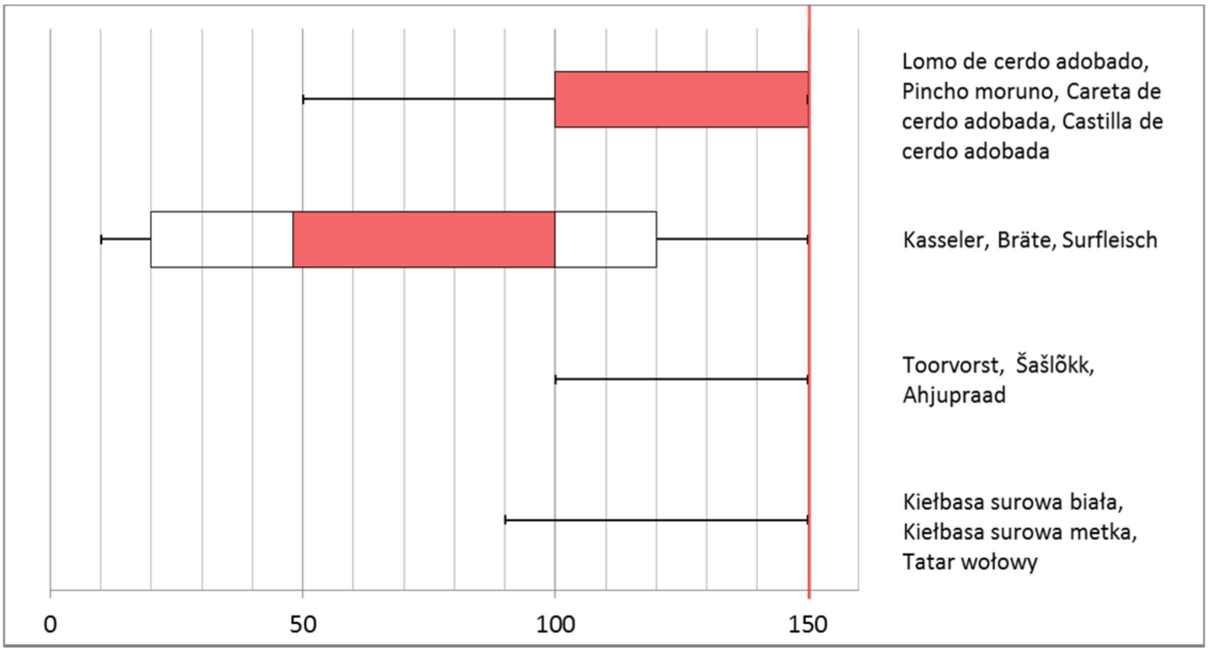
6.2.1. *Meat preparations*

The use of nitrites in meat preparations is regulated by Commission Regulation (EU) No 601/2014, which authorises producers to add a maximum of 150 mg/kg to the following types of meat preparations:

- *Lomo de cerdo adobado, Pincho moruno, Careta de cerdo adobada* and *Castilla de cerdo adobada*, typically produced in Spain;
- *Kasseler, Bräte* and *Surfleisch*, typically produced in countries such as Germany, Austria, and Luxembourg;
- *Toorvorst, Šašlõkk* and *Ahjupraad*, typically produced in Estonia, and
- *Kiełbasa surowa biała, Kiełbasa surowa metka* and *Tatar wołowy* typically produced in Poland.

The following boxplot presents the survey results for the types of meat preparations listed above.

Figure 6: Boxplot depicting use levels of nitrite in meat preparations



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=7/9/1/2 (according to preparation type).

As the figure shows, the maximum reported values for all types of meat preparations coincide with the authorised limit provided in the legislation. For two sub-categories, *Toorvorst, Šašlõkk* and *Ahjupraad* and *Kiełbasa surowa biała, Kiełbasa surowa metka* and *Tatar wołowy*, the small sample size does not allow for a boxplot to be constructed. For these two sub-categories, the horizontal line indicates the range of reported values.

The tables included in Annex 3 present the detailed answers provided by individual respondents for each sub-category of meat preparations. The tables group responses according to member states and provide the stakeholder group for each respondent, as well as the minimum amount, typical amount, and maximum amount reported for the relevant product sub-category. Comments provided by the respondent, if any, are also presented in the tables. The final rows of each table provide the overall minimum amount reported by survey respondents, the median of typical amounts and the overall maximum amount. These values form the basis of the box plot presented above. Non-heat treated processed meat

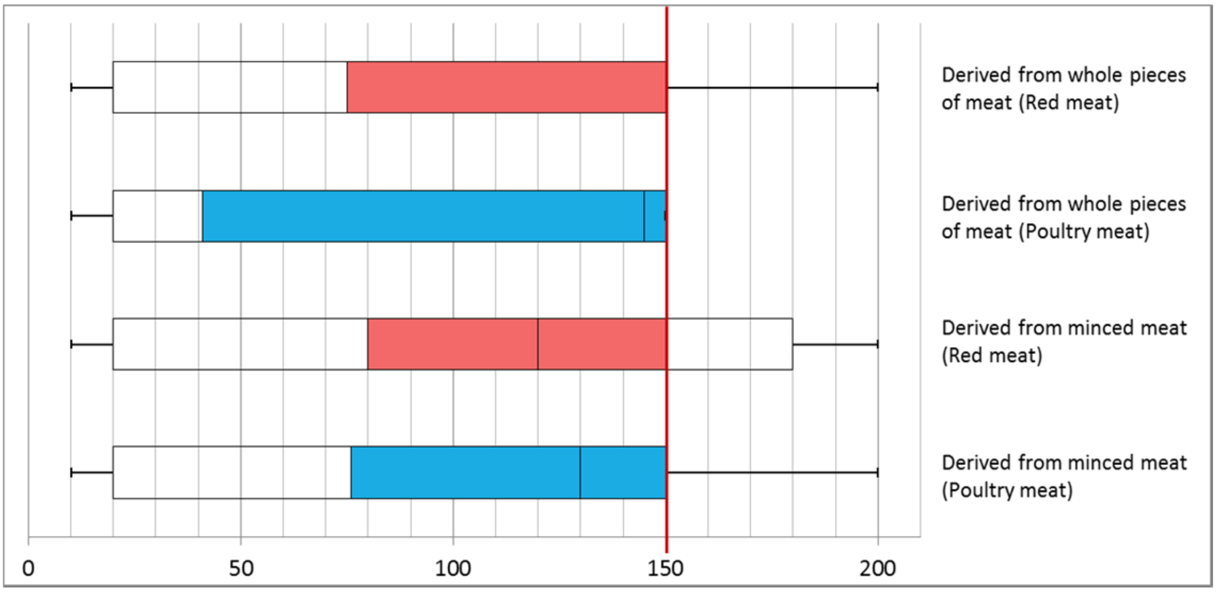
In the legislation, non-heat treated processed meat refers to products that are processed through curing, salting, smoking, drying, fermenting, marinating, pickling or maturing in order to preserve and extend the shelf life of meats.[27] Non-heat treated meat products can be produced on the basis of red meat or poultry meat, and derived from either whole pieces of meat (such as dried ham) or from minced meat (e.g. dried sausage or salami).[28] According to the legislation currently in force, producers may add a maximum of 150 mg/kg of nitrites to these meat products.

The following boxplot presents the survey results for each of the sub-categories of non-heat treated processed meat.

[27] European Commission, Guidance Document Describing the Food Categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives, 2013. http://ec.europa.eu/food/food/fAEF/additives/docs/guidance_1333-2008_descriptors_annex2_20131218_en.pdf.

[28] Minced meat is defined as boned meat that has been minced into fragments. Whole pieces of meat are those which cannot be considered to be minced meat

Figure 7: Boxplot depicting use levels of nitrite in non-heat treated processed meat



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=48/10/37/10 (according to sub-categories as listed).

As shown in the figure above, the overall maximum levels reported go beyond the legal limit for three sub-categories of non-heat treated processed meat (all except poultry meat derived from whole pieces of meat). Moreover, across all sub-categories, the minimum level of nitrites used for the production of non-heat treated processed meat products is 10 mg/kg.

The tables included in Annex 3 present the detailed answers provided by individual respondents for each sub-category of non-heat treated processed meat. The tables group responses according to member states and provide the stakeholder group for each respondent, as well as the minimum amount, typical amount, and maximum amount reported for the relevant product sub-category. Comments provided by the respondent, if any, are also presented in the tables. The final rows of each table provide the overall minimum amount reported by survey respondents, the median of typical amounts and the overall maximum amount. These values form the basis of the box plot presented above.

6.2.1. *Heat-treated processed meat*

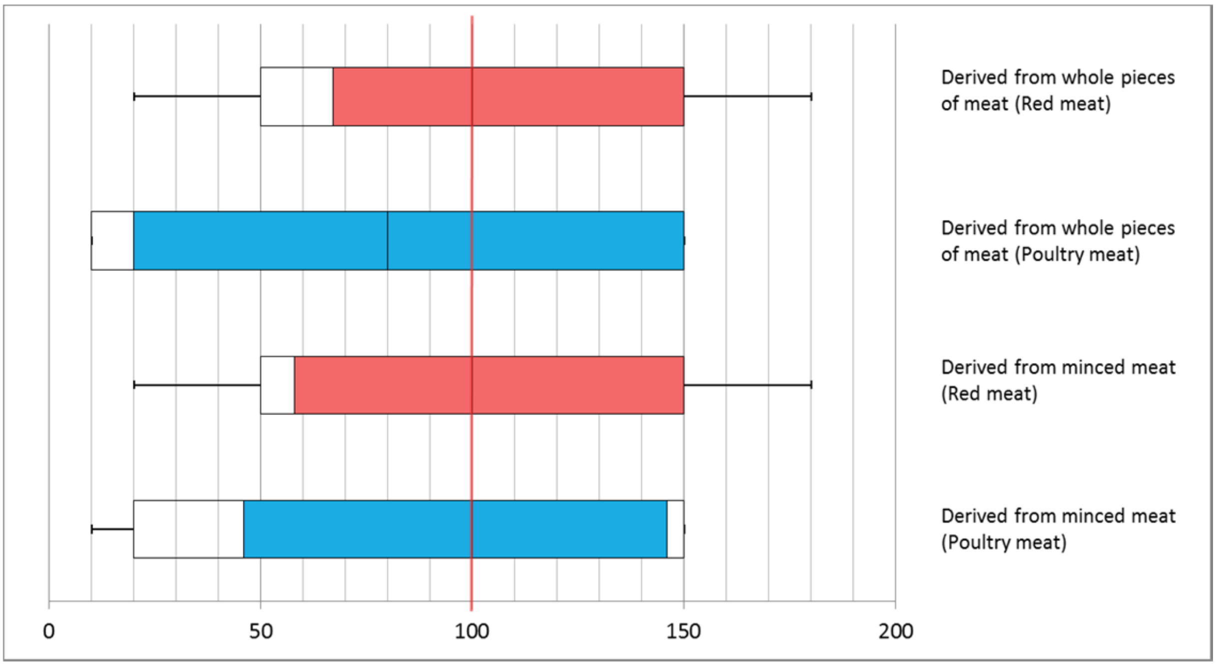
Another category of meat products for which the use of nitrites is permitted in the legislation is heat-treated processed meats, which includes products that are cooked, heat-treated and canned meat cuts.[29] One specific method used for heat treatment is sterilisation. According to the legislation, products which undergo sterilisation may be cured using a maximum added amount of 100 mg/kg.

As in the previous categories examined, sterilised meat products can be differentiated between products that are derived from whole pieces of meat such as canned whole pork, and those derived from minced meat, such as canned ground beef. A further distinction can be made between products manufactured using red meat and those which are manufactured using poultry meat.

[29] European Commission, Guidance Document Describing the Food Categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives, 2013. http://ec.europa.eu/food/food/fAEF/additives/docs/guidance_1333-2008_descriptors_annex2_20131218_en.pdf.

The following boxplot presents the survey results for each of the sub-categories of sterilised heat treated processed meat.

Figure 8: Boxplot depicting use levels of nitrite in (sterilised) heat treated processed meat

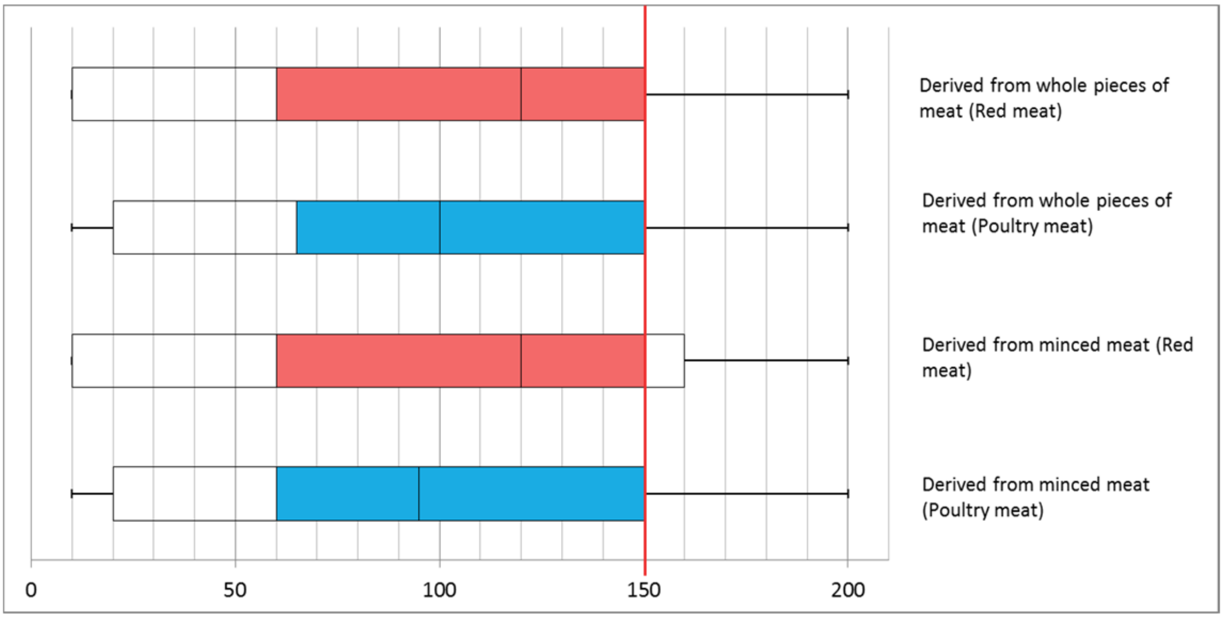


Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=19/13/21/15 (according to sub-categories as listed).

The figure above shows that while the median typical amounts reported largely coincide with the limit provided in the legislation (100 mg/kg), the maxima of typical amounts are significantly higher than this limit. For the two sub-categories of red meat (derived from whole pieces and derived from minced meat), the overall maximum levels reported reach up to 180 mg/kg.

The limit provided in the legislation is higher for products that are not sterilised but undergo other types of heat treatment (such as cooking), allowing 150 mg/kg of nitrites to be added. Examples of products that are heat treated but not sterilised include cooked ham and emulsified sausages. The following boxplot presents the survey results for each of the different sub-categories of non-sterilised heat treated processed meat.

Figure 9: Boxplot depicting use levels of nitrite in (non-sterilised) heat treated processed meat



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=54/31/43/29 (according to sub-categories as listed).

As for sterilised meat products, the figure above shows that the overall maximum reported values for other heat treated processed meat exceed the limit as provided in the legislation (150 mg/kg). However, Figure 9 also shows that for each of the sub-categories, the median of typical amounts reported lie below this limit: for both types of red meat (whole pieces and minced), the median of typical amounts reported are 120 mg/kg, for both types of poultry meat they are slightly lower.

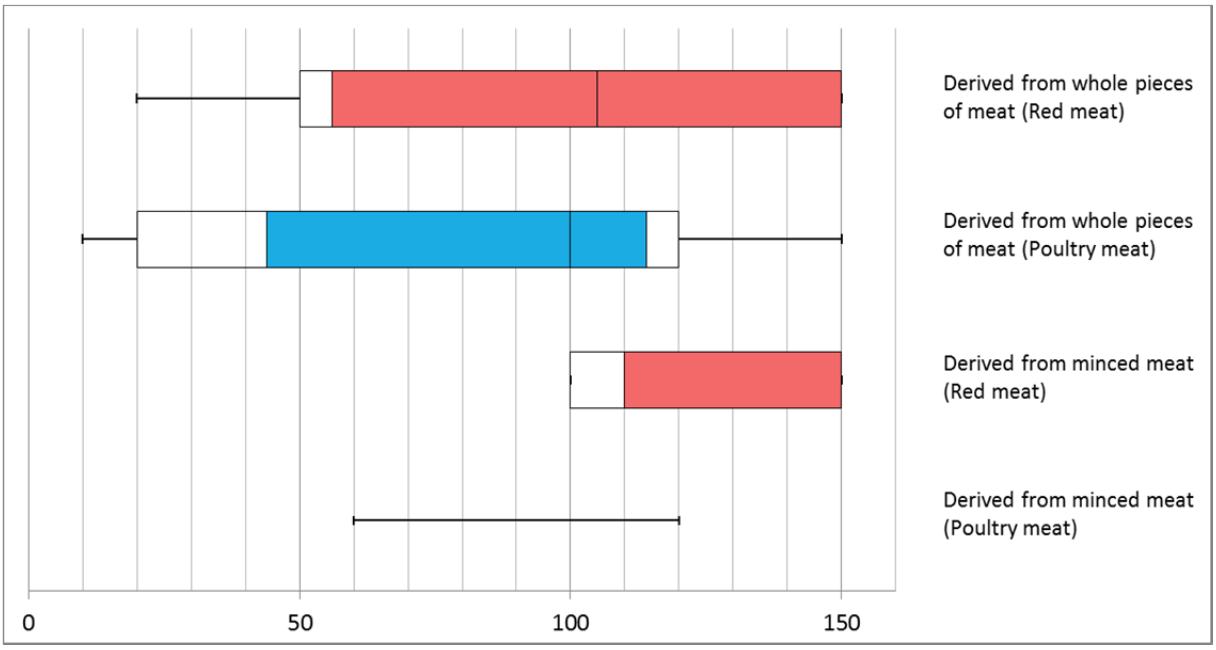
The tables included in Annex 3 present the detailed answers provided by individual respondents for each sub-category of sterilised and non-sterilised heat treated products. The tables group responses according to member states and provide the stakeholder group for each respondent, as well as the minimum amount, typical amount, and maximum amount reported for the relevant product sub-category. Comments provided by the respondent, if any, are also presented in the tables. The final rows of each table provide the overall minimum amount reported by survey respondents, the median of typical amounts and the overall maximum amount. These values form the basis of the box plots presented above.

6.2.2. *Other meat products for which nitrites are used*

While not provided for in the legislation, other meat products are manufactured with the addition of sodium or potassium nitrite. Therefore, our survey of meat business operators, their organisations, and other stakeholders asked respondents to specify the amount of nitrites added to other (non-traditional) products than those examined in the sections above. Once again, respondents providing answers to this question were invited to distinguish between meat products derived from whole pieces of meat (for instance, Filet d'Ardenne or Swedish Christmas Ham) and those derived from minced meat (such as Papillottes or Blinde vink). Moreover, they were asked to specify whether their answers related to red meat or poultry meat products.

Between two and ten respondents provided data for each sub-category. The products that were mentioned included raw smoked pork filet, bacon rib, and ham products. The following boxplot presents the survey results for each of the sub-categories relating to other meat products for which nitrites are used in practice by industry.

Figure 10: Boxplot depicting use levels of nitrite in other meat products



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=10/4/3/2 (according to sub-categories as listed).

The figure shows varying levels of nitrite used in other products which are not specified in the legislation. However, none of the reported levels used exceed the legal limit which applies for meat preparations, non-heat treated meat products, and non-sterilised heat treated meat products (i.e. 150 mg/kg).

The tables included in Annex 3 present the detailed answers provided by individual respondents for each sub-category of other meat products in which nitrites are used. The tables group responses according to member states and provide the stakeholder group for each respondent, as well as the minimum amount, typical amount, and maximum amount reported for the relevant product sub-category. Comments provided by the respondent, if any, are also presented in the tables. The final rows of each table provide the overall minimum amount reported by survey respondents, the median of typical amounts and the overall maximum amount. These values form the basis of the box plot presented above.

6.3. **Survey results on the use of nitrites in traditional meat products**

With the exception of sterilised heat treated meat products, all categories of non-traditional meat products and preparations considered in the previous section are subject to a limit of 150 mg/kg of nitrites added. In contrast, the use of nitrites in traditional meat products is mostly regulated through the imposition of limits on the residual levels of nitrites found in the final product. These traditional products, for which specific maximum levels are provided in the legislation, are produced using various curing methods and are broadly grouped into three sub-categories:

- Traditional immersion cured products;
- Traditional dry cured products;
- Other traditionally cured products.

The sections below present the survey results for each of the sub-categories and the specific product types that they include.

6.3.1. *Traditional immersion cured products*

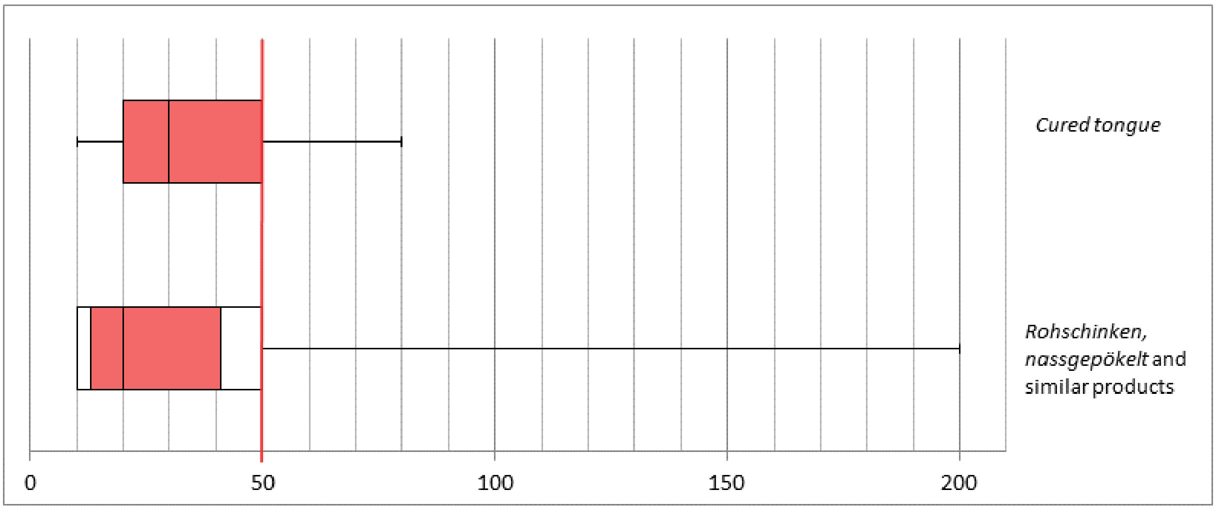
Traditional immersion cured products are those which are cured by immersion in a curing solution containing nitrites and/or nitrates, salt, and other components. This category includes products with a curing time ranging between three and 21 days. Additional processes may include injections of curing solution into the products, pre-cooking, smoking, and time allowed for stabilisation and maturation, depending on the product. The following product types fall under this category:

- *Cured tongue*;
- *Rohschinken, nassgepökelt* and similar products;
- *Wiltshire ham* and similar products;
- *Wiltshire bacon* and similar products;
- *Entremeada, entrecosto, chispe, orelheira e cabeca (salgados), toucinho fumado* and similar products;
- *Kylmâsavustettu poronliha/kallrökt renkött*;
- *Bacon, filet de bacon* and similar products.

The legislation currently in place authorises the use of nitrites in such products provided that the residual amount of nitrites contained in them at the end of the production process does not exceed the maximum limits, which range between 50 mg/kg and 175 mg/kg depending on the product type. For the final two product types listed above – *Kylmâsavustettu poronliha/kallrökt renkött* and *Bacon, filet de bacon* and similar products – a limit of 150 mg/kg of added nitrite applies, as for the products discussed under Section 6.2.

The following boxplots present the survey results for each type of traditional immersion cured products for which a maximum residual amount is provided in the legislation.

Figure 11: Boxplot depicting residual levels of nitrite in cured tongue and Rohschinken, nassgepökelt and similar products

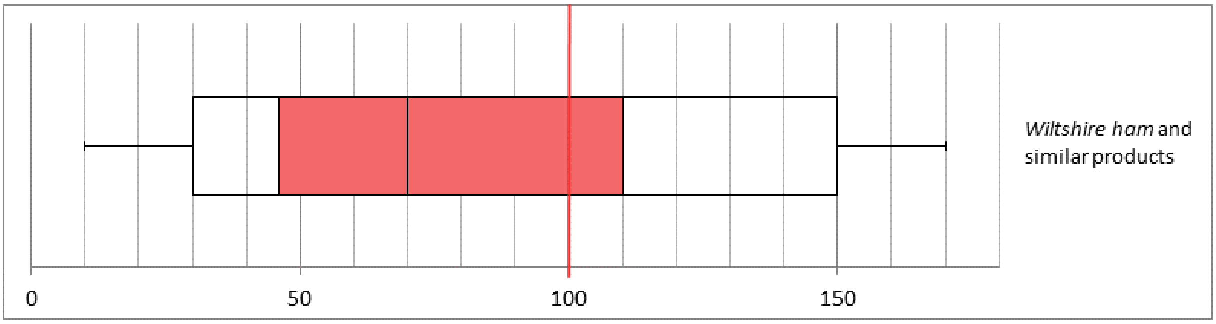


Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=7/5 (according to product type as listed).

As shown in the figure above, for both immersion cured products for which a maximum residual amount of 50 mg/kg is provided in the legislation, overall maximum reported levels exceeded this limit. However, for both product types, the maximum typical amount reported coincided with the limit specified in the legislation, with all typical values ranging between 20 and 50 mg/kg for *cured tongue* and 10 and 50 mg/kg for

Rohschinken, nassgepökelt and similar products. The boxplot below illustrates the survey results for *Wiltshire ham* and similar products.

Figure 12: Boxplot depicting residual levels of nitrite in Wiltshire ham and similar products

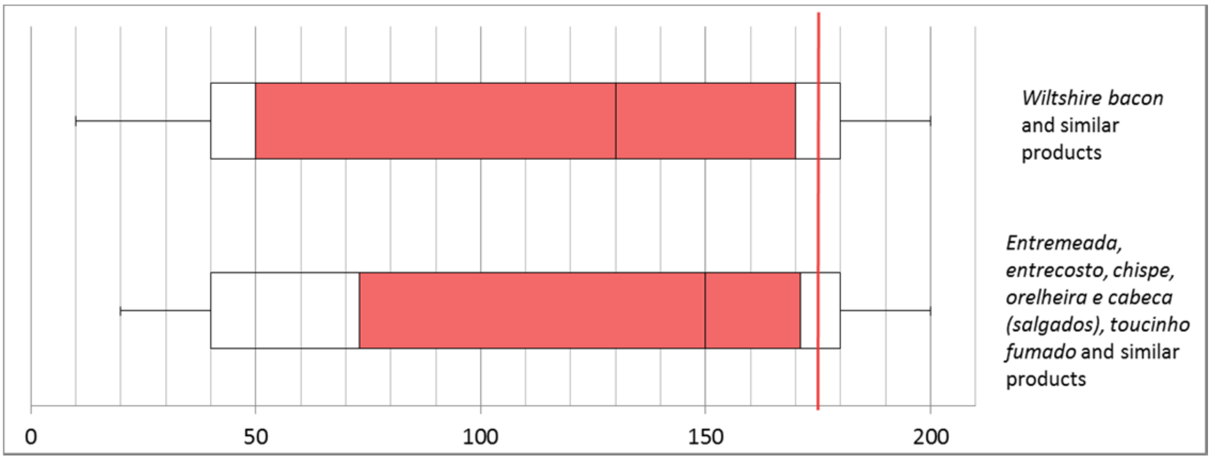


Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=9.

Similarly, for *Wiltshire ham* and similar products, the reported maximum level reached 170 mg/kg of residual nitrite, whereas the limit imposed by the legislation is currently 100 mg/kg. Moreover, the figure above shows that the 90th percentile of typical values also surpassed the legal limit, while the median of typical values reported was significantly below it, at 70 mg/kg.

The following boxplot presents the survey results for *Wiltshire bacon* and similar products as well as *Entremeada, entrecosto, chispe, orelheira e cabeca (salgados), toucinho fumado* and similar products. For both of these product types, the maximum residual amount provided in the legislation is 175 mg/kg.

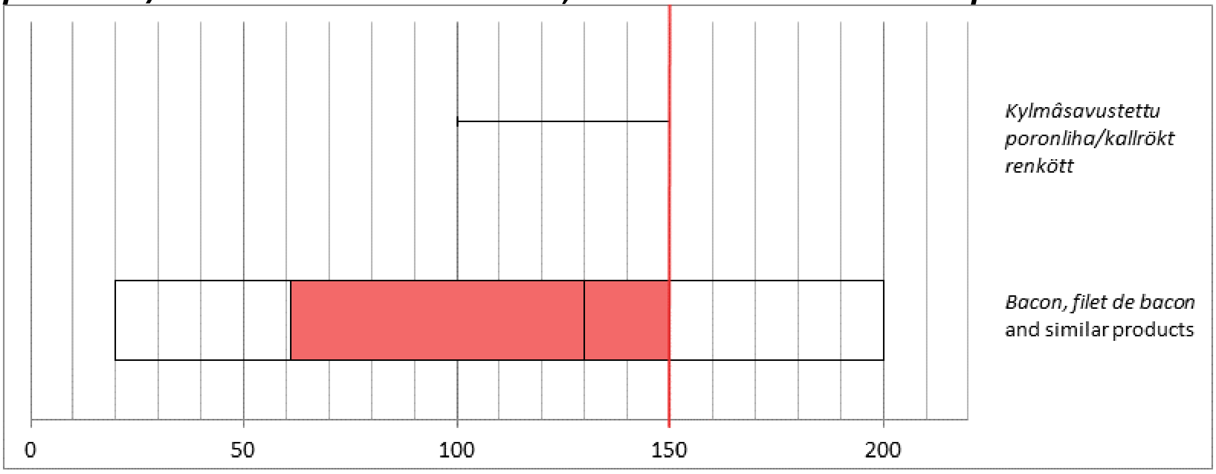
Figure 13: Boxplot depicting residual levels of nitrite in Wiltshire bacon and similar products and Entremeada, entrecosto, chispe, orelheira e cabeca (salgados), toucinho fumado and similar products



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=12/4 (according to product type as listed).

Once again, for these two product types the overall maximum reported and the maximum of typical values reached beyond the legal limit of 175 mg/kg. However, the 90th percentile and median of typical amounts reported were below the maximum residual amount authorised in the legislation for both product types. In total, the reported typical residual levels for both product types lay between 40 and 180 mg/kg. The box plot below illustrates survey results for the two immersion cured product types for which a maximum added amount is provided in the legislation.

Figure 14: Boxplot depicting use levels of nitrite in Kylmâsavustettu poronliha/kallrökt renkött and Bacon, filet de bacon and similar products



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=1/16 (according to product type as listed).

For the first product type, the limited sample sizes (one respondent) does not allow a box plot to be constructed. The range of reported values – represented by the horizontal line – stretches between 100 and 150 mg/kg. For the second product type, the overall maximum and typical maximum are both 200 mg/kg, and the 90th percentile coincides with the maximum amount as defined in the legislation. The median typical amount, however, is slightly below the limit (130 mg/kg).

The tables included in Annex 3 present the detailed answers provided by individual respondents for each sub-category of traditional immersion cured products. The tables group responses according to member states and provide the stakeholder group for each respondent, as well as the minimum amount, typical amount, and maximum amount reported for the relevant product sub-category. Comments provided by the respondent, if any, are also presented in the tables. The final rows of each table provide the overall minimum amount reported by survey respondents, the median of typical amounts and the overall maximum amount. These values form the basis of the box plots presented above.

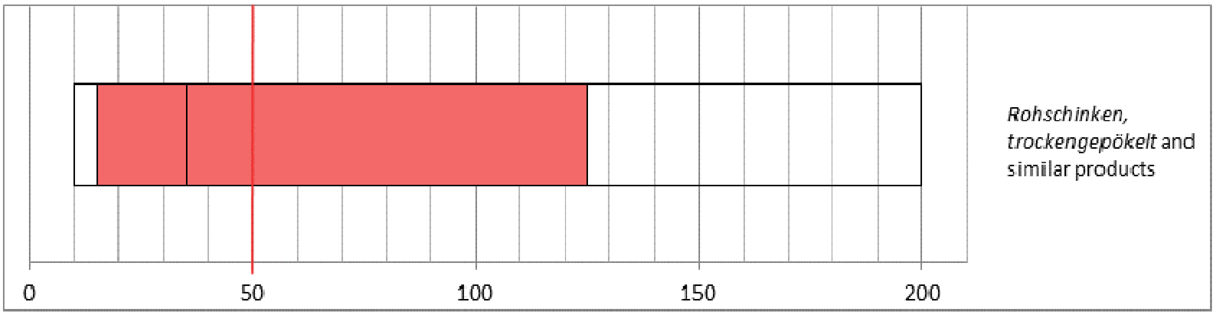
6.3.2. *Traditional dry cured products*

This section presents the results for products that are prepared using a dry curing process, which involves the dry application of a curing mixture containing nitrites and/or nitrates, salt, and other components to the surface of the meat. The process is followed by a period of stabilisation or maturation. Dry curing can take between four and 15 days, depending on the product. Products prepared according to this method include dry cured ham and dry cured bacon. For these products, the legislation provides maximum residual amounts which are authorised at the end of the production process. The following product types are specified in the legislation:

- *Rohschinken, trockengepökelt* and similar products;
- *Dry cured ham* and similar products;
- *Presunto, presunto da pa* and *paio do lombo* and similar products;
- *Dry cured bacon* and similar products.

For *rohschinken, trockengepökelt* and similar products, the legislation imposes a maximum of 50 mg/kg of residual nitrite. For *dry cured ham* and similar products, and *presunto, presunto da pa* and *paio do lombo* and similar products, a maximum of 100 mg/kg of residual nitrite are allowed. Finally, for *dry cured bacon* and similar products, the legislation authorises a maximum of 175 mg/kg of residual nitrite. The following boxplots present the survey results for each type of traditional dry cured products.

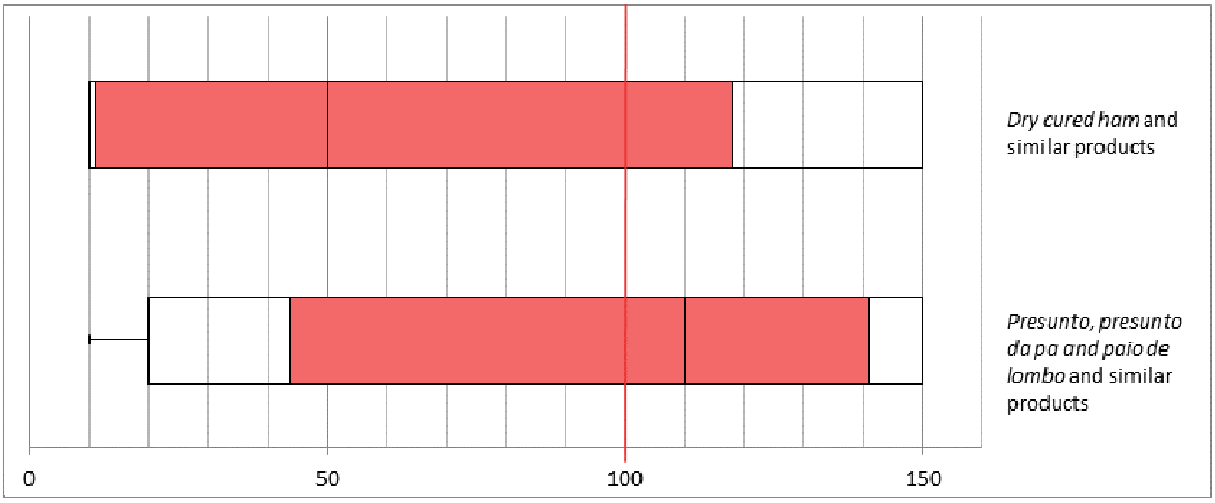
Figure 15: Boxplot depicting residual levels of nitrite in Rohschinken, trockengepökelt and similar products



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=7.

As the figure shows, the overall maximum reported was four times higher than the maximum residual amount authorised in the legislation for this product type. Moreover, the 90th percentile of typical amounts reported was also more than two times higher than the limit. On the other hand, the median typical amount provided by survey respondents was just below the maximum amount defined in the legislation, with 80 percent of respondents providing a typical value between 15 mg/kg and 125 mg/kg.

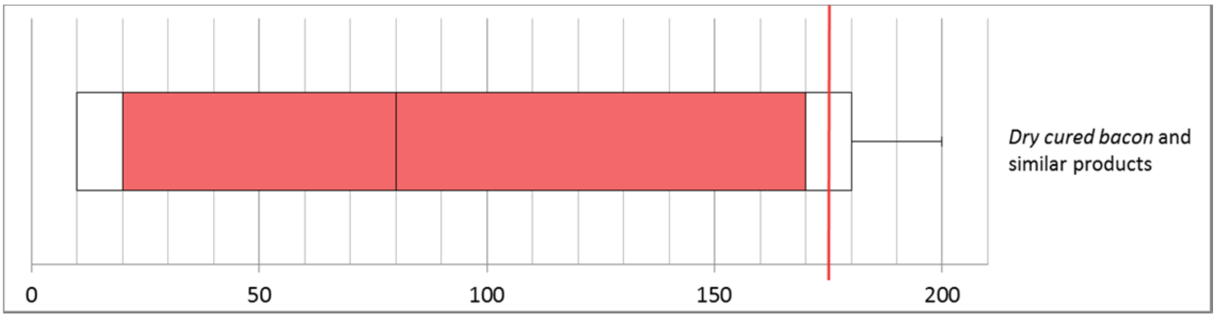
Figure 16: Boxplot depicting residual levels of nitrite in dry cured ham and similar products, and Presunto, presunto da pa and paio do lombo and similar products



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=15/4 (according to product type).

As the figure above illustrates, for both product types the range of typical values reported lies between 10 and 150 mg/kg of residual nitrite. However, while for *Presunto, presunto da pa* and *paio do lombo* and similar products the median typical value lies just above the maximum residual amount authorised, for *dry cured ham* and similar products the median typical value is half of that limit (50 mg/kg).

Figure 17: Boxplot depicting residual levels of nitrite in dry cured bacon and similar products



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=15.

The figure shows that more than 90 percent of typical values reported lie under the maximum residual amount authorised (175 mg/kg). Moreover, the median typical value reported is significantly below that limit, at 80 mg/kg.

The tables included in Annex 3 present the detailed answers provided by individual respondents for each sub-category of traditional dry cured products. The tables group responses according to member states and provide the stakeholder group for each respondent, as well as the minimum amount, typical amount, and maximum amount reported for the relevant product sub-category. Comments provided by the respondent, if any, are also presented in the tables. The final rows of each table provide the overall minimum amount reported by survey respondents, the median of typical amounts and the overall maximum amount. These values form the basis of the box plots presented above.

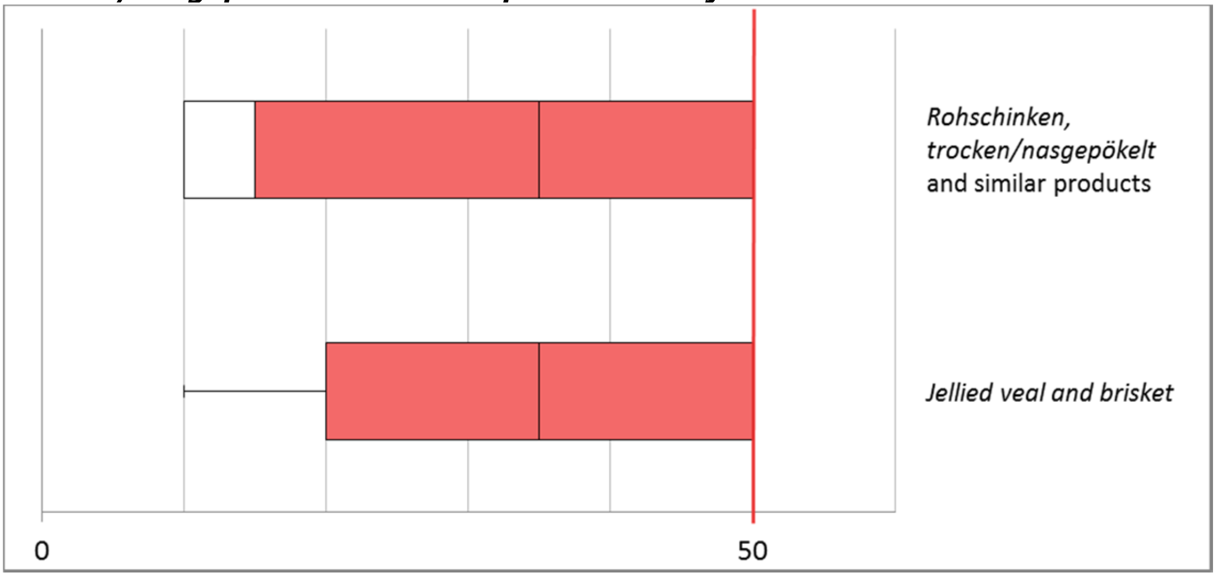
6.3.3. *Other traditionally cured products*

In addition to traditional immersion cured products and traditional dry cured products examined in the previous sections, the legislation authorises the use of nitrites in other traditionally cured products, which may include a combination of immersion and dry cured processes, processes where nitrite and/or nitrate is included in a compound product, or where the curing solution is injected into the product prior to cooking. This category includes the following product types:

- *Rohschinken, trocken/nasgepökelt* and similar products;
- *Jellied veal and brisket;*
- *Vysočina, selský salám, turistický trvanlivý salám, poličan, herkules, lovecký salám, dunjaská klobása, paprikás* and similar products.

While for the first two types of products, the limit on the use of nitrites is provided as a maximum residual amount of 50 mg/kg, for the last type the legislation provides a maximum amount added authorised of 180 mg/kg. The following boxplots present the survey results for each type of other traditionally cured products.

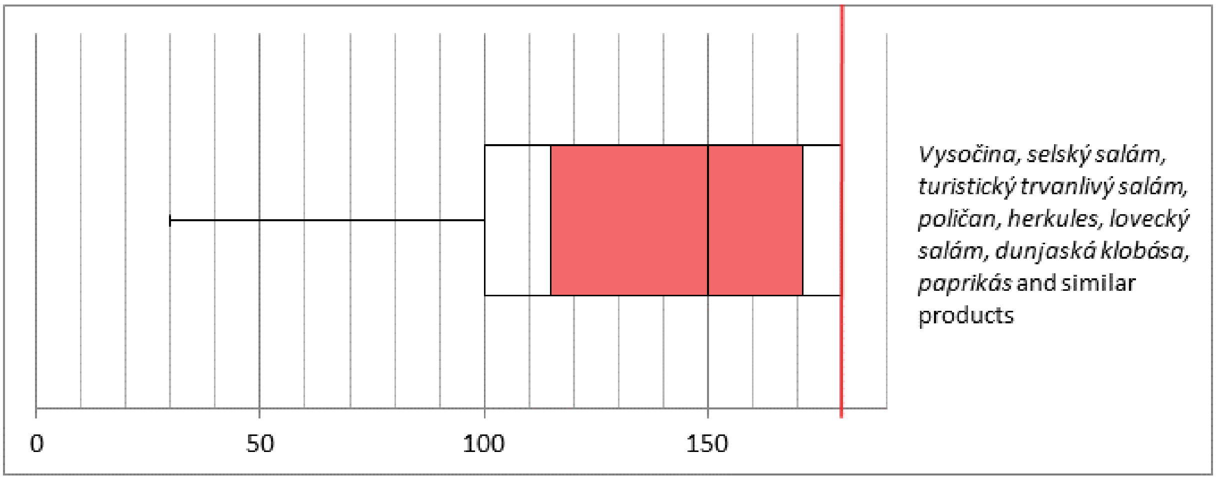
Figure 18: Boxplot depicting residual levels of nitrite in Rohschinken, trocken/nasgepökelt and similar products and jellied veal and brisket



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=6/4 (according to product type as listed).

For the types of products illustrated in the figure above, the survey results are broadly similar. The overall reported values range between 10 mg/kg and 50 mg/kg, with a median typical value of 35 mg/kg, below the maximum residual amount authorised. The following box plot presents the survey results for *Vysočina, selský salám, turistický trvanlivý salám, poličan, herkules, lovecký salám, dunjaská klobása, paprikás* and similar products.

Figure 19: Boxplot depicting use levels of nitrite in Vysočina, selský salám, turistický trvanlivý salám, poličan, herkules, lovecký salám, dunjaská klobása, paprikás and similar products



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=5.

For the final type of traditionally cured products, the overall maximum amount reported coincides with the maximum amount added authorised (180 mg/kg). The median typical amount reported is 150 mg/kg, with 80 percent of respondents reporting typical amounts of nitrite added ranging between 115 and 171 mg/kg.

The tables included in Annex 3 present the detailed answers provided by individual respondents for each sub-category of other traditionally cured products. The tables group responses according to member states and provide the stakeholder group for each respondent, as well as the minimum amount, typical amount, and maximum amount reported for the relevant product sub-category. Comments provided by the respondent, if any, are also presented in the tables. The final rows of each table provide the overall minimum amount reported by survey respondents, the median of typical amounts and the overall maximum amount. These values form the basis of the box plots presented above.

6.4. Results of literature research

The following table presents the results of the literature research concerning the use and use levels of nitrites in meat products/preparations in the EU.

Name of author(s)	*Adler-Nissen, Jens* *Ekgreen, Maria Helbo* *Risum, Jorgen*
Title of publication	**Practical Use of Nitrite and Basis for Dosage in the Manufacture of Meat Products**
Year	2014
Source/Organization	National Food Institute, Technical University of Denmark
Type of document	Report
Topics covered	Use levels; Denmark; Nitrosamines
Abstract	The use of nitrite (NaNO2) in the manufacture of cured meat products has a long tradition in the industry, dating back to the early twentieth century. Nitrite serves several technological purposes, primarily by the formation of a stable red colour in the meat and the inhibition of the growth of Clostridium botulinum. The adverse effects of nitrite can mainly be ascribed to the risk of forming nitrosamines from secondary amines and nitrite when curing meat products, in particular when they are heated to high temperatures, typically during frying. In the present report the existing EU legislation on the use of nitrite is reviewed and critically compared with Danish legislation.
Key information relevant	For bacon the EU limit of 175 mg/kg on residual nitrite is higher than the DK limit of 150 mg/kg on added nitrite. The issue of limits for nitrite in bacon is important, because bacon is usually fried and is therefore a product prone to expose consumers to nitrosamines. For cured, raw ham (“spegeskinker”) the EU limit for Rohschinken of 50 mg/kg on residual nitrite may be comparable to the DK limit of 150 mg/kg on added nitrite, considering that most of the added nitrite is decomposed during the curing process. For raw fermented sausages, the EU limit of 180 mg/kg on added nitrite for a number of specified Central European sausages is higher than the DK limit of 100 mg/kg on added nitrite for fermented sausages. For other heat-treated, but not sterilised meat products, the EU limit of 50 mg/kg on residual nitrite in the British speciality, jellied veal and brisket, is roughly comparable with a range of Danish products, where Danish legislation specifies from 60 to 150 mg/kg added nitrite.

Name of author(s)	*Binkerd, E. F.* *Kolari, O. E.*
Title of publication	**The history and use of nitrate and nitrite in the curing of meat**
Year	1975
Source/Organization	Food and Cosmetics Toxicology
Type of document	Journal article
Topics covered	Use levels; USA
Abstract	N/A
Key information relevant	(…) Experiments in which nitrite was added to sausage demonstrated that the curing period could be materially shortened, an observation similar to that noted with cuts of meat such as ham and bacon. The studies indicated "that 1/4oz. (156ppm) or less of sodium nitrite is sufficient to fix the color in 100 lb. of sausage meat". Typical nitrite values in frankfurters, bologna, luncheon meat and minced luncheon meat ranged from 40-150 ppm. On the basis of these studies, Kerr et at. (1926) concluded: (1) "From one-fourth to 1 oz. of sodium nitrite is sufficient to fix the color in 100 lb, the exact quantity depending on the meat to be cured and process to be employed." (2) "Meats cured with sodium nitrite need contain no more nitrites than meats cured with nitrates, and are free from the unconverted nitrates regularly present in nitrate-cured meats." (3) A shortening of the customary curing period may be obtained by the use of nitrite. (…) Lewis, also of the Institute of American Meat reported in 1937 an analytical survey of American cured meats as a measure of industry practice and considered how well they came within the BAI order of 1925 permitting the use of nitrite (Table 2). He concluded that the data were typical for commercially cured meats of that era, and that cured meats were well within the regulatory limit of 200 ppm nitrite. Early in 1970, there was considerable interest in this country and worldwide, especially in Europe, in the amounts of nitrite in various cured-meat products. Because of this interest, data on the residual levels of nitrite were obtained that year by the American Meat Institute Foundation from the USDA Meat Inspection Program Laboratory and the American Meat Institute Laboratory, both located in Chicago, Ill. Data on the nitrite content of various cured-meat products analysed during 1970 by the Chicago MIP laboratory are given in Table 3 (American Meat Institute Foundation, 1971); similar data obtained from the American Meat Institute Laboratory appear in Table 4 (idem 1971). Although the data are limited, the results of these two 1970 surveys indicated that the average nitrite content of commercially cured meats was low and was far less than that permitted by Federal regulations. American Meat Institute Foundation workers (Kolari & Aunan, 1972) again surveyed the amounts of nitrite in selected cured meat products in 1972 (Tables 5 & 6). In this survey, analytical data for shelf- stable and pasteurized meat products (Table 5) were obtained from a firm in the meat industry. The data in Table 6 were obtained from another firm, data being pooled from five of its plants between December 1971 and June 1972. In these studies, the products were analysed for nitrite 1-2 days after production. Average nitrite levels reported by industry in 1972 for shelf-stable, pasteurized (Table 5) and other cured

	meat products (Table 6) were again far below those permitted by Federal regulations. The amounts of nitrite used in producing the various products were determined from actual processing calculations (Table 5) or from amounts permitted by Federal regulations (Table 6). Because of the interest in amounts of nitrite and/or nitrate used by meat processors, the ranges of these materials used in 1970 in smoked cured meats were surveyed by the American Meat Institute Foundation (1971) and by the American Meat Institute in 1974 (unpublished data). The data were obtained from the major meat-packing firms and are summarized in Table 7.

Name of author(s)	*Drabik-Markiewicz, Gabriela*
Title of publication	**Chromatographic study on the factors influencing generation of selected N-nitrosamines in the course of heating cured meat**
Year	2010
Source/Organization	The University of Silesia, Institute of Chemistry
Type of document	Ph.D Thesis
Topics covered	Use levels; Nitrosamines
Abstract	N/A
Key information relevant	The permitted amount of nitrite in cured meat products is regulated by legislation. The European Customs Inventory of Chemical Substances prescribes a maximum addition of sodium nitrite at a level of 150 mg kg-1 processed meat, but in most cases, the amount added by industry is 120 mg kg-1.

Name of author(s)	*European Commission*
Title of publication	**Final report on a desk study to monitor the implementation of Directive 2006/52/EC in the EU Member States as regards the use of nitrites by the industry in the different categories of meat products and the organisation of national controls**
Year	2013
Source/Organization	European Commission
Type of document	Report
Topics covered	Denmark; Use levels
Abstract	N/A
Key information relevant	The Danish request to maintain lower maximum limits on nitrites in meat products was granted for a period of five years by Decision 2010/561/EU. During that time, the Commission had the task of monitoring the implementation of Directive 2006/52/EC in the Member States. In 2012, it carried out a desk study to monitor its implementation, which indicated that there are general monitoring programmes of foodstuffs in place based on inspection and sampling in many of the Member States. However, very few Member States indicated that they have specific programmes on nitrites. Sampling mainly takes place at processing meat plants and retailers and there are few cases of non-compliant samples for traditional cured meat products and meat products produced in the EU. In the context of sterilised meat products, most of the MS indicated that the typical amount of nitrite added by the meat industry is 100 mg/kg. PL is the only MS who declares to use a much lower typical amount (25-35 mg/kg) and a maximum amount (26-43 mg/kg) for Polish products (e.g. gulash, pork mince-mielonka wieprzowa and pork ham-szynka wieprzowa). When it comes to the maximum amount, most of the MS quoted the maximum permitted levels established by the EU legislation (100 mg/kg). For heat treated meat products derived from whole pieces of meat (e.g. cooked ham), the typical amount of nitrite added varied in the MS. The range of values varies from 25 mg/kg (some Danish meat products) to 150 mg/kg. However, most of them are in the range of 80 to 120 mg/kg. When it comes to the maximum amount, most of the MS quoted levels between 120 and 150 mg/kg. With regard to heat treated poultry meat products, the lowest typical amount of nitrite is 30 from some Estonian products and the highest is 150 mg/kg from other MS. The average range is from 80 to 120 mg/kg. When it comes to the maximum amount, most of the MS quoted levels between 120 and 150 mg/kg. Concerning other heat treated meat products derived from minced meat (e.g. mortadella, pâté) the lowest typical amount of nitrite is 60 mg/kg in some Danish and Estonian products with the exception of the Danish traditional product "leverpostej" where nitrites are not permitted according to Annex IV to Regulation (EC) No 1333/2008. The highest typical amount is 150 mg/kg from other MS. The average range is from 80 to 120 mg/kg. When it comes to the maximum amount, most of the MS quoted levels between 120 and 150 mg/kg. For non-heat treated meat products derived from whole pieces of meat together (e.g. dried ham, bacon), the lowest typical amount of nitrite is 50 mg/kg from some Romanian products and the highest is 150 mg/kg from other MS. The average range is from 80 to 120 mg/kg. When it comes to the maximum

	amount, most of the MS quoted levels between 120 and 150 mg/kg. Regarding non-heat treated meat products derived from minced meat (e.g. salami, chorizo) the lowest typical amount of nitrite is 20 mg/kg from some Danish products followed by some Latvians and Romanian products at the level of 50 mg/kg. The highest is 150 mg/kg from other MS. The average range is from 120 to 150 mg/kg. When it comes to the maximum amount, most of the MS quoted levels between 120 and 150 mg/kg. Concerning marinated meat, 20 MS did not provide any data either because nitrites are not added to this type of product, or because the levels added are not known. For those MS who replied, they indicated that the level varied from 50 to 150 mg/kg the average level being 90 mg/kg. When it comes to the maximum amount, these MS quoted levels between 50 and 150 mg/kg. Most Member States reported having taken action in cases of non-compliance. The establishment of maximum limits of nitrosamines in final product was not welcomed by responding Member States. Likewise, respondents to the desk study indicated that the replacement of maximum ingoing amounts by indicative ingoing amounts should not take place. The report concluded that the possibility of reviewing the current maximum levels of nitrite should be explored, considering that in most Member States nitrites are usually added to meat products at levels lower than the maximum permitted levels.

Name of author(s)	*European Commission*
Title of publication	**Reports of the scientific committee for food (thirty-eighth series)**
Year	1997
Source/Organization	European Commission
Type of document	Report
Topics covered	Use levels; Nitrosamines
Abstract	N/A
Key information relevant	Analysis of foods for nitrate and nitrite ion remains somewhat problematic. Various methods have been applied in different laboratories and there are no reference materials available with the contents of nitrate and nitrite certified in a relevant matrix which could be used to check recoveries and analytical performance. A number of published studies have not given details of their intra- and inter laboratory analytical quality control procedures and this hinders comparison of data obtained in different laboratories. There are wide disparities in published results and it is clear that comparisons of levels of nitrate in vegetables in different commodities or in different Member States must be conducted with some circumspection. It should also be noted that differences in methodologies for reporting estimates of dietary intake hampers direct comparison between countries. Reported data on nitrite contents of cured meats are as follows: Bacon – 24 mg/kg; Ham – 26 mg/kg; Chopped ham and pork – 4 mg/kg; Tongue – 17 mg/kg; Corned beef – 5 mg/kg; Luncheon meat – 24 mg/kg; Cured pork shoulder – 5 mg/kg; Chicken pâté– 4 mg/kg; Liver sausage – 4 mg/kg; Liver pâté – 7 mg/kg; Cured beef – 11 mg/kg; Cured turkey – 54 mg/kg.

Name of author(s)	*European Food Safety Authority*
Title of publication	**Scientific Opinion: Statement on nitrites in meat products**
Year	2010
Source/Organization	EFSA Journal 2010; 8(5)
Type of document	Journal article
Topics covered	Use levels; Nitrosamines
Abstract	The Panel on Food Additives and Nutrient Sources added to Food assess the data provided by the Danish authorities, evaluating in particular whether this information, or any other new scientific developments, indicate that there is scientific evidence for a revision of the maximum limits on nitrites in food adopted in Directive 2006/52/EC. The Panel considered that the terms of reference could be answered by considering three issues including 1) whether the data provided by the Danish authorities would support re-evaluation of the ADI for nitrite, 2) whether the current exposure to nitrite from the proposed uses and use levels would exceed the ADI and 3) what nitrite levels would be required to achieve its preservative effects. The Panel concludes that the data provided by the Danish authorities do not provide a basis to revise the ADI of 0.07 mg/kg bw/day for nitrite. The Panel notes that in several European countries the mean exposure at Tier 2 is above the ADI. At Tier 3, the adult high consumers are just above the ADI while for high consumer children exposure is 2.5 times above the ADI, and the higher range of the mean exposure of children is close to the ADI. The Panel concludes, in line with the SCF assessment in 1995 that exposure to preformed nitrosamines in food should be minimized by appropriate technological practices such as lowering the levels of nitrate and nitrite added to foods to the minimum required to achieve the necessary preservative effect and to ensure microbiological safety. Evaluation of the technological need for the maximum use levels for nitrite adopted in Directive 2006/52/EC of 5 July 2006 is outside the remit of the Panel. However, the Panel notes that this issue has been adequately assessed by others and that the technological need is product specific.
Key information relevant	The Panel noted that residual levels reported for cured meat products were based on extensive analytical data realised from several surveys conducted in Denmark between 1995 and 2006 and France between 2000 and 2006. Furthermore the ANS Panel notes that these average residual levels were generally below 60 mg/kg meat product.

Name of author(s)	*Heraud, Fanny* *Volatier, Jean-Luc* *Leblanc, Jean-Charles*
Title of publication	**Assessment of Dietary Exposure of Nitrate and Nitrite in France**
Year	2009
Source/Organization	Food Additives and Contaminants, Vol. 25, Issue 8, 2009, pp. 971-988.
Type of document	Journal article
Topics covered	France; Use levels
Abstract	The aim of this study was to assess the dietary exposure of nitrate and nitrite in France. 13 657 concentration levels of nitrate and nitrite measured in food, representing 138 and 109 food items respectively and coming from French monitoring programs between 2000-2006, were used. Depending on the non-detected and non-quantified analysis treatment, lower and upper concentration mean estimates were calculated for each food item. These were combined with consumption data of 1474 adults and 1018 children from the French national individual consumption survey (INCA1), conducted in 1999 and based on a seven-day food record diary. 18% of spinaches, 6% of salads, 10% of cheeses, 8% of meat products and 6% of industrial meat products exceeded the European nitrate maximum level or maximum residual level. 0.4% of industrial meat products and 0.2% of meat products exceeded their European nitrite maximum level or maximum residual level. Nitrate dietary exposure averaged 40% of the Acceptable Daily Intake (ADI, 3.7 mg kg -1 bw day-1) for adults and 51 - 54% of the ADI for children with the major contributors being, for adults and children respectively, vegetables (24 and 27% ADI), potatoes (5 and 11% ADI) and water (5 and 5% ADI). The individual nitrate dietary intake of 1.4% (Confidence Interval (CI95th) [0.8; 2.0]) to 1.5% (CI95th [0.9; 2.1]) of adults and 7.9% (CI95th [6.2; 9.6]) to 8.4% (CI95th [6.7; 10.1]) of children were higher than the ADI. Nitrite dietary exposure averaged 33 - 67% of ADI (0.06 mg kg -1 bw day-1) for adults and 67 - 133% of ADI for children, with contributions of additive food-vectors at 33% ADI for adults and 50 – 67% ADI for children. The individual nitrite dietary intake of 0.7% (CI95th [0.3; 1.1]) to 16.4% (CI95th [14.5; 18.3]) of adults and 10.5% (CI95th [8.6; 12.4]) to 66.2% (CI95th [63.3; 69.1]) of children were higher than the ADI.
Key information relevant	Nitrite dietary exposure in France averaged 33 - 67% of ADI for adults and 67 - 133% of ADI for children. The main contributors to exposure were additive food-vectors, which contributed on average 1 to 19 times more than the other food items. Subjects whose nitrite intakes exceeded the ADI were high consumers of meat products and industrial meat products. Study results also showed that 0.4% of industrial meat products and 0.2% of meat products exceeded 100 mg kg -1 of nitrite concentration, but mean concentrations in these food items were below 50 mg kg -1, except in Rosette (94 mg kg -1).

Name of author(s)	*Herrmann, S.S.* *Duedahl-Olesen, L.* *Granby, K.*
Title of publication	**Occurrence of volatile and non-volatile N-nitrosamines in processed meat products and the role of heat treatment**
Year	2015
Source/Organization	Food Control, Vol. 48, pp. 163-169.
Type of document	Journal article
Topics covered	Use levels; Nitrosamines; In situ; Denmark; Belgium
Abstract	Most of the available data on the occurrence of N-nitrosamines (NA) in processed meat products have been generated in the 1980s and 1990s and especially data on the occurrence of non-volatile NA (NVNA) are scarce. Therefore we have studied the levels of volatile nitrosamines (VNA) and NVNA in processed meat products on the Danish market (N= 70) and for comparison also products on the Belgian market (N= 20). The effect of heat treatment on the NA levels, in selected samples, was also studied, in order to enable an evaluation of how preparation before consumption affects the levels of NA. For the Danish products the mean levels of the VNA were generally low (<0.8 µg kg-1), whereas the mean levels of the NVNA were considerably higher (<118 µg kg-1). Slightly higher mean levels were indicated for the Belgian products (i.e. VNA <1.5 µg kg-1 and NVNA <270 µg kg-1). The sums of VNA were higher than 10 mgkg-1 for one Danish sample and two Belgian samples. Levels of up to 2000 and 4000 µg kg-1 of N-nitroso-thiazolidine-4-carboxylic acid (NTCA) an NVNA occurred in the Danish and the Belgian samples, respectively. The majority of the Danish processed meat products contain NVNA but also VNA occur. The levels of NA are comparable with those reported in previous and recent studies; however the frequency in which they are found may be lower and thereby also the mean contents. The levels of N-nitrosopiperidine (NPIP) increased by frying and baking, whereas varying impacts were observed for N- nitrosoproline (NPRO), N-nitrosodimethylamine (NDMA), N-nitrosopyrrolidine (NPYR), N-nitrosodiethylamine (NDEA) and N-nitrosomethylaniline (NMA) depending on the type of product and/or the heat treatment. The levels of the NVNA, NTCA and N-nitroso-2-methyl-thiazolidine 4-carboxylic acid (NMTCA) decreased after frying and baking.
Key information relevant	[…] Samples were analysed for residual levels of nitrite or nitrate in order to study a possible correlation between residual levels of nitrite or nitrate and the levels of NA. The levels of VNA and NVNA were examined in six selected products before and after heat treatment. A method we recently developed and validated allowed for the simultaneous quantification of several VNA and NVNA in the meat products. *Meat products on the Danish market* - All samples were analysed by the LCeUV method and the samples taken by the Danish Veterinary and Food Administration during fall 2012 were also analysed by the FIA based method shortly after sampling. Significantly higher nitrite levels were found when the sample were analysed briefly after sampling than when they had been stored at -18 to -20°C for several month. Thus the nitrite was not stable under these storage conditions. It was therefore decided to use the analytical results obtained by the FIA based method for the samples taken by Danish Veterinary and Food Administration and the analytical results obtained by the LCeUV method for the remaining samples. Good correlation was found

between the nitrate contents determined using the two methods. Thus the nitrate contents were stable during storage at -18 to -20°C. The nitrite (NaNO2) levels ranged from < 3 mg kg $^{-1}$ to 36 mg kg $^{-1}$ with a mean content of 6.0 mg kg $^{-1}$. The five highest levels of nitrite were found in two samples of kassler (36 and 19 mg kg $^{-1}$), a sample of meat sausage (luncheon meat) (28 mg kg $^{-1}$) and in two dinner sausages (26 and 20 mg kg $^{-1}$). In general, salamis contained low levels of nitrite ($\leq$3mg kg $^{-1}$) and accounted for the majority of the samples with a high content of nitrate (15-120 mg kg $^{-1}$). No correlation between the detected residual levels of nitrite and/or nitrate and the levels of the individual levels of the detected NA could be demonstrated.

Meat products on the Belgian market- The nitrite (NaNO2) levels in the Belgian samples ranged from 0.3 mg kg $^{-1}$ to 25 mg kg $^{-1}$ with a mean content of 4.0 mg kg $^{-1}$. The nitrate (NaNO3) levels ranged from 1.5mg kg $^{-1}$ to 178mg kg $^{-1}$with a mean value of 32.9 mg kg $^{-1}$. No significant difference in the nitrite and nitrate levels found in the Danish and the Belgian samples could be determined when applying the student t-test (one tailed, type 2, P 0.95). The fact that no differences, in the levels of nitrite or nitrate, could be detected, between the samples taken from the Danish market and the Belgian market, is in good agreement with the progress in the legislation. Initially the use of nitrite and nitrate was regulated by Directive 95/2/EC laying down maximum residual levels of nitrites and nitrates as well as ‘indicative ingoing amounts’. However, since poor correlation has been demonstrated between added amounts and the resulting residual amounts, the legislation was altered by the implementation of Directive 2006/52/EC which defines maximum amounts for E 249 potassium nitrite and E 250 sodium nitrite that may be added during manufacturing.

Name of author(s)	*Honikel, Karl-Otto*
Title of publication	**The use and control of nitrate and nitrite for the processing of meat products**
Year	2008
Source/Organization	Meat Science
Type of document	Journal article
Topics covered	Use levels; Effect on colour; Nitrosamines
Abstract	Nitrate and nitrite are used for the purpose of curing meat products. In most countries the use of both substances, usually added as potassium or sodium salts, is limited. Either the ingoing or the residual amounts are regulated by laws. The effective substance is nitrite acting primarily as an inhibitor for some microorganisms. Nitrite added to a batter of meat is partially oxidized to nitrate by sequestering oxygen - thus it acts as an antioxidant - a part of nitrite is bound to myoglobin, forming the heat stable NO-myoglobin, a part is bound to proteins or other substances in meat. Nitrate may be reduced to nitrite in raw meat products by microorganisms. As oxidation and reduction may occur, the concentrations of nitrite plus nitrate in a product has to be controlled and measured especially if the residual amounts are regulated. This sum of both compounds is important for the human body. Intake of nitrate with food leads to its absorption over the digestive tract into the blood. In the oral cavity nitrate appears again where it is reduced to nitrite. With the saliva the nitrite is mixed with food, having the same effect as nitrite in a batter (inhibiting growth of some pathogenic microorganisms) and swallowed. In the stomach nitrite can eventually form carcinogenic nitrosamines in the acidic environment.
Key information relevant	In the last decades ascorbic acid or ascorbate, respectively, isoascorbate (erythorbate) is used in cured meat batters. There is a reaction of ascorbate with oxygen discussed forming dehydroascorbate and thus reducing the amount of nitrite which could be oxidized to nitrate. But ascorbate seems also to react with nitrite (nitrous acid or NO). Dahl, Loewe, and Bunton (1960), Fox and Ackerman (1968) and Izumi et al. (1989) show that ascorbate also reacts with ‘‘nitrite’’ and binding the resulting NO. The bound NO seems to be able to react as NO with other meat ingredients. Ascorbate is also added to reduce the formation of nitrosamines. The sequence of reactions of ascorbate preventing nitrosamine formation has not been fully elucidated. It may be due to the reduction of residual nitrite in meat products by ascorbate (EFSA, 2003) or the binding of NO to ascorbate and its retarded release. Furthermore, ascorbate in batters reduces the toxin production by proteolytic clostridium botulinum types A and B together with nitrite and salt (Robinson, Gibson, & Roberts, 1982). (…) Nitrite was added to meat products sometimes in too high amounts and e.g. in Germany some people died in the 3rd decade of the 20th century due to intoxication by nitrite in meat products. Germany solved the problem in 1934 with the Nitrit-Pokelsalz-Gesetz (nitrite curing salt law). It enforced that the use of nitrite in meat products is only allowed in premixes with table salt; its content should be 0.5% and must not exceed 0.6%. Only nitrate could be added directly to meat batters. 0.5% means that with 20 g nitrite curing salt/kg of batter (2%) 100 mg nitrite/kg batter (100 ppm) would be added. In the 1950s, the Fleischverordnung (meat regulation) limited the residual amount to 100 mg sodium nitrite/kg in ready-to-eat meat products. In raw hams 150

mg $NaNO_2$/kg were permitted. Also nitrate restrictions were applied. In the Fleischverordnung of 1982 nitrate was limited to some non-heated products with ingoing amounts of 300, respectively, 600 mg/kg and residual amounts of 100– 600 mg/kg product. (…)

The oxidation of nitrite to nitrate in meat also explains why in meat products to which only nitrite has been added nitrate will be found in considerable concentrations. In Figs. 5 and 6, the nitrite and nitrate concentrations of German meat products are shown. The emulsion type and cooked sausages and cooked hams are manufactured with nitrite only but they contain a mean of 20–30 mg nitrate/kg as also shown in Table 3 in a very recent survey. Nitrite is in most cases lower than nitrate in the finished product with concentration below 20 mg nitrite/kg in the median value. Only a few samples of cooked and raw sausages and raw ham exists above 60 mg nitrite/kg which also have higher nitrate concentrations. In the raw products nitrate may have been added. It could be assumed that the concentration of nitrate in a sausage where only nitrite is added is related to the nitrite content. Fig. 7 shows that with emulsion type sausages (only nitrite curing salt is used) the residual amounts of nitrite and nitrate exhibit no relationship above 20 mg residual nitrite/kg. There is no generally recognizable increase of nitrate with increasing residual amounts of nitrite. Without nitrite addition a residual amount of nitrate up to 30 mg/kg is probably due to the added drinking water and spices into the batter (0–50 mg nitrate/l).

When does the nitrite disappear in the product? Table 4 shows results from Russian colleagues (Kudryashow, 2003). The largest decrease is observed during the manufacturing up to the end of the heating process. This early loss amounts usually to about 65% independent of the ingoing concentrations. Within 20 days of cold storage the concentrations drop further to a third of the concentration after heating. The disappearance continues until 60 days of cold storage. Table 5 confirms the results. It furthermore shows that a higher pH value retards the disappearance of nitrite. It also confirms the results of Table 3 that nitrate concentrations are already high at day 0 after heating. Nitrate also falls in concentrations with time of storage. The reduction during storage is slower with increasing pH. Table 6 shows the influence of different heat treatment inmeat homogenates. To muscles with different pH, 100 mg nitrite/kg was added and the homogenate was either mildly heated (pasteurized) or sterilized. The nitrite and nitrate concentrations immediately after heating and 12 days of storage were measured. The results were: The higher the heating, the greater is the loss of nitrite. The formation of nitrate is also reduced. The residual nitrite plus nitrate added at no time of measurement to 100 mg/kg. Immediately after pasteurization both added to about 75 mg/kg. Sterilisation and storage reduced the added concentrations even further. Both compounds seem to react with other ingredients and are no longer analytically measured as inorganic nitrite or nitrate. The addition of ascorbate and polyphosphate show that the disappearance of nitrite is accelerated by ascorbate in the raw batter (Table 7). Heating for 7 min to 80°C leads to a slower loss of nitrite. Heating for additionally 1 h at 70°C retards the loss even longer. This is probably due to the inactivation of microorganisms and inactivation of enzymes by heating. With ascorbate and even more by polyphosphates the retarding by heating is also observed. Nitrite in all cases described here is partially oxidized to nitrate. In many experiments (see Tables 5 and 6) about 10–40% of the nitrite is oxidized to nitrate. This is known since decades. Already in 1978 Cassens et al. postulated that nitrite is bound to various meat constituents.

The red colour of cured meat products is one of the important effects of nitrite in meat products. The red colour is developing in a number of complicated reaction steps until NO-myglobin (Fe^{2+}) is formed. Myoglobin exists in a muscle in three states, in which the cofactor haem, a porphyrin ring with an iron ion in its centre binds different ligands or in which the iron exists in the Fe^{2+} or Fe^{3+} state. In the native myoglobin, the porphyrin moiety (Fig. 8) is supported in the ligand binding by amino acids of the protein in the neighbourhood. In the "original'' state myoglobin with Fe^{2+} in the porphyrin cofactor does not bind any ligand maybe a water molecule. In the presence of oxygen the myoglobin can bind an O_2 molecule and it becomes bright red. The iron ion is in the Fe^{2+} state. But oxygen and other oxidizing agents like nitrite can oxidize the Fe^{2+} to Fe^{3+}. The formed metmyoglobin (MetMb) is brown. The ''original'' myoglobin (Mb), the oximyoglobin (MbO_2) and the metmyoglobin are occurring together in meat. In a muscle in a live animal there is very little metmyoglobin which increases post-mortem with the disappearance of oxygen except when meat is MAP-packed with high oxygen content. The three states of myoglobin have three characteristics absorbance spectra between 400 and 700 nm. As the three are in a kind of equilibrium to each other, the spectra have an isosbestic point at 525 nm where all three absorption curve cross which each other. The absorbance of this wave- length can be used for detecting the percentage of each form in meat. Nitrosomyoglobin has a spectrum which has similar maximum wavelength like oximyoglobin (Fig. 9). Oxygen and NO are biatomic molecules. A similar biatomic molecule CO also binds to myoglobin and also very tight. In some countries (e.g. USA and Norway) MAP packaging of meat with 1–2% CO is permitted. By reducing enzymes or chemical reactions with reducing agent like ascorbate the $Fe3+$ is reduced to $Fe2+$. The NO formed from $N2O3$ can bind to the myoglobin ($Fe2+$) and forms a heat stable NO-myoglobin. Oximyoglobin is not heat stable and dissociates. The meat turns grey or brown. On heating the NO-myoglobin the protein moiety is denatured but the red NO-porphyrin ring system (called often nitroso-myochromogen) still exists and is found in meat products heated to 120°C. This heat stable red colour will change on bacterial spoilage and it fades on UV light. The first one is advantageous as the consumer recognizes spoilage like in fresh meat which also changes colour on spoilage. In most recent years the riddle about the red colour of cured raw hams like Parma ham without added nitrite or nitrate has been solved. Various authors could show and proof that the $Fe2+$ in the porphyrin ring is exchanged with $Zn2+$ which gives the products a pleasant red colour. Nitrite addition prevents the exchange.

(…) As heated meat products are produced from fresh meat (chilled or frozen) no amines are available. In raw nitrate- cured meat products the nitrite concentration is rather low. Thus the formation of $NO+$ is rather unlikely. In products heated above 130°C nitrosamines can be formed. Bacon frying, cured sausage grilling or frying of cured meat products as pizza toppings may experience such conditions that nitrosamines are formed. Table 9 shows the results of an investigation by Deierling, Hemmrich, Groth, and und Taschan (1997). In German foods only beer and pizza exhibited dimethyl-nitrosamine in detectable amounts. Thus nitrosamines occur only in small amounts and they are easily avoidable by proper frying, grilling and pizza baking. A data base for nitrosamines in foods together with other processing related residues are published by Jakszyn et al. (2004). Besides amines also amides and unsaturated fatty acids or derivatives of the latter can react with nitrite or its derivatives. Fatty acids or its derivatives can form alkylnitrites. About their concentrations very little are known about their presence in meat products. To the database Jakszyn et al. (2004) is referred. In this context, it should be mentioned that nitrosamines can be present in elastic rubber nettings for meat products which may contaminate the edible parts of e.g. cooked ham.

Name of author(s)	*Hsu, James* *Arcot, Jayashree* *Alice Lee, N.*
Title of publication	**Nitrate and nitrite quantification from cured meat and vegetables and their estimated dietary intake in Australians**
Year	2009
Source/Organization	Food Chemistry, Vol. 115, Issue 1, 2009, pp. 334-339.
Type of document	Journal article
Topics covered	Australia; Use levels; Nitrosamines
Abstract	High dietary nitrate and nitrite intake may increase the risk of gastro-intestinal cancers due to the in vivo formation of carcinogenic chemicals known as N-nitroso compounds. Water and leafy vegetables are natural sources of dietary nitrate, whereas cured meats are the major sources of dietary nitrite. This paper describes a simple and fast analytical method for determining nitrate and nitrite contents in vegetables and meat, using reversed-phase HPLC-UV. The linearity R2 value was >0.998 for the anions. The limits of quantification for nitrite and nitrate were 5.0 and 2.5 mg/kg, respectively. This method is applicable for both leafy vegetable and meat samples. A range of vegetables was tested, which contained <23 mg/kg nitrite, but as much as 5000 mg/kg of nitrate. In cured and fresh meat samples, nitrate content ranged from 3.7 to 139.5 mg/kg, and nitrite content ranged from 3.7 to 86.7 mg/kg. These were below the regulatory limits set by food standards Australia and New Zealand (FSANZ). Based on the average consumption of these vegetables and cured meat in Australia, the estimated dietary intake for nitrate and nitrite for Australians were 267 and 5.3 mg/adult/day, respectively.
Key information relevant	The results of this study confirmed the consensus view that the largest source of dietary nitrite is cured meat products. It also established that intake levels in Australia were well below the recommended maximum ADI. Under the Austra- lian Food Standard Code 1.3.1 schedule 1, 125 mg/kg of nitrite in a form of potassium or sodium salt is permitted in cured, dried, and slow dried cured meat; whereas in commercially sterile and canned cured meat, the maximum nitrite (potassium or sodium salts) permitted is 50 mg/kg. For slow dried cured meat, the max- imum allowed nitrate (potassium or sodium salts) is 500 mg/kg (FSANZ, 2007–2008). Using similar detection method as Reinik et al. (2005), [Butt et al.] found the mean sodium nitrite and nitrate concentrations in ham were 20.8 and 68 mg/kg, respectively. However in this study, the nitrite concentration in ham averaged at 34.2 ± 5.6 mg/kg and nitrate concentration was lower at 19.0 mg/kg (Table 2). Some manufacturers add less nitrite but more nitrate as a nitrite reserve. This may also explain the differences in the findings by Öztekin et al. (2002), where the nitrite and nitrate contents in ham were 4.0 and 35.6 mg/kg, respectively. Dionex Corporation (1998) found the nitrite and nitrate contents in ham to be 11.6 and 5.4 mg/kg, respectively, whereas salami contained 108.0 mg/kg nitrite and 98.5 mg/kg nitrate. Using capillary electrophoresis, the nitrite and nitrate content in salami detected were 24.3 and 43.6 mg/kg, respectively (Öztekin et al., 2002). Compared to their findings, the current study showed that the salami contained no nitrite but much more nitrate at 142.5 mg/kg (Table 2). Although the extraction

	methods were sim- ilar the temperature used in our study was higher, apart from the differences that may be attributed to the manufacturing practices. Stalikas, Konidari, and Nanos (2003) used similar extraction temperature and reported that nitrate and nitrite contents in salami were 54 and 84 mg/kg, respectively. Thus differences are more likely to be due to the manufacturing processes. It was reported by Dennis, Key, Papworth, Pointer, and Massey (1990) that the mean nitrite content in bacon was 24.0 mg/kg and for nitrate was 43.0 mg/kg, whereas nitrite and nitrate in ham were 56.0 and 22.0 mg/kg, respectively. They used similar extraction and detection methods but with an anion exchange column. Both bacon and ham products in this study contained less nitrate and nitrite (Table 2) in comparison. Siu and Henshall (1998) who found that nitrite and nitrate contents in salami were 108.0 and 98.5 mg/kg, respectively, and 11.6 and 5.4 mg/kg for ham, respectively. Sample extraction procedures used in the current study were similar to Marshall and Trenerry (1996), but they omitted the heating step. This may explain the low nitrite content of less than 10 mg/kg in salami, leg ham and bacon. However the nitrate contents were higher at 141.5, 132.5 and 48.0 mg/kg, respectively. Different cured meat products may require different ratio of nitrite and nitrate as preservatives. Since fresh meat does not naturally contain nitrite (Table 2), its nitrite and nitrate contents have not been extensively tested. However, based on this study, the nitrate content in minced beef and medallion beef were within the range found in cured meat products (Table 2).

Name of author(s)	*Leth, Torben* *Fagt, Sisse* *Nielsen, Steffen*
Title of publication	**Nitrite and nitrate content in meat products and estimated intake in Denmark from 1998 to 2006**
Year	2011
Source/Organization	Food Additives and Contaminants, Vol. 25, Issue 10, 2008, pp.1237-1245.
Type of document	Journal article
Topics covered	Denmark; Use levels
Abstract	The content of nitrite and nitrate in cured meat products has been monitored in Denmark seven times in the period from 1995 to 2006. The maximum permitted added amounts of sodium nitrite in Denmark (60 mgkg-1 for most products up to 150 mgkg-1 for special products) was not exceeded, except for a few samples in 2002. The intake, mean and intake distribution, of sodium nitrite was calculated from 1998 to 2006 with data from the Danish dietary survey conducted in 2000-2002 on Danes from 4 to 75 years of age. The amounts used by industry were relatively stable through the whole period with levels varying between 6 and 20 mg sodium nitrite kg-1 with sausages, meat used for open sandwiches and salami type of sausages as the greatest contributors. The mean intake of sodium nitrate was around 1 mg day-1, which is very low compared to the total intake of 61 mg day-1. The mean intake of sodium nitrite was in mg kg-1 bw day-1 for men and women was 0.017 and 0.014, 0.009 and 0.008 and 0.007 and 0.003 in the age groups 4-5 years, 6-14 years and 15-75 years, respectively, which was much lower than the ADI value of 0.09 mg kg-1bw day-1. The 99 percentile for the group of 4 year olds was 0.107 and 0.123 mg kg-1bw day-1 for boys and girls, respectively, and the 95 percentile 0.057 and 0.073 mg kg-1bw day-1 for boys and girls, respectively, highest for the girls. With less than 100 boys and girls in the age group 4-5 years only a small number of individuals were responsible for the high intake. The conversion of nitrate to nitrite in the saliva and the degradation of nitrite during production and storage must also be considered when evaluating the intake of nitrite.
Key information relevant	The mean value of all the samples is typically about 20% lower than the mean value of samples with content over the detection limit (data not shown). In very few samples the maximum permitted level of nitrite was exceeded and that was back in 2002 and earlier. A few declaration errors were found every year mainly due to declaration of nitrite, which could not be found in the sample, probably because the nitrite was used up during production and storage. No nitrite was used in liver paste, where it is not allowed. However, in paté nitrite was generally used. In the group meat for open sandwiches, fat and medium fat nitrite was found in more than half of the samples. However, the results show that it was also possible to produce meat products in these groups without using nitrite. Products like bacon and sausage of the saveloy type often contained nitrite, while smoked saddle and loin fillet were often without added nitrite. Salami was mainly without nitrite, while the other sausage types in this group often contained nitrite. Also sausages usually contained nitrite. The average level of nitrite seemed fairly stable over the years although with some variation and with a low level in 2005. However, in 2006 the level of nitrite increased again. The levels varied in the different food groups from 9 to 20 mg kg -1 of sodium

nitrite for sausages, fat and lean meat for open sandwiches, and salami type of sausages with the highest content. In 2006, the mean sodium nitrite found was 0 mg/kg in liver paste, 6.6 mg/kg in pâté, 18.9 mg/kg in meat for open sandwiches (fat), 15.4 mg/kg in meat for open sandwiches (lean), 10.9 mg/kg in salami, and 11.6 mg/kg in sausages.

In terms of dietary intake of nitrite, average intake in Denmark was around 16-19% of the ADI value (the ADI value is fixed at 0.06 mg nitrite (nitrite ion) or 0.09 mg sodium nitrite kg-1bw day-1). However, endogenous conversion of nitrate to nitrite in saliva must be taken into account, and is reported to be between 5% and 20% of total nitrate. For children between 4 and 14 years of age, this led in many cases to an intake higher than the ADI. Another aspect to consider is the fact that there is no direct relationship between the in-going and the residual amount of nitrite. Instead, the degradation of nitrite added to meat is influenced by several factors like pH-value, storage temperature, heat treatment of the meat and the presence of reducing substances. In particular, added ascorbate will increase the rate of degradation of nitrite.

Name of author(s)	*Verkleij, T.J.* *Stekelenburg, F.K.* *Stegeman, D.*
Title of publication	**Effects of reducing the amount of nitrite in organic meat products**
Year	2006
Source/Organization	Food and Biotechnology Innovations
Type of document	Journal article
Topics covered	Effect on colour; Organic; Use levels
Abstract	The organic production chain of pork is well controlled and only a small list of additives, (mentioned in EC Directive 2092/91) may be used. Since years, profound discussion is going on in the EC for the use of nitrite (E250) as an additive in processing of meat and meat products. For organic meat products the range of ingoing nitrite is determined to produce a cured meat color with sufficient color stability and provide the same level of product safety compared to regular meat products. By a reduction of the amount of ingoing nitrite to an extend of approximately 80 mg/kg, the color development, color stability and product safety will be sufficient to reach a shelf life of 65 days.
Key information relevant	Based on literature information organic cured ham and luncheon meat with three levels (0, ca 50 and ca 85 mg/kg) ingoing sodium nitrite were prepared. A generally applied product flow of 5 weeks at 4°C before slicing, MAP packaging of sliced product, retail storage for 5 weeks at 7°C with light source of 880 lux (12 hours on a day) only the last week was simulated. At several moments analyses were performed. (…) Nitrite concentrations declined sharply after production for both type of products to about 15 – 25% of the ingoing level and steadily declined further during storage to a final amount of 2.5 – 6 ppm. The color of both products with nitrite were still acceptable compared to the one without nitrite. At 7°C and 10°C. C. botulinum didn't grow in both lean and fat products, without or with nitrite, during a storage period of 12 weeks. Botulinum toxin was not determined. At 15°C growth of C. botulinum was detected earlier in products without nitrite (Figure 1). Botulinum toxin was detected in lean luncheon meat without nitrite after 6 weeks, in fat luncheon meat without nitrite after 8 to 12 weeks and in lean luncheon meat with 54 mg/kg nitrite after 12 weeks. Complete abandoning of nitrite in the processing of organic meat products is not advisable. This will result in serious color instability of the product compared to conventional products and from this point of view the product doesn't look as consumers expect. By a reduction of the amount of nitrite to an extend of approximately 80 mg/kg ingoing, the color development and stability will be sufficient to reach a shelf life of 65 days. During production, heating, cooling and storage, the amount of residual nitrite level in this case will be far less than the 50 mg/kg as mentioned in EU Directive 2092/91. The risk of botulinum toxin formation will increase at storage temperatures above 10°C.

Name of author(s)	*Stegeman, D.* *Hulstein, J.* *Verkleij, J.* *Stekelenburg, K.*
Title of publication	**Reducing the amount of nitrites in the production of pasteurized organic meat products: experiments on industrial scale**
Year	2007
Source/Organization	Agrotechnology and Food Sciences Group
Type of document	Report
Topics covered	C. botulinum, Effect on colour; Use levels
Abstract	In this study, cooked organic cured ham products and Bologna type sausages have been produced in an industrial setting with regular and two reduced amounts of nitrite. Nitrite levels in the recipe have been reduced by a factor two and four. The residual nitrite analysis showed that nitrite concentrations declined sharply after production for both type of products to about 10 – 15% of the ingoing level and further declined during storage time of about 7 weeks (of which 3-4 weeks as sliced packaged product) to a final amount in the range of the detection limit of 2 ppm. No significant difference is found between the different ingoing levels. Applying the two reduced levels of ingoing nitrite still gave the desired cured colour for Bologna type sausage as well as for ham after cooking. During 30 days storage at 7 °C of the sliced and packaged product and 26 hours illumination at retail condition, the colour of all ham samples did not fade. For the Bologna type sausage no colour fading occurred during in the slices products during a 25 day period storage and 22 hour illumination in the products prepared with 158 and 79 ppm ingoing nitrite, while a small colour change occurred for the samples prepared with 40 ppm nitrite after being exposed to light for more than 8 hours. Challenge tests with L. monocytogenes were carried out on the prepared products. Both recipes were inoculated with a cocktail of three types of L. monocytogenes at a dosage of 1000 bacteria per gram product. The tests showed no increase in growth of the Listeria bacteria on the Bologna type sausage products prepared with 178 and 79 ppm nitrite during the storage period of 32 days at 7 °C, while a rather small increase by a factor 5 was seen during mentioned storage period in the Bologna type sausage prepared with 40 ppm nitrite. In all ham products the number of L. monocytogenes bacteria increased by 2 log units in circa 1.5 weeks storage at 7 °C. This dissimilarity is probably due to a difference in water activity between the ham and the bologna type sausage products, i.e. about 0.965 vs. 0.973. It can be concluded that, under practical conditions (production and handling under hygienic conditions, cold storage at temperatures below 7°C and aw in accordance to the shelf life), nitrite content in organic cooked cured ham and Bologna type of sausage can be reduced to 40 ppm ingoing amount. Some products can lose their cured colour somewhat earlier when exposed to an extended light source. Intelligent logistics and handling can prevent this

	discoloration. It is expected that a maximum value of 80 ppm ingoing nitrite will be set by the future EU legislation for organic meat products. Based on the present study a stable colour is expected for ham and Bologna type of sausage produced in compliance with the latest EU regulation EC 2092/91 according the recipes used in this study.
Key information relevant	From the colour experiments it is concluded that the same colour is developed in the manufactured ham and Bologna type sausage products with a reduced ingoing nitrite content of 40 ppm and about 80 ppm compared to products with an ingoing nitrite content of about 160 ppm. During the entire storage period of about 4 weeks at 7 °C the cured colour did not fade in the ham products prepared with 40 to 157 ppm nitrite, where the products were subjected to light of about 450 lux during 26 hours in the last period of the storage time. For the manufactured Bologna type sausage products with 79 and 158 ppm ingoing nitrite, also colour was stable during the storage period of 22 days with illumination during 22 hours. The products prepared with 40 ppm nitrite, however showed, reduced colour stability and started to become a bit brownish after about 8-16 hours illumination with 450 lux. From the challenge test with ham and Bologna type sausage with standard, medium and low nitrite levels it can be conclude that L. monocytogenes as well as lactic acid bacteria are not particularly sensitive to nitrite. Differences in growth rate of these bacteria in both products with different nitrite contents were small. Differences in water activity (aw value) between the ham products and the Bologna type sausages appeared to have a more pronounced effect on inhibition of lactic acid bacteria, whereas the relative low water activity in combination with the presence of lactate in the Bologna type sausage almost completely inhibited the growth of L. monocytogenes during the storage period of 32 days at 7°C. For meat products with higher water activity and/or absence of lactate L. monocytogenes can only be controlled by prevention of contamination due to stringent hygiene during production.

6.5. Results of expert workshop

The first of the workshop sessions related to the use and use levels of nitrites in the different categories of meat products and preparations. Regarding the use levels reported by survey respondents for **meat preparations and non-traditional meat products**, most members of the expert panel considered that the survey results (with median typical values reported ranging from 80 to 150 mg/kg of nitrite added across the categories) reflect the current practices of industry. However, it was emphasised that reported maximum levels were very high, and there is little information available regarding why there are these different levels, as there is no technological basis for this variation. According to the panel, factors that may explain why producers use higher levels of nitrites than are authorised in the legislation include a lack of knowledge of the legal limits and a strong emphasis of "being on the safe side" using traditional approaches.

It was also pointed out that producers often determine their use levels based on traditional recipes, which do not take into consideration improvements in hygiene practices. As one panel member put it: *"Meat industry is very traditional and won't change anything if not necessary. To me, this shows very clearly that people have not realised how much better hygiene is today than in older times. The survey results are telling the real situation in the meat industry."* The panel considered that there are no clear country differences in the typical amounts used by industry for non-traditional meat products and preparations, with the exception of Denmark (where different limits apply) and for some specific products such as Parma ham (in which nitrite is not used).

Concerning the different categories in the legislation, the panel emphasised that the current categorisation of meat products and preparations is overly complicated and should be replaced by a categorisation based on the technology used in the production process. Moreover, it was concluded that the additional category of *'Other meat products for which nitrites are used'* included in the questionnaire is of little relevance.

Regarding the use and use levels of nitrites in **traditional meat products** – for which legal limits are mainly based on residual amounts –, the panel highlighted the difficulty for producers to accurately report residual amounts of nitrite in their products at the end of the production process. This is because the depletion of nitrite throughout the production process depends on a large number of factors, including the type of product, fat content, pH, temperature, the use of nitrates, and the size of the product. Using the example of dry cured ham, a panel member that had conducted relevant measurements considered 20 mg/kg to 50 mg/kg residual amount to be realistic, while 150 mg/kg was considered to be a very high value. The panel concluded that the median of reported values could be used as a realistic indication of the levels used in practice, although attention should also be paid to the high residual levels reported.

Again, the panel discussed reasons such as producers' lack of knowledge about the maximum authorised limits and the use of traditional methods as possible explanations for reported values exceeding legal limits. As for non-traditional products and preparations, a possible explanation for the variation in values reported brought forward by the panel relates to the different approaches adopted by producers: while some try to minimise the use of nitrites and nitrates in their products, others continue to use traditional recipes or maximum amounts "to be on the safe side". In addition, in some cases the country for which the product is marketed may influence nitrite levels. One participant mentioned the EC's 2013 report which found that producers use lower levels of nitrite when targeting the Danish market than when producing for other EU countries, for the same product.[30] This suggests that levels of nitrites used in practice may be a reaction to the limit provided in the legislation. Another possible reason for the variation in reported values relates to the different levels of nitrates used by producers, which influences the residual amount of nitrite as measured at the end of the production process.

The panel considered that for most products, it is possible to calculate the ingoing amount and that defining the maximum limit as an added amount is preferable. However, a clear caveat in defining limits as ingoing amounts is that it is not possible to control the amounts added in practice by producers, making enforceability a challenge. Moreover, the panel noted that for some products – in particular traditional dry cured or immersion cured products – it is difficult to calculate the ingoing amount. Problems with using residual amounts as maximum limit are that in this case it remains not known which amounts of nitrite have been added, and residual amounts of nitrite remaining at the end of the production process depends on a large number of factors (e.g. pH, temperature, amount of lean meat exposed to the nitrite).

After an extensive discussion, the panel concluded that legislation should continue to define maximum levels as amounts added. In addition, guidance documents and tools could be provided to producers and inspectors to facilitate the calculation of ingoing amounts, with reporting requirements regarding the use of nitrites and checks of recipes being options for better enforcement. Moreover, the panel emphasised that the categorisation of different products and preparations should be clear and simple, including as few categories as possible. The panel pointed out that if the objective is to reduce exposure to nitrite, NO_3 and NO_2 should be regulated together, to avoid producers reducing nitrite levels while simultaneously increasing nitrate levels to compensate the reduction.

Concerning realistic values for residual amounts in traditional meat products, the panel considered that a maximum residual amount of 175 mg/kg for traditional meat products was too high, and proposed 50 mg/kg as a more realistic limit.

[30] European Commission Health and Consumers Directorate-General, Final Report on a Desk Study to Monitor the Implementation of Directive 2006/52/EC in the EU Member States as Regards the Use of Nitrites by the Industry in the Different Categories of Meat Products and the Organisation of National Controls, 2013, p. 2.

7. THE EFFECT OF NITRITE ON MEAT COLOUR, TASTE, AND PRESERVATION

In this section, we present the study results concerning the technological uses of nitrites in meat products and preparations. In particular, we examine the effect of nitrite on meat colour, taste, and preservation, especially protection against *Clostridium botulinum*. We first present survey results for meat preparations and non-traditional meat products, then the survey results for traditional meat products, followed by the results from the literature research and the expert workshop across all categories.

7.1. Survey results for meat preparations and non-traditional meat products

7.1.1. *Meat preparations*

In our survey, respondents were asked to provide the minimum amount of nitrites required in practice to achieve the technological needs related to protection against Clostridium botulinum and for colouring and flavouring purposes. In providing their answers, respondents were asked to differentiate between meat preparations derived from red meat and preparations derived from poultry meat. For meat preparations derived from red meat, the following values were provided in our survey:

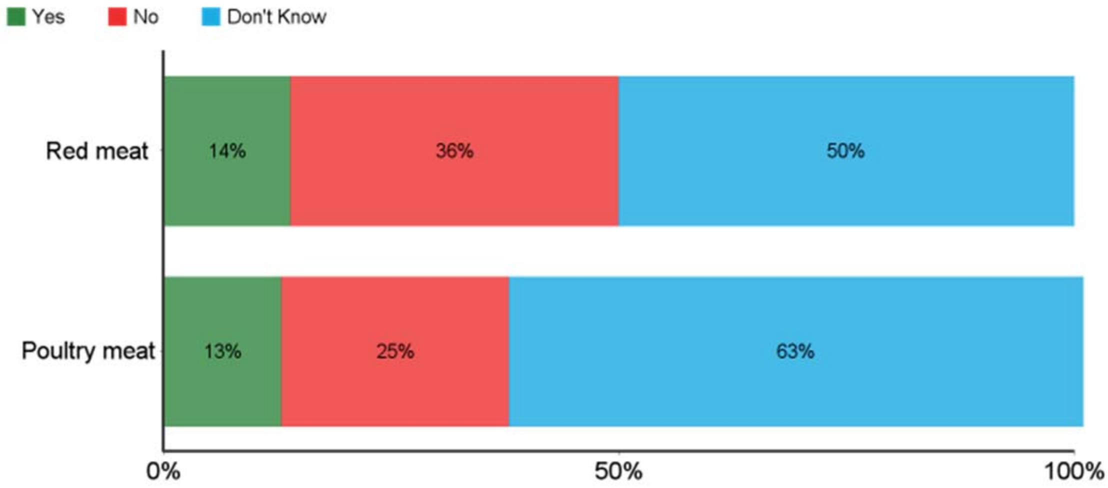
- Minimum amount added required in practice *for protection against Clostridium botulinum*: Values provided by respondents ranged from 20 to 150 mg/kg (Median 100 mg/kg);
- Minimum amount added required in practice for *colouring purposes*: Values provided by respondents ranged from 10 to 150 mg/kg (Median 55 mg/kg);
- Minimum amount added required in practice for *flavouring purposes*: Values provided by respondents ranged from 10 to 150 mg/kg (Median 80 mg/kg).

For meat preparations based on poultry meat, the following values were provided in our survey:

- Minimum amount added required in practice for *protection against Clostridium botulinum*: Values provided by respondents ranged from 50 to 150 mg/kg (Median 80 mg/kg);
- Minimum amount added required in practice for *colouring purposes*: Values provided by respondents ranged from 20 to 150 mg/kg (Median 55 mg/kg);
- Minimum amount added required in practice for *flavouring purposes*: Values provided by respondents ranged from 30 to 150 mg/kg (Median 80 mg/kg).

Survey respondents were also asked to consider whether the maximum added amount authorised could be reduced without compromising microbiological safety. The figure below illustrates the assessment of survey respondents for meat preparations derived from red meat and from poultry meat.

Figure 20: "Could the maximum added amount authorised be reduced without compromising microbiological safety?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=14 (red meat) /8 (poultry meat).

As the figure shows, 14% and 13% of the relatively small number of respondents who answered to this question considered that the maximum added amount authorised could be reduced for meat preparations derived from red meat and from poultry meat respectively. More than one third (36%) considered that such a reduction could not be achieved without compromising microbiological safety in meat preparations derived from red meat, while half (50%) did not know. For preparations derived from poultry meat, one quarter (25%) considered that the maximum added amount authorised could not be reduced, and nearly two thirds (63%) did not know.

Those respondents who considered that the maximum added amount could be reduced without compromising microbiological safety suggested that the amount could be reduced to levels ranging between 10 and 100 mg/kg (for red meat) and 100 to 120 mg/kg (for poultry meat).

The tables in Annex 4 of this report present the detailed answers provided by individual respondents, which form the basis for the summary figures above.

7.1.2. *Non-heat treated processed meat*

As for meat preparations, survey respondents were asked to provide the minimum amount of nitrites required in practice to achieve the technological needs related to protection against *Clostridium botulinum* and for colouring and flavouring purposes in non-heat treated processed meat products. Once again, the survey differentiated non-heat treated processed meat products according to whether they are derived from red meat or from poultry meat.

For non-heat treated processed meat derived from red meat, the following values were provided in our survey:

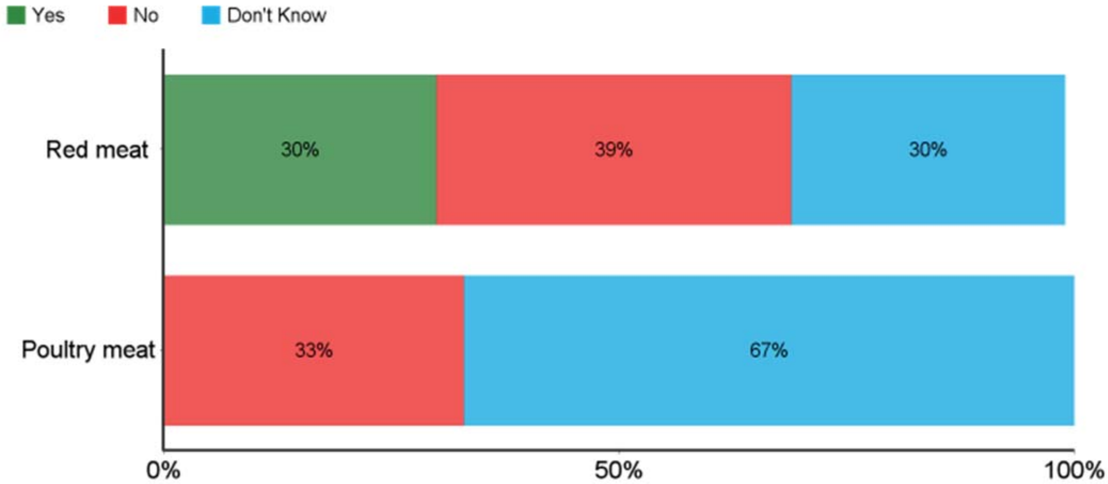
- Minimum amount added required in practice for *protection against Clostridium botulinum*: Values provided by respondents ranged from 10 to 150 mg/kg (Median 100 mg/kg);
- Minimum amount added required in practice for *colouring purposes*: Values provided by respondents ranged from 20 to 150 mg/kg (Median 60 mg/kg);
- Minimum amount added required in practice for *flavouring purposes*: Values provided by respondents ranged from 20 to 150 mg/kg (Median 60 mg/kg).

For non-heat treated processed meat derived from poultry meat, the following values were provided in our survey:

- Minimum amount added required in practice for *protection against Clostridium botulinum*: Values provided by respondents ranged from 50 to 150 mg/kg (Median 95 mg/kg);
- Minimum amount added required in practice for *colouring purposes*: Values provided by respondents ranged from 50 to 150 mg/kg (Median 70 mg/kg);
- Minimum amount added required in practice for *flavouring purposes*: Values provided by respondents ranged from 30 to 150 mg/kg (Median 70 mg/kg).

Again, survey respondents were asked to consider whether the maximum added amount authorised could be reduced without compromising microbiological safety. The figure below illustrates the assessment of survey respondents for non-heat treated meat products derived from red meat and from poultry meat.

Figure 21: "Could the maximum added amount authorised be reduced without compromising microbiological safety?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=23 (red meat) / 6 (poultry meat).

The figure above shows that while 30 percent of the 23 respondents who provided their assessment considered that the maximum added amount authorised in non-heat treated processed meat could be reduced for products derived from red meat, none of the only 6 respondents that answered regarding poultry meat considered such a reduction to be possible for products derived from this type of meat. For both sub-categories, approximately one third considered that such a reduction could not be achieved (39% and 33% respectively), while the remaining respondents did not know (30% and 67% respectively).

Suggested amounts to which the maximum level could be reduced ranged between 50 and 120 mg/kg for red meat; for poultry meat, although no respondents considered that the maximum added amount could be reduced without compromising microbiological safety, one respondent who replied "Don't know" nonetheless suggested reducing the maximum amount to 50 mg/kg.

The tables in Annex 4 of this report present the detailed answers provided by individual respondents, which form the basis for the summary figures above.

7.1.3. *Heat treated processed meat*

Survey questions related to the minimum amount of nitrites required in practice to achieve the technological needs related to protection against *Clostridium botulinum* and for colouring and flavouring purposes in heat treated processed meat distinguished between sterilised meat and non-sterilised products. As mentioned before, the legislation provides a maximum added amount of 100 mg/kg for sterilised products; for non-sterilised products that undergo heat treatment (e.g. cooking) the maximum limit is 150 mg/kg.

7.1.3.1. Sterilised heat-treated processed meat

As for the previous categories of meat products and preparations, survey respondents were asked to differentiate between meat products derived from red meat and those derived from poultry meat. For sterilised products derived from red meat, the following values were provided in our survey:

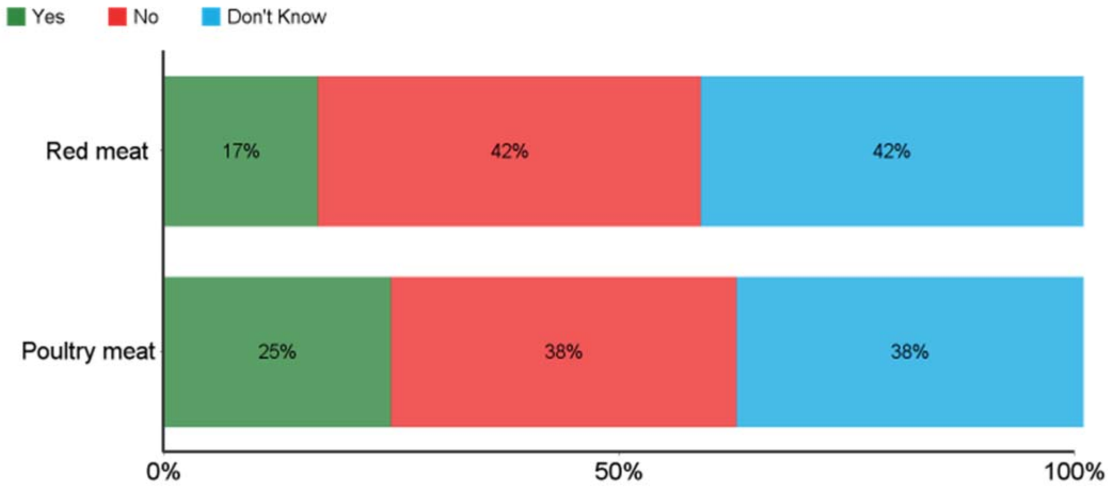
- Minimum amount added required in practice for *protection against Clostridium botulinum*: Values provided by respondents ranged from 50 to 150 mg/kg (Median 100 mg/kg);
- Minimum amount added required in practice for *colouring purposes*: Values provided by respondents ranged from 40 to 100 mg/kg (Median 50 mg/kg);
- Minimum amount added required in practice for *flavouring purposes*: Values provided by respondents ranged from 10 to 100 mg/kg (Median 50 mg/kg).

For sterilised products based on poultry meat, the following values were provided in our survey:

- Minimum amount added required in practice for *protection against Clostridium botulinum*: Values provided by respondents ranged from 60 to 150 mg/kg (Median 90 mg/kg);
- Minimum amount added required in practice for *colouring purposes*: Values provided by respondents ranged from 10 to 100 mg/kg (Median 50 mg/kg);
- Minimum amount added required in practice for *flavouring purposes*: Values provided by respondents ranged from 10 to 100 mg/kg (Median 60 mg/kg).

Moreover, the survey asked respondents to consider whether the maximum added amount authorised could be reduced without compromising microbiological safety. The figure below illustrates the assessment of survey respondents for sterilised products derived from red meat and from poultry meat.

Figure 22: "Could the maximum added amount authorised be reduced without compromising microbiological safety?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=12 (red meat) / 8 (poultry meat).

As the figure above shows, nearly one fifth (17%) and one quarter of respondents who provided their assessment considered that the maximum added amount authorised could be reduced for red meat and poultry meat without compromising microbiological safety. 42% and 38% respectively disagreed, with the remaining 42% and 38% stating that they did not know.

Respondents who considered that the maximum added amount authorised could be reduced suggested values between 60 and 80 mg/kg for sterilised products derived from red meat, and values between 10 and 60 mg/kg for sterilised products deriving from poultry meat.

The tables in Annex 4 of this report present the detailed answers provided by individual respondents, which form the basis for the summary figures above.

7.1.3.2. Non-sterilised heat-treated processed meat

Our survey asked respondents to consider the same set of questions concerning the minimum levels of nitrites required to achieve technological needs and the possibility to reduce the maximum level authorised in heat treated but non-sterilised meat products.

Survey respondents were asked to differentiate between meat products derived from red meat and those derived from poultry meat. For non-sterilised heat treated products derived from red meat, the following values were provided in our survey:

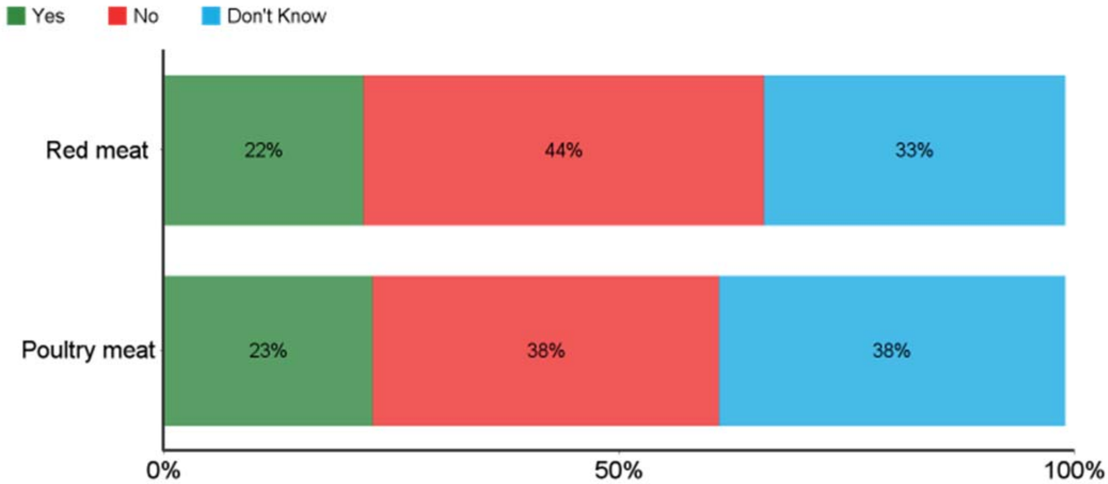
- Minimum amount added required in practice for *protection against Clostridium botulinum*: Values provided by respondents ranged from 10 to 150 mg/kg (Median 100 mg/kg);
- Minimum amount added required in practice for *colouring purposes*: Values provided by respondents ranged from 10 to 150 mg/kg (Median 60 mg/kg);
- Minimum amount added required in practice for *flavouring purposes*: Values provided by respondents ranged from 10 to 150 mg/kg (Median 70 mg/kg).

For non-sterilised heat treated products based on poultry meat, the following values were provided in our survey:

- Minimum amount added required in practice for *protection against Clostridium botulinum*: Values provided by respondents ranged from 50 to 150 mg/kg (Median 80 mg/kg);
- Minimum amount added required in practice for *colouring purposes*: Values provided by respondents ranged from 10 to 150 mg/kg (Median 50 mg/kg);
- Minimum amount added required in practice for *flavouring purposes*: Values provided by respondents ranged from 30 to 150 mg/kg (Median 60 mg/kg).

The figure below illustrates the assessment of respondents concerning the possibility to reduce the maximum added amount authorised without compromising microbiological safety for non-sterilised heat treated products derived from red meat and from poultry meat.

Figure 23: "Could the maximum added amount authorised be reduced without compromising microbiological safety?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=27 (red meat) / 13 (poultry meat).

As shown above, approximately one fifth (22%) of respondents considered that the maximum amount could be reduced for non-sterilised heat treated products derived from red meat, 44% considered that this could not be done, with the remaining 33% answering "Don't know." The results were similar for non-sterilised heat treated products derived from poultry meat, with 23% of respondents assessing that the maximum amount could be reduced, 38% considering such a reduction could not be achieved, and 38% selecting "Don't know."

Respondents who considered that the maximum added amount authorised could be reduced suggested values between 80 and 120 mg/kg for non-sterilised heat treated products derived from red meat, and values between 80 and 100 mg/kg for non-sterilised heat treated products deriving from poultry meat.

The tables in Annex 4 of this report present the detailed answers provided by individual respondents, which form the basis for the summary figures above.

7.1.4. *Other meat products for which nitrites are used*

As described in Section 6.2.2, some products are manufactured with the addition of nitrites even though the legislation does not explicitly provide a maximum limit for them. Such products include *Filet d'Ardenne*, *Swedish Christmas ham*, *Papillotes*, and *Blinde vink*. In our survey, respondents were asked to provide their assessment concerning the minimum amount of nitrites required in practice to achieve the technological needs related to protection against Clostridium botulinum and for colouring and flavouring purposes. As for the previous categories of meat products and preparations, answers were provided separately for other meat products derived from red meat and from poultry meat.

For other meat products derived from red meat, the following values were provided in our survey:

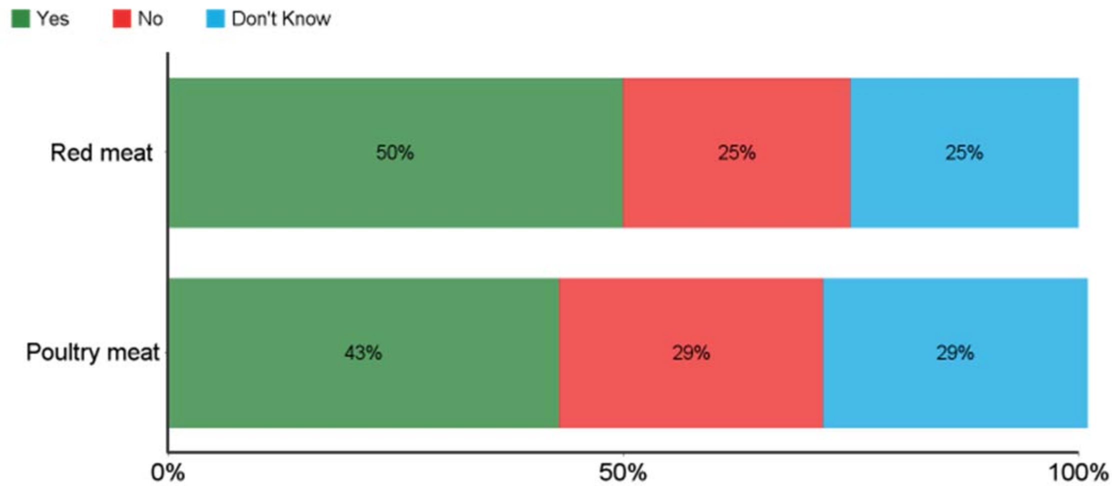
- Minimum amount added required in practice for *protection against Clostridium botulinum*: Values provided by respondents ranged from 60 to 180 mg/kg (Median 90 mg/kg);
- Minimum amount added required in practice for *colouring purposes*: Values provided by respondents ranged from 50 to 180 mg/kg (Median 60 mg/kg);
- Minimum amount added required in practice for *flavouring purposes*: Values provided by respondents ranged from 30 to 180 mg/kg (Median 80 mg/kg).

For other meat products derived from poultry meat, the following values were provided in our survey:

- Minimum amount added required in practice for *protection against Clostridium botulinum*: Values provided by respondents ranged from 60 to 180 mg/kg (Median 80 mg/kg);
- Minimum amount added required in practice for *colouring purposes*: Values provided by respondents ranged from 40 to 180 mg/kg (Median 55 mg/kg);
- Minimum amount added required in practice for *flavouring purposes*: Values provided by respondents ranged from 30 to 120 mg/kg (Median 65 mg/kg).

Survey respondents were also asked to consider whether the maximum added amount authorised could be reduced without compromising microbiological safety. The figure below illustrates the assessment of survey respondents for other meat products derived from red meat and from poultry meat.

Figure 24: "Could the maximum added amount authorised be reduced without compromising microbiological safety?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=9 (red meat) / 8 (poultry meat).

As depicted in the figure, 50% of respondents who provided an assessment considered that the maximum added amount authorised could be reduced for other products derived from red meat without compromising microbiological safety. One quarter (25%) of respondents considered that this could not be done, with another quarter (25%) of respondents selecting "Don't know". For other products derived from poultry meat, a slightly lower proportion of respondents (43%) considered that the maximum added amount authorised could be reduced, with 29% considering this could not be done. A further 29% of respondents did not know.

Respondents who considered that the maximum added amount authorised could be reduced suggested values between 60 and 100 mg/kg for other products derived from both red meat and poultry meat

The tables in Annex 4 of this report present the detailed answers provided by individual respondents, which form the basis for the summary figures above.

7.2. Survey results for traditional meat products

7.2.1. *Traditional immersion cured products*

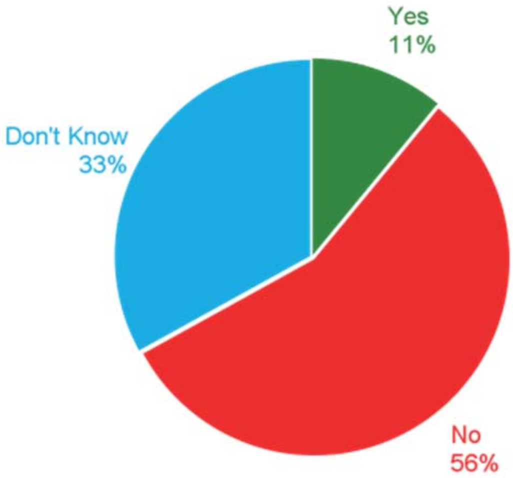
The use of nitrites in traditional immersion cured products is mainly regulated through the provision of maximum residual amounts authorised in the legislation, with the exception of two product types.[31] Depending on the product sub-category, the amount of residual nitrites permitted in traditional immersion cured products vary between 50 and 175 mg/kg. For these types of products, respondents were asked to provide the minimum residual amount of nitrites required in practice to achieve the technological needs related to protection against *Clostridium botulinum* and for colouring and flavouring purposes. The following values were provided in our survey:

- Minimum residual amount required in practice for protection against Clostridium botulinum: Values provided by respondents ranged from 10 to 170 mg/kg (Median 50 mg/kg);
- Minimum residual amount required in practice for colouring purposes: Values provided by respondents ranged from 10 to 170 mg/kg (Median 50 mg/kg);
- Minimum residual amount required in practice for flavouring purposes: Values provided by respondents ranged from 10 to 170 mg/kg (Median 50 mg/kg).

Survey respondents were also asked to assess whether the maximum residual amount currently provided in the legislation could be reduced without compromising microbiological safety. The results for this survey question are depicted in the figure below.

[31] These are Kylmâsavustettu poronliha/kallrökt renkött; bacon and filet de bacon and similar products. For these traditional products, a maximum amount added of 150 mg/kg is provided in the legislation and were not included in the survey question.

Figure 25: "Could the maximum residual amount authorised be reduced without compromising microbiological safety?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=9.

For traditional immersion cured products, more than half of respondents (56%) who provided an assessment considered that the maximum residual amount currently authorised in the legislation could not be reduced without compromising microbiological safety. While 11% (i.e. one respondent) considered the maximum residual amount could be reduced, one third (33%) of respondents did not know whether this could be done.

The respondent who replied "Yes" to this question (a company) suggested that the maximum residual amount could be reduced to 100 mg/kg for traditional immersion cured products.

The tables in Annex 4 of this report present the detailed answers provided by individual respondents, which form the basis for the summary figures above.

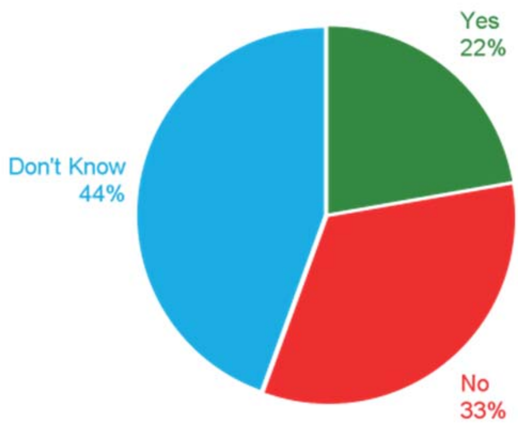
7.2.2. *Traditional dry cured products*

All traditional dry cured products are regulated through a maximum residual amount provided in the legislation which ranges from 50 to 175 mg/kg of residual nitrites in the finished product. In our survey, respondents were asked to provide their assessment of the minimum residual amount of nitrites necessary in practice to achieve the technological needs related to protection against *Clostridium botulinum* and for colouring and flavouring purposes. The following values were provided in our survey for traditional dry cured products:

- Minimum residual amount required in practice for protection against Clostridium botulinum: Values provided by respondents ranged from 10 to 170 mg/kg (Median 20 mg/kg);
- Minimum residual amount required in practice for colouring purposes: Values provided by respondents ranged from 10 to 170 mg/kg (Median 40 mg/kg);
- Minimum residual amount required in practice for flavouring purposes: Values provided by respondents ranged from 10 to 170 mg/kg (Median 30 mg/kg).

Survey respondents were then asked to assess whether the maximum residual amount currently provided in the legislation could be reduced without compromising microbiological safety. The results for this survey question are depicted in the figure below.

Figure 26: "Could the maximum residual amount authorised be reduced without compromising microbiological safety?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=9.

As the figure above shows, most respondents who provided an assessment (44%) did not know whether the maximum residual amount currently provided in the legislation for traditional dry cured products could be safely reduced. Moreover, while 22% (i.e. two respondents) considered this could be done with compromising microbiological safety, one third (i.e. three respondents) disagreed.

The two respondents who considered that the maximum residual amount could be reduced for traditional dry cured products suggested the limit could be lowered to 50 mg/kg or 100 mg/kg.

The tables in Annex 4 of this report present the detailed answers provided by individual respondents, which form the basis for the summary figures above.

7.2.1. *Other traditionally cured products*

With the exception of one type of product,[32] the use of nitrites in other traditionally cured products is authorised in the legislation upon the condition that the residual amount of nitrite in the finished product does not exceed 50 mg/kg. In light of this current limit, respondents were asked to provide the minimum residual amount of nitrites required in practice to achieve the technological needs related to protection against *Clostridium botulinum* and for colouring and flavouring purposes. The following values were provided in our survey:

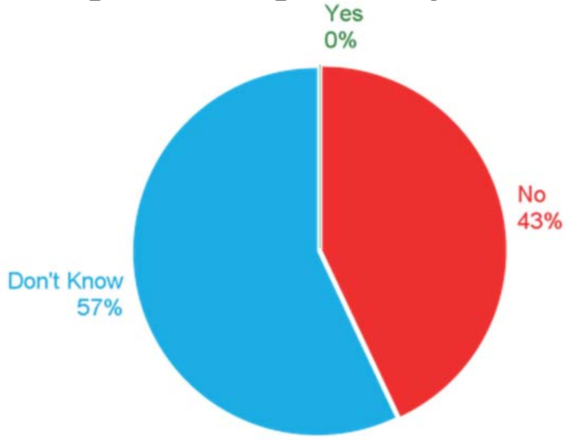
- Minimum residual amount required in practice for *protection against Clostridium botulinum*: Values provided by respondents ranged from 10 to 150 mg/kg (Median 30 mg/kg);
- Minimum residual amount required in practice for *colouring purposes*: Values provided by respondents ranged from 10 to 150 mg/kg (Median 40 mg/kg);
- Minimum residual amount required in practice for *flavouring purposes*: Values provided by respondents ranged from 10 to 150 mg/kg (Median 50 mg/kg).

Survey respondents were then asked to assess whether the maximum residual amount currently provided in the legislation could be reduced without compromising

[32] For *vysočina, selský salám, turistický trvanlivý salám, poličan, herkules, lovecký salám, dunjaská klobása, paprikás* and similar products a maximum amount added authorised is provided in the legislation (180 mg/kg). This category was not included in the survey question.

microbiological safety. The results for this survey question are depicted in the figure below.

Figure 27: "Could the maximum residual amount authorised be reduced without compromising microbiological safety?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=7.

As shown above, of the seven respondents who provided their assessment, none considered that the current maximum residual amount of nitrites authorised in other traditionally cured products could be reduced without compromising microbiological safety. More than half (i.e. four respondents) did not know whether such a reduction could be achieved, while the remaining three respondents selected "No".

The tables in Annex 4 of this report present the detailed answers provided by individual respondents, which form the basis for the summary figures above.

7.3. **Results of literature research**

The following table presents the results of the literature research concerning the effect of nitrite on meat colour, taste, and preservation.

Name of author(s)	*N/A*
Title of publication	**Vers une recommendation de reduction du taux de nitrites dans les differentes familles de charcuterie**
Year	2010
Source/Organization	IFIP - Institut du Porc
Type of document	Summary sheet
Topics covered	Effect on colour; Effet on taste; C.botulinum; France
Abstract	N/A
Key information relevant	The aim of this study was to carry out a review of literature in order to establish whether it is possible to reduce the quantity of nitrites used in the production of meat products while preserving the microbiological and sensorial quality (colour, aroma) of those products. From the microbiological perspective, a reduction of nitrites will essentially have an impact on the growth of Clostridium botulinum and the toxin produced by the bacterium. To continue the control of the bacterium through nitrites, it will be difficult to reduce levels below 80 mg/kg of added sodium nitrite. Based on previous research cited in this document, this quantity seems sufficient to guarantee the development of the colour and aroma specific to meat products. On the other hand, it should be noted that a simultaneous reduction of nitrite and other inhibitors such as salt leads to an inevitable reduction in the safety and shelf life of product, causing an increase of non-compliant products. Therefore, a reduction [in the level of nitrites], especially if it is major, should be systematically accompanied by a consideration of each company based on an analysis of the microbiological risk, in particular of Clostridium botulinum. It should lead professionals to increase the level of food safety by e.g. using ascorbate, modifying the process to ensure the destruction of Clostridium spores, acidification of the product or a reduction of water activity, and good management of the cold chain during the shelf life of the product.

Name of author(s)	*N/A*
Title of publication	**Impact des nitrites et de traitement thermique sur la couleur des produits hachés cuits**
Year	2013
Source/Organization	IFIP - Institut du Porc
Type of document	Summary sheet
Topics covered	Effect on colour
Abstract	N/A
Key information relevant	The study examined the influence of different levels of ntirite content on the development of colour in pate and sausages. The objective was to determine the minimum amount necessary to obtain a satisfactory color in pate de campagne and finely-ground sausages (frankfurters). The colour was evaluated using measurements made by a spectrophotometer. The intensity of the red colour is proportional to the angle of the red hue H*. The increase of nitrite content leads to an increase in H*. The increase is strong until 30 mg/kg, and more moderate until 100 mg/kg. The difference is more significant in sausages, for which the original colour of the raw material is less strong. In the pate de campagne, the presence of liver leads the original colour to be more intense, decreasing the influence of nitrites. The development of colour through the reaction of nitrites with myoglobin is a function of time and temperature.

Name of author(s)	*Doolaege, Evelyne H. A.* *Vossen, Els* *Raes, Katleen* *De Meulenaer, Bruno* *Verhé, Roland* *Paelinck, Hubert* *De Smet, Stefaan*
Title of publication	**Effect of rosemary extract dose on lipid oxidation, colour stability and antioxidant concentrations, in reduced nitrite liver pâtés**
Year	2012
Source/Organization	Meat Science
Type of document	Journal article
Topics covered	Effect on colour; Effect on taste; Alternatives to nitrites
Abstract	The oxidative stability of liver pâté was investigated in relation to different doses of rosemary extract (RE) and sodium nitrite. Colour stability, lipid oxidation (TBARS) and concentrations of ascorbic acid, α-tocopherol, carnosic acid and nitrite were measured on the batters before cooking and on the cooked liver pâté before and after exposure to light and air for 48 h at 4°C. Results showed that the use of RE significantly reduced lipid oxidation, whereas it had no effect on colour stability. Ascorbic acid and nitrite concentrations were significantly higher and lower respectively when RE was added. RE dose-dependently increased the concentration of carnosic acid. Lower sodium nitrite doses resulted in significantly lower nitrite concentrations and slightly lower TBARS values. It was concluded that in liver pâté sodium nitrite levels may be lowered to 80 mg/kg without negatively affecting colour and lipid stability and that the use of RE may help in maintaining lipid stability.
Key information relevant	The present study only focussed on lipid and colour stability in a reduced nitrite meat product. Nitrite also contributes to the typical flavour of cured meat products. Sensory analyses would be valuable to assess the effects of reducing nitrite and the use of other additives on flavour and consumer acceptability. In addition, the protective effect of nitrite against spore forming bacteria especially Clostridium botulinum needs to be considered. (…) The addition of a rosemary extract to porcine liver pâté had a positive effect on retarding lipid oxidation and maintaining higher concentrations of the antioxidants ascorbic acid, α-tocopherol and carnosic acid. Furthermore, it was found that the sodium nitrite dose, added to the liver pâté, could be reduced from 120mg/kg to 80mg/kg when rosemary extract was added, without negative effects on lipid oxidation, antioxidant level and colour stability.

Name of author(s)	*European Food Safety Authority*
Title of publication	**Opinion of the Scientific Panel on Biological Hazards on the request from the Commission related to the effects of Nitrites / Nitrates on the Microbiological Safety of Meat Products**
Year	2003
Source/Organization	European Food Safety Authority
Type of document	Report
Topics covered	C. botulinum; Preservation
Abstract	N/A
Key information relevant	Nitrites exert a concentration-dependent antimicrobial effect in cured meat products, including inhibition of Clostridium botulinum. Their antimicrobial effects are pH-dependent, and increase ten-fold for each unit fall in pH. Researchers have identified various factors that may contribute to the extent of antimicrobial protection, including the input concentration of nitrite, the residual nitrite concentration, salt concentration, the addition of sodium ascorbate, heat treatment, storage temperature, the initial pH of the meat, and the initial spore load. Moreover, the presence of iron markedly influences the antimicrobial effect of nitrite. There is still no universally accepted explanation of the control of C. botulinum in meat products. There is not a direct relationship between the input nitrite and the residual nitrite. The Panel considered that the ingoing amount of nitrite contributes to the protection against C. botulinum, rather than the residual amount. The amount of nitrite necessary varies between products. Some meat products can be produced without nitrite, if certain other conditions are met, although these are not strictly “cured meat products”. In other products, ingoing nitrite levels of 50-150mg/kg are required. The Panel considered that “indicative ingoing amount” should be replaced by “maximum ingoing amount”. Despite substantial research efforts, no alternative for sodium nitrite has been identified. (…) The Panel agrees with the view of the Scientific Committee on Food (SCF) (expressed in section 3.1.1 of the Opinion of 19 October 1990) that 50 – 100 mg added nitrite (as sodium nitrite) per kg of meat products may suffice for many products. In other products, especially those with a low salt content and having a prolonged shelf-life, addition of between 50-150 mg/kg nitrite is necessary to inhibit the growth of C. botulinum.

Name of author(s)	*Glass, Kathleen* *Sawyer, Christopher* *Claus, James*
Title of publication	**Minimum Nitrite Levels Required to Control Listeria monocytogenes on Ready-to-Eat Poultry Products Manufactured with Lactate and Diacetate**
Year	2008
Source/Organization	University of Wisconsin-Madison
Type of document	Report
Topics covered	Use levels; Preservation; Effect on colour
Abstract	Lactate and diacetate are more effective in inhibiting Listeria monocytogenes in cured ready-to-eat (RTE) meats than in uncured products, but no study has identified the threshold level of nitrite required to prevent L. monocytogenes growth in these products. The objective of this project was to compare the antilisterial effect of various nitrite levels in RTE sliced turkey product manufactured with lactate and diacetate. Treatments were manufactured using a central composite design for 4 variables, sodium nitrite, sodium chloride, potassium lactate, and sodium diacetate, with 5 levels for each variable (total 30 runs; center point replicated 6 times). Ranges for antimicrobial testing included 0-120 ppm nitrite, 0.8-3.6% NaCl, 0-3.2% lactate, and 0- 0.24% diacetate. Sliced finished products were surface inoculated with 3-log CFU/g L. monocytogenes, vacuum-packaged, stored at 4 or 7°C, and assayed for changes in populations of L. monocytogenes for up to 18 and 12 weeks, respectively. Listerial growth (defined as a 1-log increase) was highly variable for samples formulated with 30 and 60 ppm nitrite. Average growth for replicates of the center point treatment formulated with 60 ppm was observed at sampling intervals ranging between 9 and 18 weeks at 4°C. Formulations with similar lactate-diacetate-NaCl combinations but 120 and 0 ppm nitrite supported growth at 13-15 weeks and 4-6 weeks, respectively. Treatments with other combinations of lactate-diacetate-NaCl and 90 ppm nitrite supported growth similar to that which was predicted by the commercial model. Inhibition of L. monocytogenes was decreased by 3 to 6 weeks in several treatments with 30 ppm nitrite compared with the predictive model, but the addition of low nitrite levels delayed growth by 3 weeks or more compared to the control without nitrite. Addition of nitrite was the overall controlling factor on cooked product color. In general the cured color was not influenced by the addition of the non-nitrite antimicrobial ingredients. Treatments containing 30 to 120 ppm nitrite did not differ in cooked color. The minimum of 30 ppm nitrite was sufficient to produce a pink cured color in contrast to the absence of pink in the no nitrite control. These results suggest that a minimum 30 ppm nitrite will enhance the antilisterial activity of lactate-diacetate in RTE poultry, but as with other traditional antimicrobials, the effect is concentration dependent.
Key information relevant	While studies have verified that the addition of lactate and diacetate combinations inhibit growth of L. monocytogenes in cured meat products (with sodium nitrite), these organic acid salts are less effective in uncured products. High levels of lactate and diacetate that are inhibitory in high-moisture uncured products usually have a negative effect on sensory properties and may discourage customers from repurchase.

	No published literature has specifically reported the minimum level of nitrite required to affect the growth suppression of L. monocytogenes in the presence of lactate and diacetate. However, the hypothesis of this study was that nitrite added at levels which are lower than the traditionally-used 156 ppm may have a synergistic or additive antilisterial effect with lactate and diacetate in ready-to-eat meat products. Its results showed that nitrite levels as low as 30 ppm have an observable effect in inhibiting L. monocytogenes, but the effect is concentration dependent with adequate activity estimated at >70 ppm.

Name of author(s)	*Graham, Ann F.* *Mason, David R.* *Peck, Michael W.*
Title of publication	**Predictive model of the effect of temperature, pH and sodium chloride on growth from spores of non-proteolytic Clostridium botulinum**
Year	1996
Source/Organization	International Journal of Food Microbiology
Type of document	Journal article
Topics covered	C. botulinum
Abstract	Non-proteolytic strains of Clostridium botulinum are capable of growth at chill temperatures and thus pose a potential hazard in minimally-processed chilled foods. The combined effect of pH (5.0-7.3), NaCl concentration (0.1-5.0%) and temperature (4-30°C) on growth of non-proteolytic C. botulinum in laboratory media was studied. Growth curves at various combinations of pH, NaCl concentration and temperature were fitted by the Gompertz and Baranyi models, and parameters derived from the curve-fit were modelled. Predictions of growth from the models were compared with data in the literature and this showed them to be suitable for use with fish, meat and poultry products. This model should contribute to ensuring the safety of minimally-processed foods with respect to non-proteolytic C. botulinum.
Key information relevant	In total, 78 sets of conditions were tested, but growth was not observed in 20. A test resulting in no growth cannot be modelled using this technique, which leaves 58 growth curves to construct the model. In the first stage of modelling, the fitting of a curve to the original bacterial counts, good fits were obtained by both the Gompertz and the Baranyi models. In the second stage of modelling, the fitting of a quadratic response surface to the quantities derived from the curve-fit, the R2 statistics for the Gompertz model were 88.5% for In (p) and 86.6% for In (lag time). The R2 statistic for the Baranyi model was 90.4% for In(h). The root mean square error (rmse) provides a measure of the goodness of fit of a model to the data used to produce it. The lower this figure, the closer the fit of the model to the data. Values for the rmse of the Gompertz based models of In (g) and In (lag time) were 0.43 and 0.50 respectively. The rmse for In (,u) in the Baranyi model was 0.39, indicating a better fit to the experimental data. There was good agreement between experimental and predicted values for doubling time and lag time. Doubling times derived from the Baranyi model tended to be slightly higher than those derived from the Gompertz model. Both models predicted that optimal conditions for growth were temperatures between 25 and 28°C, pH between 6.6 and 6.7 and a NaCl concentration less than 1%. Growth was not observed at pH less than 5.1 or at 5% NaCl.

Name of author(s)	*Honikel, Karl-Otto*
Title of publication	**The use and control of nitrate and nitrite for the processing of meat products**
Year	2008
Source/Organization	Meat Science
Type of document	Journal article
Topics covered	Use levels; Effect on colour; Nitrosamines
Abstract	Nitrate and nitrite are used for the purpose of curing meat products. In most countries the use of both substances, usually added as potassium or sodium salts, is limited. Either the ingoing or the residual amounts are regulated by laws. The effective substance is nitrite acting primarily as an inhibitor for some microorganisms. Nitrite added to a batter of meat is partially oxidized to nitrate by sequestering oxygen - thus it acts as an antioxidant - a part of nitrite is bound to myoglobin, forming the heat stable NO-myoglobin, a part is bound to proteins or other substances in meat. Nitrate may be reduced to nitrite in raw meat products by microorganisms. As oxidation and reduction may occur, the concentrations of nitrite plus nitrate in a product has to be controlled and measured especially if the residual amounts are regulated. This sum of both compounds is important for the human body. Intake of nitrate with food leads to its absorption over the digestive tract into the blood. In the oral cavity nitrate appears again where it is reduced to nitrite. With the saliva the nitrite is mixed with food, having the same effect as nitrite in a batter (inhibiting growth of some pathogenic microorganisms) and swallowed. In the stomach nitrite can eventually form carcinogenic nitrosamines in the acidic environment.
Key information relevant	(…) The red colour of cured meat products is one of the important effects of nitrite in meat products. The red colour is developing in a number of complicated reaction steps until NO-myglobin (Fe2+) is formed. Myoglobin exists in a muscle in three states, in which the cofactor haem, a porphyrin ring with an iron ion in its centre binds different ligands or in which the iron exists in the Fe2+ or Fe3+ state. In the native myoglobin, the porphyrin moiety (Fig. 8) is supported in the ligand binding by amino acids of the protein in the neighbourhood. In the “original’’ state myoglobin with Fe2+ in the porphyrin cofactor does not bind any ligand maybe a water molecule. In the presence of oxygen the myoglobin can bind an O2 molecule and it becomes bright red. The iron ion is in the Fe2+ state. But oxygen and other oxidizing agents like nitrite can oxidize the Fe2+ to Fe3+. The formed metmyoglobin (MetMb) is brown. The ‘‘original’’ myoglobin (Mb), the oximyoglobin (MbO2) and the metmyoglobin are occurring together in meat. In a muscle in a live animal there is very little metmyoglobin which increases post-mortem with the disappearance of oxygen except when meat is MAP-packed with high oxygen content. The three states of myoglobin have three characteristics absorbance spectra between 400 and 700 nm. As the three are in a kind of equilibrium to each other, the spectra have an isosbestic point at 525 nm where all three absorption curve cross which each other. The absorbance of this wave-length can be used for detecting the percentage of each form in meat. Nitrosomyoglobin has a spectrum which has similar maximum wavelength like oximyoglobin (Fig. 9). Oxygen and NO are biatomic molecules. A similar biatomic molecule CO also binds to myoglobin and also very tight. In some countries (e.g. USA and Norway) MAP packaging of meat with 1–2% CO is permitted. By reducing enzymes or chemical reactions with

reducing agent like ascorbate the Fe^{3+} is reduced to Fe^{2+}. The NO formed from N_2O_3 can bind to the myoglobin (Fe^{2+}) and forms a heat stable NO-myoglobin. Oximyoglobin is not heat stable and dissociates. The meat turns grey or brown. On heating the NO-myoglobin the protein moiety is denatured but the red NO-porphyrin ring system (called often nitroso-myochromogen) still exists and is found in meat products heated to 120°C. This heat stable red colour will change on bacterial spoilage and it fades on UV light. The first one is advantageous as the consumer recognizes spoilage like in fresh meat which also changes colour on spoilage. In most recent years the riddle about the red colour of cured raw hams like Parma ham without added nitrite or nitrate has been solved. Various authors could show and proof that the Fe^{2+} in the porphyrin ring is exchanged with Zn^{2+} which gives the products a pleasant red colour. Nitrite addition prevents the exchange.

Name of author(s)	*Hustad, G. O.* *Cerveny, J. G.* *Trenk, H.* *Deibel, R. H.* *Kautter, D. A* *Fazio, T.* *Johnston, R. W.* *Kolari, O. E.*
Title of publication	**Effect of sodium nitrite and sodium nitrate on botulinal toxin production and nitrosamine formation in wieners**
Year	1973
Source/Organization	Applied Microbiology
Type of document	Journal article
Topics covered	C. botulinum, Effect on colour, Effect on taste, Nitrosamines
Abstract	Wieners were formulated and processed approximating commercial conditions as closely as possible. Twenty-four batches of product were made with the addition of six levels of sodium nitrite (0, 50, 100, 150, 200, and 300 µg/g), four levels of sodium nitrate (0, 50, 150, and 450 mug/g), and two levels of Clostridium botulinum (0 and 620 spores/g). After formulation, processing, and vacuum packaging, portions of each batch were incubated at 27°C or held for 21 days at 7°C followed by incubation at 27°C for 56 days. The latter storage condition approximated distribution of product through commercial channels and potential temperature abuse at the consumer level. Samples were analyzed for botulinal toxin, nitrite, and nitrate levels after 3, 7, 14, 21, 28, and 56 days of incubation. When nitrite was not added, toxic samples were detected after 14 days of incubation at 27°C. At the lowest level of nitrite added (50 µg/g), no toxic samples were observed until 56 days of incubation. Higher levels of nitrite completely inhibited toxin production throughout the incubation period. Nine uninoculated samples, representing various levels and combinations of nitrite and nitrate, were evaluated organoleptically. The flavor quality of wieners made with nitrite was judged significantly higher (P = 0.05) than of wieners made without nitrite. The nine samples were negative for 14 volatile nitrosamines at a sensitivity level of 10 ng/g. The results indicated that nitrite effectively inhibited botulinal toxin formation at commercially employed levels in wieners and that detectable quantities of nitrosamines were not produced during preparation and processing of the product for consumption.
Key information relevant	The development of toxin in the wiener samples was markedly influenced by the level of nitrite added to the meat. Only two samples containing 50 µg of added nitrite per g became toxic after 56 days storage at 27°C. Nitrite concentrations above this level completely suppressed toxin formation in all samples. Toxin was present in 79 of 220 nitrite-free samples. Eighty-one of the 1,320 samples examined were toxic. Toxin was not detected until the

product was incubated at 27°C for at least 14 days. A factor that may govern growth and toxin production is the relatively uniform distribution of nitrite in the product. The probability of spore contact with nitrite, or some reaction product of nitrite, would be enhanced in this finely comminuted, well-mixed product, as compared to a coarsely comminuted or larger particle-type product that is not thoroughly mixed. Although residual levels of nitrite were gener ally low during storage (Table 1), toxin was not detected in inoculated product initially formulated to contain 100 µg or more of nitrite per g. The level of nitrite at the time of manufacture rather than the level of residual nitrite is the key protective factor in inhibiting toxin production.

Characteristic cured meat color was absent in the nitrite-free samples. No differences were observed in the color of wieners containing the various levels of nitrite. The color of wieners made without nitrite but smoked with hickory sawdust has been described as brown of varying intensity on the surface and grey in the interior. Smoke apparently contains ,sufficient oxides of nitrogen to react with myoglobin to form small amounts of the nitroso meat pigment on the surface of the product. In the study reported herein, liquid smoke imparted a characteristic reddish-brown surface color to the wieners made with added nitrite; nitrite-free wieners had a light brown surface color. The flavor quality of wieners containing 50 to 300 µg of nitrite per g was judged significantly higher (P = 0.05) than for wieners made without nitrite. Flavor quality was not affected by nitrate. Similar data on the effect of nitrite and nitrate on flavor have been reported. Taste panel scores for tenderness and juiciness were not affected by either nitrite or nitrate.

Name of author(s)	*Lund, Barbara M.* *Peck, Michael W.*
Title of publication	**Clostridium botulinum**
Year	2013
Source/Organization	Guide to Foodborne Pathogens
Type of document	Book chapter
Topics covered	C. botulinum
Abstract	N/A
Key information relevant	(…) Spores of C. botulinum can survive for long periods in air and can germinate in the presence of oxygen, but vegetative cells are sensitive to oxygen and gradually die. The concentration of oxygen present and the resulting oxidation-reduction potential can therefore have a controlling effect on survival and growth of the bacterium in the environment, in foods, and during experiments. In foods and other environments that appear to be aerobic, microaerobic or anaerobic conditions may be present or may result from the metabolism of aerobic and facultative microorganisms and allow growth of C. botulinum. Spores of Group I C. botulinum have much greater heat resistance than that of Group II strains. These proteolytic strains are of major concern in determination of the heat-processing given to canned, low-acid foods (foods with a pH higher than 4.5 or 4.6). The minimum temperature allowing growth is 10–12 °C, so that growth is prevented by effective refrigeration. Heating spores of non-proteolytic C. botulinum at about 80 °C results in sublethal damage by inactivating enzymes involved in germination. Lysozyme can enable germination of the sublethally damaged spores and subsequent growth of the organism. Enzymes with lysozyme activity are present in many foods; thus the apparent heat-resistance of spores in foods can depend on the presence or absence of enzymes with lysozyme activity. Usually the presence of lysozyme does not increase the estimated heat-resistance of spores of Group I strains. Group II strains can multiply at temperatures as low as 3 °C, making these bacteria of concern in foods that are produced using a mild heat treatment and are intended to have an extended shelf life at refrigeration temperatures. The ability of spores of C. botulinum to survive heat treatment and the effect of temperature, pH, salt concentration and other factors on growth of the bacteria (Table 6.3) determine the methods used to prevent survival and growth of C. botulinum in foods (Table 6.9). Control can be expressed by the Protection Factor, Pr, which is the number of decimal reductions in the probability of growth and toxin production. This can be the sum of the number of 10-fold reductions in viable spores caused by lethal treatments, Ds, and the number of reductions in the probability of growth caused by inhibition, In. Pr = Ds + In. Category 1- The term low-acid foods is applied to foods with a pH higher than 4.5, or 4.6 in the United Kingdom and United States, respectively; these foods could allow growth of C. botulinum. The heat treatment used during canning of these foods resulted from experiments by Esty and Meyer (1922), in which the heat resistance of large numbers of spores of over 100 strains of C. botulinum was tested. This led to the calculation that inactivation of

about 1012 of the most heat-resistant spores of C. botulinum would require heating at 121.1 °C (250 °F) for 2.52 min giving a 12D process, or Pr = 12. Thus, if one viable spore of C. botulinum was present in each of 1012 cans before heating, one of those 1012 cans would contain one viable spore after the heat treatment. Treatment for one min at 121.1 °C is designated as an Fo1 process, and for low-acid, canned foods, except those containing curing salts, processing to an Fo3 as a minimum value is used to inactivate C. botulinum. Spoilage organisms with a greater heat resistance than C. botulinum are liable to be present in foods and a higher Fo treatment is needed commonly to achieve 'commercial sterility'. The use of this standard has ensured the usual safety of commercially-canned foods, and botulism incidents associated with commercial canned food are primarily the result of failure to deliver the specified process. In addition to the use of an adequate heat treatment, precautions are needed to prevent post-processing contamination of canned foods by access of bacteria through the seams of cans during cooling. The process criterion of heating at 121 °C for at least 3 min (Fo3), or an equivalent process, is used for thermal processing of shelf-stable, low-acid foods. In general, the use of new methods, such as pressure-assisted thermal sterilization, for production of such foods will require an equivalent Pr. Spoilage organisms with greater resistance than C. botulinum spores to combined pressure and heat treatment may necessitate the use of increased treatment.

Category 2 - Shelf-stable, canned cured meats receive a minimal heat process that does not inactivate C. botulinum spores, but some injury occurs. The combination of nitrite and salt prevents outgrowth from the injured spores. Pr for these foods has been estimated as ~6.6–8.

Category 3 - The great majority of evidence shows that C. botulinum does not multiply in 'acid' foods with a pH <4.5–4.6. Canned acid foods can be given a heat treatment much lower than an Fo3 process, and any spores of C. botulinum are liable to survive in these foods. A few cases of botulism have resulted after survival and multiplication of other microorganisms in an acid canned food has raised the pH and allowed growth and toxin formation by surviving C. botulinum.

Category 4 - The safety of raw, dry-salted products relies on maintenance below 5 °C until the salt content has established an internal aw below 0.96.

Category 5 - Fermented sausages rely on a combination of reduced pH (4.6–5.3), resulting from fermentation of added sugar by lactic acid bacteria, and reduced aw (<0.95) sometimes combined with use of nitrite/nitrate and sometimes smoking.

Category 6 - Outbreaks of botulism have occurred in Inuit populations in Alaska and Northern Canada resulting from consumption of putrid raw meat of marine animals. Fish products may pose a greater risk than meat products because of the extent of contamination with C. botulinum spores, and safety relies on strict control of refrigeration.

Category 7 - The safety of perishable, cooked cured meats depends on a combination of factors. In canned Bologna-style sausage (3% brine, pH 6.0, cooked to a core temperature of 76 °C), containing 83 mg NaNO2/kg after storage for six months at 5 °C the Pr was estimated as >8, but in a product containing no NaNO2 and stored at 8 °C the Pr was estimated as 4.6. (…)

Category 10 - This includes prepared foods sealed in air-tight containers, as well as vacuum- and modified atmosphere-packed foods. The safety of foods in this category usually depends on a mild heat treatment combined with refrigeration and other preservative factors. The cooking will not inactivate spores of proteolytic C. botulinum and may only damage spores of non-proteolytic C. botulinum. Storage of these foods at 3 °C or lower would prevent growth of C. botulinum, but maintenance at ≤3 °C is only possible in a dedicated, in-house system such as is specified in the UK Department of Health Guidelines on Cook-Chill and Cook-Freeze systems. In the UK, the Food Standards Agency has advised that, in addition to chill temperatures (specified ≤8 °C as in England and Wales), which should be maintained throughout the food chain, the following factors should be used singly or in combination to prevent growth and toxin production by non-proteolytic C. botulinum in prepared chill foods with an assigned shelf life of more than 10 days. The shelf

	life will begin as soon as the controlling factor(s) have been first applied: - a heat treatment at 90 °C for 10 minutes or equivalent lethality (the product should be heated in the sealed final pack, or after heating the product should be packed under conditions that minimize microbiological contamination) - a pH of 5 or less throughout the food and throughout all components of complex foods - a minimum salt level of 3.5% in the aqueous phase throughout the food and throughout all components of complex foods - a water activity of 0.97 or less throughout the food and throughout all components of complex foods a combination of heat and preservative factors which can be shown consistently to prevent growth and toxin production by non-proteolytic C. botulinum throughout storage. A heat treatment at 90 °C for 10 min combined with storage at <8 °C for up to 42 days gave Pr = 6 for non-proteolytic C. botulinum.

Name of author(s)	*Macdougall, Douglas B.* *Mottram, Donald S.* *Rhodes, Douglas N.*
Title of publication	**Contribution of nitrite and nitrate to the colour and flavour of cured meats**
Year	1975
Source/Organization	Journal of the Science of Food and Agriculture
Type of document	Journal article
Topics covered	Effect on colour; effect on taste
Abstract	The formation of nitric oxide myoglobin from nitrite and myoglobin involves a complex series of reactions not all of which are completely understood even now, and the stability of the cured colour, so important from the marketing point of view, continues to be investigated. The amount of nitrite necessary for complete formation of nitric oxide myoglobin is very small and the presence of no more than 25 mg/kg of nitrite in the cured meat is enough to ensure an adequately stable colour. At least four times this level is essential to produce a full development of the typical cured flavour. Very little is known of the mechanism of the reactions leading to the formation of cured flavours in cooked products or of the identity of the volatile substances responsible for it.

Name of author(s)	*Mulvey, Liz* *Everis, Linda* *Leeks, David* *Hughes, Holly* *Wood, Ann*
Title of publication	**Alternatives to Nitrates and Nitrites in Organic Meat Products**
Year	2010
Source/Organization	Camden Technology Limited, for Defra (UK Department for Environment, Food and Rural Affairs)
Type of document	Report
Topics covered	Alternatives to nitrites; Effect on colour; Effect on taste; C. botulinum; Nitrosamines; Preservation; Use levels
Abstract	A requirement of Commission Regulation (EC) 889/2008 (EC 2008a), which laid down detailed rules to further elaborate Council Regulation (EC) 834/2007 (EC 2007a) on organic production and labelling of organic products, is a re-examination of the use of nitrates and nitrites in cured organic meats with a view to withdrawing these additives by the end of 2010. In order to inform Defra of the possible effects of this action in the UK, this Defra funded project (Defra Project Reference OF0389) includes a literature review of alternatives to nitrates and nitrites in meat products, an analysis of the microbiological issues relating to nitrates and nitrites in meat products with regard to shelf life and pathogenic organisms and a consultation with industry about the implications of this legislation.
Key information relevant	The chemistry of nitrite in cured meat is a complex issue as nitrite is a very reactive compound. The intensity of cured meat colour is related to the concentration of nitric-oxide stabilised myoglobin in the muscle, not the nitrite level. The addition of ascorbic acid, ascorbate or erythorbate can increase the conversion of nitrite to nitric oxide and consequently speed up the reaction. Cured meat flavour may be related to prevention of lipid oxidation, although the use of other antioxidants does not result in similar flavour. Nitrite levels in cured meats fall during storage and the level of residual nitrite is usually comparable in a range of products irrespective of in-going amount. It would appear that nitrite can be inhibitory to a range of pathogens at in-going levels of 50mg/kg to 200mg/kg when used in combination with low storage temperature, reduced pH (i.e.<6.0) and increased salt levels (up to 3%). Any change to a single one of these factors will disturb the balance of the preservation system. In order to maintain safety and shelf-life, the formulation of cured meat products may need to be altered to include additional preservative measures such as sorbate or lactate. Overall, there is no single alternative to nitrite available that can produce all the cured characteristics including microbial stability, colour and flavour. Products made without nitrite or suitable alternatives would be expected to have a shorter shelf life, be grey or dark in colour and require very high standards of hygiene during production and distribution, and may not remain safe if abused by the consumer.

Name of author(s)	*Sindelar, Jeffrey J* *Milkowski, Andrew L*
Title of publication	**Sodium Nitrite in Processed Meat and Poultry Meats: A Review of Curing and Examining the Risk/Benefit of Its Use**
Year	2011
Source/Organization	American Meat Science Association White Paper Series, Vol. 3, 2011
Type of document	Journal article
Topics covered	Effect on colour; Effect on taste; Preservation; C. botulinum; Nitrosamines; In situ
Abstract	N/A
Key information relevant	Research conducted since the mid-1980s has suggested that nitrite is a significant molecule important for human health. As a product of enzymatic synthesis in humans, nitric oxide controls blood pressure, immune response, wound repair, and neurological functions. Very little nitrite is needed to induce a cured colour, but higher levels are required to prevent rapid fading and non-uniform curing. Much of the nitrite added during the product manufacturing is either depleted through a series of reactions or physically lost during certain manufacturing steps. Typically, between 10 and 20 percent of the originally added nitrite normally remains after the manufacturing process and those levels decline during storage. Although the chemistry is poorly understood, nitrites are very important for the development of flavour. This may be partially related to the role nitrite plays in retarding lipid oxidation. Nitrite also has many antimicrobial functions. Its effect against C. botulinum has long been known, but it also controls development of other pathogens. Since the 1970s, the presence of nitrosamines in meat products has been massively reduced. While nitrosamines can still be formed endogenously, this is also the case with other foods. The article therefore calls into question the IARC's classification of nitrite ingestion in conditions leading to endogenous nitrosation as probably carcinogenic. An end to the use of nitrites in meat products would have negative effects on both consumers and manufacturers, such as reduction in storage time. The residual levels of either nitrate or nitrite are not a clear reflection of the ingoing levels. Low levels of residual nitrite in ham, for example, may be due to low ingoing levels or to a long processing that allows an intense degradation (among other things). For this reason, Directive 2006/52/EC changed the regulation to refer to maximum ingoing levels, rather than maximum residual levels (with some exceptions). In terms of flavour, the addition of nitrate and nitrite is considered by this study to be essential for flavour development as nitrite reacts with a large number of meat components and affects the reactions occurring in the meat product during processing. Although the distinctive taste of cured meat is probably related to the antioxidant effect of nitrite, the specific compounds responsible of the cured meat flavour have not been identified.

Name of author(s)	*Stegeman, D.* *Hulstein, J.* *Verkleij, J.* *Stekelenburg, K.*
Title of publication	**Reducing the amount of nitrites in the production of pasteurized organic meat products: experiments on industrial scale**
Year	2007
Source/Organization	Agrotechnology and Food Sciences Group
Type of document	Report
Topics covered	C. botulinum, Effect on colour; Use levels
Abstract	In this study, cooked organic cured ham products and Bologna type sausages have been produced in an industrial setting with regular and two reduced amounts of nitrite. Nitrite levels in the recipe have been reduced by a factor two and four. The residual nitrite analysis showed that nitrite concentrations declined sharply after production for both type of products to about 10 – 15% of the ingoing level and further declined during storage time of about 7 weeks (of which 3-4 weeks as sliced packaged product) to a final amount in the range of the detection limit of 2 ppm. No significant difference is found between the different ingoing levels. Applying the two reduced levels of ingoing nitrite still gave the desired cured colour for Bologna type sausage as well as for ham after cooking. During 30 days storage at 7 °C of the sliced and packaged product and 26 hours illumination at retail condition, the colour of all ham samples did not fade. For the Bologna type sausage no colour fading occurred during in the slices products during a 25 day period storage and 22 hour illumination in the products prepared with 158 and 79 ppm ingoing nitrite, while a small colour change occurred for the samples prepared with 40 ppm nitrite after being exposed to light for more than 8 hours. Challenge tests with L. monocytogenes were carried out on the prepared products. Both recipes were inoculated with a cocktail of three types of L. monocytogenes at a dosage of 1000 bacteria per gram product. The tests showed no increase in growth of the Listeria bacteria on the Bologna type sausage products prepared with 178 and 79 ppm nitrite during the storage period of 32 days at 7 °C, while a rather small increase by a factor 5 was seen during mentioned storage period in the Bologna type sausage prepared with 40 ppm nitrite. In all ham products the number of L. monocytogenes bacteria increased by 2 log units in circa 1.5 weeks storage at 7 °C. This dissimilarity is probably due to a difference in water activity between the ham and the bologna type sausage products, i.e. about 0.965 vs. 0.973. It can be concluded that, under practical conditions (production and handling under hygienic conditions, cold storage at temperatures below 7°C and aw in accordance to the shelf life), nitrite content in organic cooked cured ham and Bologna type of sausage can be reduced to 40 ppm ingoing amount. Some products can lose their cured colour somewhat earlier when exposed to an extended light source. Intelligent logistics and handling can prevent this

	discoloration. It is expected that a maximum value of 80 ppm ingoing nitrite will be set by the future EU legislation for organic meat products. Based on the present study a stable colour is expected for ham and Bologna type of sausage produced in compliance with the latest EU regulation EC 2092/91 according the recipes used in this study.
Key information relevant	From the colour experiments it is concluded that the same colour is developed in the manufactured ham and Bologna type sausage products with a reduced ingoing nitrite content of 40 ppm and about 80 ppm compared to products with an ingoing nitrite content of about 160 ppm. During the entire storage period of about 4 weeks at 7 °C the cured colour did not fade in the ham products prepared with 40 to 157 ppm nitrite, where the products were subjected to light of about 450 lux during 26 hours in the last period of the storage time. For the manufactured Bologna type sausage products with 79 and 158 ppm ingoing nitrite, also colour was stable during the storage period of 22 days with illumination during 22 hours. The products prepared with 40 ppm nitrite, however showed, reduced colour stability and started to become a bit brownish after about 8-16 hours illumination with 450 lux. From the challenge test with ham and Bologna type sausage with standard, medium and low nitrite levels it can be conclude that L. monocytogenes as well as lactic acid bacteria are not particularly sensitive to nitrite. Differences in growth rate of these bacteria in both products with different nitrite contents were small. Differences in water activity (aw value) between the ham products and the Bologna type sausages appeared to have a more pronounced effect on inhibition of lactic acid bacteria, whereas the relative low water activity in combination with the presence of lactate in the Bologna type sausage almost completely inhibited the growth of L. monocytogenes during the storage period of 32 days at 7°C. For meat products with higher water activity and/or absence of lactate L. monocytogenes can only be controlled by prevention of contamination due to stringent hygiene during production.

Name of author(s)	*Stegeman, D.* *Verkleij, T. J.*
Title of publication	**Reduction of nitrite in the production of organic meat products: a literature survey - part 2/update**
Year	2010
Source/Organization	Wageningen UR Food & Biobased Research
Type of document	Report
Topics covered	Alternatives to nitrites; Organic; Preservation
Abstract	In the production of meat products like cold meats, nitrites and nitrates are used for several reasons: for forming and stabilizing the red, cured meat colour, obtaining a cured aroma, and for antimicrobial and anti-oxidative reasons. The use of nitrite curing salt in organic products, however, is very much subject for debate. Being additional non-organic components, nitrite and nitrate, in principle, are a non-desired components in organic products. However, for safety reasons it is allowed to use nitrites and nitrates at low levels (and thus ending up with low levels of residual nitrite). Another option to circumvent the addition of non-organic components (and thus labelling of these E-numbers) in organic meat products is adding organic nitrate by using plant extracts. This way however, residual nitrite levels - reducing nitrite basically is meant to reduce the residual nitrite content - are not known. To determine the present state of art, a previously performed literature study on reducing the amounts of nitrite in meat products has been updated. This update shows that although internationally several studies have been published on this subject, no significant new insights have been published in the literature over the last years. Several studies on producing nitrite-free organic products have been published concluding from experiments that it is possible to produce safe meat products without using sodium nitrite. However, frequently, even in these studies, it is still advised to use a reduced amount of sodium nitrite as an extra hurdle or a safety precaution. In practice, also products without nitrite addition are sold on the market. However, often it is not clear if nitrate from plant extracts is being used in these products. Several present publications focus on the use of nitrate rich vegetable powders/extracts in combination with starter cultures to replace the addition of nitrite curing salts. Complete systems (vegetable powers in combination with starter cultures) are commercial available nowadays and used by several producers of meat products. Increasingly knowledge is present about the required incubation time and temperature to end up with the desired cured colour for different products. The main reason to reduce ingoing nitrite in meat products is to reduce the residual nitrite level. In contrast to that, rather little attention is given to the amount of residual nitrite in the final meat products prepared this way. Also no studies are found focussing on the effect of this nitrate- nitrite route on survival and outgrowth of Clostridium botulinum or Clostridium perfringens. No real systematic studies have been found on the exact processes that take place when nitrite is replaced by these additives, and only few studies are published on the anti-micro bacterial effects of these kinds of additives. From the different studies showing different results, it may be concluded that still much is unknown about the theory of using nitrate-containing

	vegetable to replace sodium nitrite. Extra research is needed regarding possible required alterations in processing (especially for cooked cured products) when vegetable extracts are used instead of sodium nitrite. Altogether, applying these vegetable systems at present seem premature, and confusing, if not even misleading with the present declaration, for consumers and it may give an unjustified sense of safety.
Key information relevant	Although internationally, several studies have been published on reducing the amounts of nitrite in meat products, no significant new insights have been encountered in the literature of the last years compared to the last literature survey. Studies on producing nitrite-free organic products that conclude form experiments it is possible to produce safe meat products without using sodium nitrite have been published. However, frequently, even in these publications, it is still advised to use a reduced amount of sodium nitrite as an extra hurdle or a safety precaution to prevent botulism. The last years, new studies have been published on the use of nitrate rich vegetable powders/extracts in combination with starter cultures. These products are added to the meat product and during an incubation period of 30 minutes to several hours at about 40 °C, nitrate is reduced to nitrite enabling the meat product to turn pink during further process steps. No real systematic studies have been found on the exact processes that take place when nitrite is replaced by these additives. Increasingly knowledge is present about the required incubation time and temperature to end up with the desired cured colour for different products. However, not many studies are published on the anti-micro bacterial effects of these kinds of additives, especially not on the anti-botulinum effect. From the studies in general, a positive anti-micro bacterial effect of the vegetable powders can not be concluded. For many consumers and producers, colour indicates the safety of the product. When using vegetable extracts to replace nitrite, the right colour of the product, though, still does not guarantee a food safe product. Also not much attention is given to the amount of residual nitrite in the final meat products prepared this way, whereas reducing residual nitrite is the aim of reducing ingoing nitrite content. Some studies indicate that the residual amounts of nitrite are significantly lower than when nitrite containing curing salt is used, while other studies show the opposite. From the different studies showing different results, it may be concluded that still much is unknown about the theory of using nitrate-containing vegetable to replace sodium nitrite. Extra research is needed regarding possible required alterations in processing (especially for cooked cured products) when vegetable extracts are used instead of sodium nitrite. Despite of this, several commercial systems (vegetable powers in combination with starter cultures) are already available on the market. It is known that these systems are used by several German organic meat producers. The exact composition and origin (organic vs. conventional) is not known. Because the way to declare these systems is not clear yet, it is not known how frequently they are used and in what kind of products the systems are applied. Overall, if these vegetable systems are used it may be confusing, if not even misleading with the present declaration, for consumers and it may give them an unjustified sense of safety.

Name of author(s)	*Thomas, Caroline* *Mercier, Frederic* *Tournayre, Pascal* *Martin, Jean-Luc* *Berdagué, Jean-Louis*
Title of publication	**Effect of nitrite on the odourant volatile fraction of cooked ham**
Year	2013
Source/Organization	Food Chemistry, 139 (1-4)
Type of document	Journal article
Topics covered	Effect on taste
Abstract	The aim of this work was to reliably identify the key odour compounds in cooked ham and acquire new knowledge on the role of sodium nitrite on the formation of its aroma. Gas chromatography coupled with mass spectrometry and (or) olfactometry was used. In all, 24 odourants were identified in the volatile fraction of cooked ham. Their main origins are discussed. Orthonasal sniffing of the hams was used to study how these substances contributed to the overall aroma of the product. The aroma of cooked ham is a balance between that of certain sulfur compounds produced during cooking and that of oxidation compounds commonly found in cooked meats. In the absence of nitrite, this balance is disturbed by extensive formation of oxidation compounds that mask the meaty notes induced by the sulfur compounds.
Key information relevant	The sensory analysis of hams by orthonasal sniffing, also performed by the 8 sniffers, extended the information obtained by GC–MS/8O. These analyses focused on the descriptors ‘‘cooked ham odour’’ and ‘‘cooked pork meat odour’’, which, according to industrial operators, characterise the odour of nitrite-cured and nitrite-free ham respectively. A predominant ‘‘cooked pork meat’’ odour represents, for most consumers, an odour defect in cooked ham (Lücke, 2008; Sindelar, 2011). The sensory analysis of hams by orthonasal sniffing showed (Fig. 4) that without added nitrite, the ‘‘cooked ham’’ score fell from 5.7 to 4.3/10 ($p < 0.05$), but the ‘‘cooked pork meat’’ odour score rose from 3.3 to 6.5/10 ($p < 0.001$). This result confirms the degradation of the cooked ham aroma when nitrite is absent. Given that nitrite demonstrably plays (i) a major role in the formation of numerous fatty acid oxidation products, and (ii) a less important role in the formation of other odourous compounds (derived from the degradation of sulfur-containing precursors, or of other unspecified origin), we can consider that the oxidation products are mostly responsible for the observed changes in the odour of cooked ham without nitrite. Olfactory masking of compounds possessing a ‘‘meaty, empyreumatic’’ note by fatty acid oxidation products, which have ‘‘vegetable, herbaceous, fruity, floral’’ notes, would account for the effect of nitrite on the odour of cooked ham. Our results indicate that among aldehydes, hexanal may play an important role in the masking of the ‘‘cooked ham’’ note, as the perception of this compound by chromatography–olfactometry was very weak for nitrite-cured hams and very intense for nitrite- free ones. Hence hexanal appears to be a good instrumental marker for the antioxidant action of

	nitrite in cooked ham, in line with literature reports indicating that its level is proportionally linked to acceptability (Shahidi, 1989; Shahidi & Pegg, 1994) or to aroma defects (Frankel, 1991) in meat products. (…) Preparation with and without sodium nitrite showed that the addition of nitrited salt in ham production is not directly involved in the production of the odourous substances that give nitrite-cured pork products their specific aroma. The absence of nitrite simply favours the oxidation of fatty acids, and in particular the production of aldehydes, which will mask the odour of the sulfur- containing compounds responsible for the aromatic note typical of nitrite-cured pork products. Thus the odour of nitrite-cured pork products is merely the outcome of a balanced perception of certain sulfur-containing compounds and fatty acid oxidation products, among which aldehydes hold an important place.

Name of author(s)	*Toldra, Fidel* *Aristoy, M-Concepcion* *Flores, Monica*
Title of publication	**Relevance of nitrate and nitrite in dry-cured ham and their effects on aroma development**
Year	2009
Source/Organization	Grasas y Aceites, Vol. 60, Issue 3, 2009, pp. 291-296.
Type of document	Journal article
Topics covered	8.3.4.2; Effect on taste
Abstract	Potassium and sodium salts of nitrite (E 249 and E 250) and nitrate (E 251 and E 252) are authorised for use under certain levels in several foodstuffs such as non-heat-treated, cured and dried meat products, other cured meat products, canned meat products and bacon. The key point in the use of nitrate and nitrite as preservatives is to find a balance between ensuring the microbiological safety of the ham and keeping as low as possible the level of nitrosamines in the final product. Nitrites and nitrates are authorised as additives for dry-cured ham in the Directive 2006/52/EC of 5 July 2006 that modifies previous Council Directive 95/2/EC on food additives other than colours and sweeteners. The effect of nitrate and its reduction to nitrite in controlling the lipid oxidation process during the ham ripening is very important for the development of the characteristic cured flavour. The main benefits and drawbacks of the use of nitrites and nitrates in dry-cured ham and how these levels may affect its flavour are discussed in this manuscript.
Key information relevant	It is well known that oxidative rancidity is delayed in nitrite cured meats. The exact mechanisms for this antioxidant action is still under discussion since four different mechanisms have been proposed: i) Reaction of nitrite with heme pigments forming a stable complex, i) action in tissue membranes by stabilizing its unsaturated lipids, iii) action of nitrite as a metal chelator and iv) the formation of nitroso compounds that can act as radical scavengers. Nitrite is reported to produce a characteristic cured meat flavour even though the chemical changes involved, probably due to its antioxidant activity, are not well understood. The differences in volatile composition of uncured and cured cooked pork was analysed and reported in the 1990s These authors determined the effect of curing, essentially the addition of nitrite, in the development of cured cooked flavour. The main differences between both types of products were detected in the content of carbonyl compounds. These authors indicated that carbonyl compounds are essential contributors to the flavour of uncured meat. However, they could not elucidate the compounds responsible of the cured meat flavour. In summary, the addition of nitrate and nitrite is essential for flavour development as nitrite reacts with a large number of meat components and affects the reactions occurring in the meat product during processing. Therefore, it is necessary to know the processing conditions and additives added to the meat product to elucidate the compounds responsible for the flavour in the final product. So, the effects of nitrate and nitrite on the sensory quality of dry-cured lacón, a typical product in northwestern of Spain, have been recently studied by Lorenzo et al (2008a,b). The protein degradation and also the fat acidity values, as an index of fat hydrolysis, occurring during the manufacture of dry-cured lacón, were reported to be only moderate when compared with ham

	dry-curing process, and additives did not significantly affect both processes; proteolysis and lipolysis. Neither the free fatty acid content nor their profile were significantly affected by the use of such additives. Nevertheless, sensory analysis comparing dry-cured lacón with and without such additives, revealed that the use of additives seems to improve the colour (higher intensity of the red colour and brightness in the lean and lower dryness) and the odour (intensity and typical odour of cured meats attributes) of the final product confirming the importance of nitrite. On the other hand, a recent study comparing 5 different commercial brands of socalled uncured hams with the nitrite-/added control ham did not find differences in sensory attributes. Finally, the effect of nitrate and nitrite has been assayed against main muscle proteolytic and lipolytic enzymes that play an important role in the processing of dry-cured ham and its flavour development. These curing agents have not shown a relevant effect on such enzymes under the assayed conditions.

Name of author(s)	*Verkleij, T.J.* *Stekelenburg, F.K.* *Stegeman, D.*
Title of publication	**Effects of reducing the amount of nitrite in organic meat products**
Year	2006
Source/Organization	Food and Biotechnology Innovations
Type of document	Journal article
Topics covered	Effect on colour; Organic; Use levels
Abstract	The organic production chain of pork is well controlled and only a small list of additives, (mentioned in EC Directive 2092/91) may be used. Since years, profound discussion is going on in the EC for the use of nitrite (E250) as an additive in processing of meat and meat products. For organic meat products the range of ingoing nitrite is determined to produce a cured meat color with sufficient color stability and provide the same level of product safety compared to regular meat products. By a reduction of the amount of ingoing nitrite to an extend of approximately 80 mg/kg, the color development, color stability and product safety will be sufficient to reach a shelf life of 65 days.
Key information relevant	Based on literature information organic cured ham and luncheon meat with three levels (0, ca 50 and ca 85 mg/kg) ingoing sodium nitrite were prepared. A generally applied product flow of 5 weeks at 4°C before slicing, MAP packaging of sliced product, retail storage for 5 weeks at 7°C with light source of 880 lux (12 hours on a day) only the last week was simulated. At several moments analyses were performed. (…) Nitrite concentrations declined sharply after production for both type of products to about 15 – 25% of the ingoing level and steadily declined further during storage to a final amount of 2.5 – 6 ppm. The color of both products with nitrite were still acceptable compared to the one without nitrite. At 7°C and 10°C. C. botulinum didn't grow in both lean and fat products, without or with nitrite, during a storage period of 12 weeks. Botulinum toxin was not determined. At 15°C growth of C. botulinum was detected earlier in products without nitrite. Botulinum toxin was detected in lean luncheon meat without nitrite after 6 weeks, in fat luncheon meat without nitrite after 8 to 12 weeks and in lean luncheon meat with 54 mg/kg nitrite after 12 weeks. Complete abandoning of nitrite in the processing of organic meat products is not advisable. This will result in serious color instability of the product compared to conventional products and from this point of view the product doesn't look as consumers expect. By a reduction of the amount of nitrite to an extend of approximately 80 mg/kg ingoing, the color development and stability will be sufficient to reach a shelf life of 65 days. During production, heating, cooling and storage, the amount of residual nitrite level in this case will be far less than the 50 mg/kg as mentioned in EU Directive 2092/91. The risk of botulinum toxin formation will increase at storage temperatures above 10°C.

Name of author(s)	*Zsarnoczay, Gabriella*
Title of publication	**Effect of different nitrite-concentrations in meat products**
Year	2011
Source/Organization	Hungarian Meat Research Institute
Type of document	Ph.D thesis
Topics covered	Effect on colour; Effect on taste
Abstract	N/A
Key information relevant	(…) [H]eat treated models (Bologna sausage) and non heat treated models (dry sausage) were prepared with different nitrite concentrations (0, 50, 100, 150 mg/kg) following the domestic technology. Bologna sausage was stored for 90 days at 4 °C and 12 °C, while dry sausage was stored for 43 days at 4 °C without packaging as well as vacuum packed and in MAP. As a result, the following conclusions could be made concerning Bologna sausages: Analyzing the results of color measurements it was stated, that Bologna sausage without added nitrite was the most pale, the least red in terms of red color intensity and color. When increasing nitrite concentration color of the product turns red and deeper. No differences were found between Bologna sausage samples with 100 and 150 mg/kg added nitrite. Color characteristics hardly change during storage. As it was shown 50 kg/mg added nitrite is sufficient for proper color formation. As a result of different added nitrite content in dry sausage the following conclusions can be made: Total pigment content of nitrite-less sausage was the lowest as expected for its lowest nitrosopigment content. Total pigment contents of sausages with 100 and 150 mg/kg added nitrite did not differ. In case of dry sausages 100 mg/kg initial nitrite content is necessary for saturating the hem. The extent of reddening depended on the added nitrite, as expected. As for color characteristics color of sausages in visible range differed from each other. Samples with no and with 50 mg/kg nitrite were rather grey, while those with 100 and 150 mg/kg were nice red. The higher the initially added nitrite the nicer red was the color, explainable because of more intensive reddening, yet there was no difference between samples with 100 and 150 mg/kg, in other words 100 mg/kg is sufficient for proper color formation. Differences in color remained till the end of storage in unpacked samples, but equalized when prepacked. Red color intensity during light exposure decreased no matter what the nitrite content was. This reduction depended on storage time. The older the product the lower the initial red color intensity and the more rapid was the reduction to constant value. Sausages without added nitrite were worst in all sensory characteristics. Increase of nitrite until 100 mg/kg improved all the characteristics. This was not remarkable in case of color and texture, while hardly ever were found differences in terms of aroma, flavor and overall acceptance between samples with 100 and 150 mg/kg. This means that with dry sausages 100 mg/kg added nitrite is sufficient for proper sensory characteristics. With increasing storage time sensory features became lower similarly as with heat treated sausages, mainly flavor and aroma deteriorate, which are main sensory characteristics. By day 29 of storage the value of these characteristics is reduced to 25% of

	initial value. Cancerogenic nitrosamines can be formed only at low pH-value and at high temperature. The concentration of nitrite necessary for the formation of the highest amount of DMNA ever detected is by 15 000 less than that of the nitrite concentration applied in practice when manufacturing a meat product. If no nitrite is added nitrite content of meat is also 60 times as high as necessary for formation of DMNA. For this reason reduction of added nitrite (even if by 50%) makes hardly ever sense. Sensory characteristics of meat products deteriorate continuously during storage even in gas tight containers. Color is fading, intensity of aroma and flavor decreases. Organoleptic scores for Bologna sausage are halved by day 30 of storage and to 25% with dry sausages. This should mean that manufacturing of meat products with very long shelf-life does not serve the interest of consumers since not only sensory value is reduced but also more additives are necessary.

7.4. **Results of expert workshop**

The second of the workshop sessions was dedicated to a discussion of the technological uses for nitrites in meat products and preparations, examining the results from the survey and literature research concerning the effect of nitrites on meat colour, taste, and preservation. For each of these three main technological uses, experts of the panel were asked to consider whether the survey results reflect the current knowledge and which amount they would consider to be an appropriate point of reference for achieving them. While initially the discussion concerning the effect of nitrites on the microbiological safety of meat products was intended to centre on *Clostridium botulinum,* a number of experts considered that this focus should be broadened to include other bacteria, such as *Listeria*, which are also relevant challenges to food safety.

Examining the survey results concerning the minimum amount of nitrites required for **colouring purposes,** the panel considered that the range of median values reported (55 to 70 mg/kg added) is sufficient for colour formation in **non-traditional meat products and preparations**, although these levels may not be enough to ensure colour stability throughout the product shelf life, particularly for cooked or sliced products. 80 mg/kg was suggested as a level that would suffice to ensure colour stability. For **traditional products,** the panel noted that the colour of the product mainly depends on the ingoing amount of nitrite rather than the residual amount remaining at the end of the production process. At the same time, however, it was emphasised that a higher residual amount of nitrite leads to a more stable colour. A majority of members of the expert panel agreed that 20 to 30 mg/kg of residual nitrite is an appropriate range to ensure colour stability in most traditional meat products, with 40 to 50 mg/kg of residual nitrite needed for some products to safeguard colour stability. Another conclusion concerning colour formation in traditional products noted by the panel related to the lower levels of nitrite needed for products undergoing injection, in comparison with the outward application of nitrite for larger pieces of meat.

Concerning the minimum amount of nitrites required for **flavouring purposes**, the panel confirmed that nitrites contribute to the typical flavour of cured meat products and preparations. Members of the expert panel considered that the range of median values reported (50 to 80 mg/kg of added nitrite) provides meaningful guidance for safeguarding taste-related aspects in **non-traditional meat products and preparations**, while acknowledging differences in products and consumer expectations. The panel emphasised that the use of additives should focus mainly on food safety, and that there is no indication that higher levels of nitrites are required for flavouring purposes than for ensuring microbiological safety. The panel also considered that the range of median values reported (30 to 50 mg/kg of residual nitrite) is a meaningful point of reference across **traditional products** and across countries for flavouring purposes.

For achieving **microbiological safety** in **non-traditional meat products and preparations,** most members of the expert panel that had an opinion regarding this aspect agreed that the range of 80 to 100 mg/kg of nitrite added would be reasonably safe for a majority of products, when used in combination with other hurdles to safeguard microbiological safety. However, the panel also emphasised that it is not possible to reach a firm conclusion for all products and all situations, acknowledging that microbiological safety is dependent upon a large number of factors. One panel member highlighted concerns regarding any change of legal limits: *"What we presently do appears to be safe, if we are going to change it, we need evidence. Is this median amount [80 to 100 mg/kg of nitrite] enough [to safeguard microbiological safety]? I think probably not. So if the question is: am I prepared to accept the median? No, I am not. Might it be OK in some foods? Yes. But I don't know which ones […]. I think we can reduce nitrite safely in some products, but I don't know which ones. In these foods,* *safety requires a combination of hurdles and any reduction in the nitrite concentration requires a thorough understanding of the contribution of these hurdles to safety."*

The panel concluded that a possible point of reference for lowering maximum limits of nitrites while safeguarding microbiological safety could be countries or product categories for which stricter maximum levels already apply or have applied in the past. These include:

- According to the Danish experience, 60 mg/kg of added nitrite is sufficient for most products, with levels of 100 mg/kg and 150 mg/kg necessary for some categories;
- In Finland, former national legislative limits allowed the use of up to a maximum of 120 mg/kg of nitrite;
- The German Fleischverordnung previously in force provided a limit of 100 mg/kg for boiled and cooked sausages, with a higher level of 150 mg/kg authorised for raw sausages;
- The limit of 80 mg/kg imposed on organic meat products also provides an indication that it may be possible to reduce the use levels of nitrite, without compromising microbiological safety. Also, there are nitrite-free organic meat products on the market in various countries.

It was also suggested that a reduced maximum added amount of nitrites could be foreseen, with a process put in place for industry to identify products for which a higher limit needs to apply because of safety considerations.

Concerning the technological need for nitrites in order to achieve microbiological safety in **traditional meat products,** the panel suggested that the varying limits on the maximum residual amount authorised in the legislation are mainly a result of the traditional production processes rather than technological or safety considerations. One expert considered that both the ingoing and residual amount of nitrite contribute to the microbiological safety of meat products. It was emphasised that – with the exception of sterilised meat products, for which nitrite is not needed to ensure microbiological safety – some amount of residual nitrite is needed in meat products for protection against non-proteolytic *Clostridium botulinum*, although the panel could not establish a value that would constitute an appropriate point of reference. Concerning the different strains of *Clostridium botulinum*, the panel noted that non-proteolytic *Clostridium botulinum* is able to grow at 3°C, while proteolytic *Clostridium botulinum* cannot grow at temperatures below approximately 10 to 12°C.

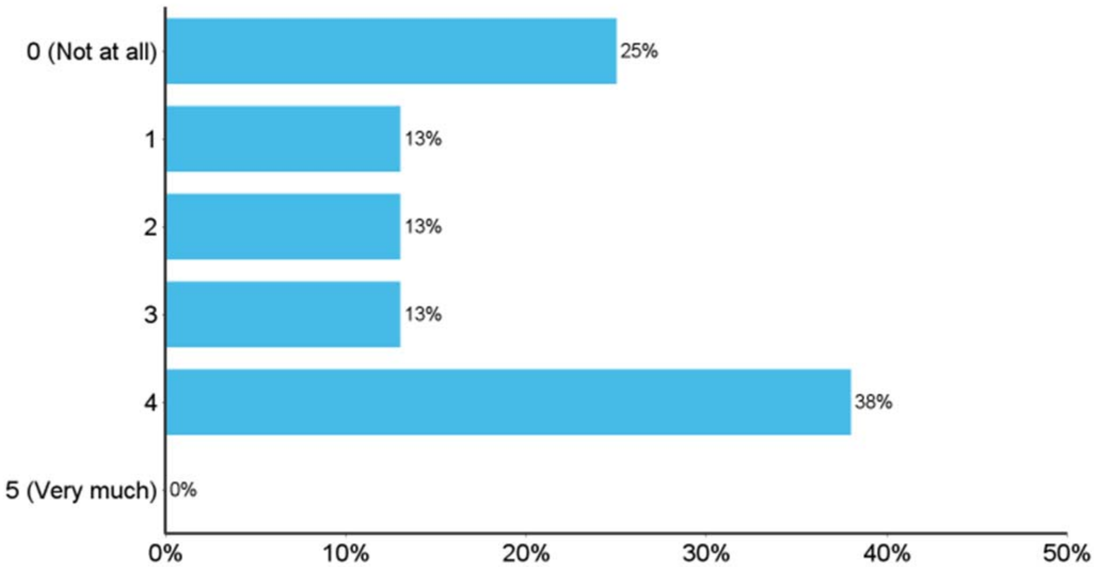
8. THE FORMATION OF NITROSAMINES

This section presents the study results concerning the potential formation of nitrosamines resulting from the addition of nitrites to meat products and preparations. Results from the literature research, survey and expert workshop are provided relating to nitrosamine formation occurring in the production process (*in situ*) as well as in the stomach (*in vivo*).

8.1. Survey results

The EU legislation (Annex II of Regulation (EC) 1333/2008 as amended by Commission Regulation (EU) 1129/2011) establishing the limits of nitrites to be used in meat products acknowledges that the use of nitrites in meat may lead to the formation of nitrosamines. Therefore, the legislation seeks to find a balance between the need for microbiological safety and the risk of nitrosamine formation. In our survey, researchers were asked to assess on a scale from 0 (indicating not at all) to 5 (very much) the extent to which the current maximum amounts regarding the use of nitrites achieve an appropriate balance between ensuring a high level of protection against microbiological activity and preventing the formation of nitrosamines. The figure below presents the survey results for this question.

Figure 28: "In your view, to what extent do the current maximum amounts regarding the use of nitrites achieve an appropriate balance between ensuring a high level of protection against microbiological activity and preventing the formation of nitrosamines?"



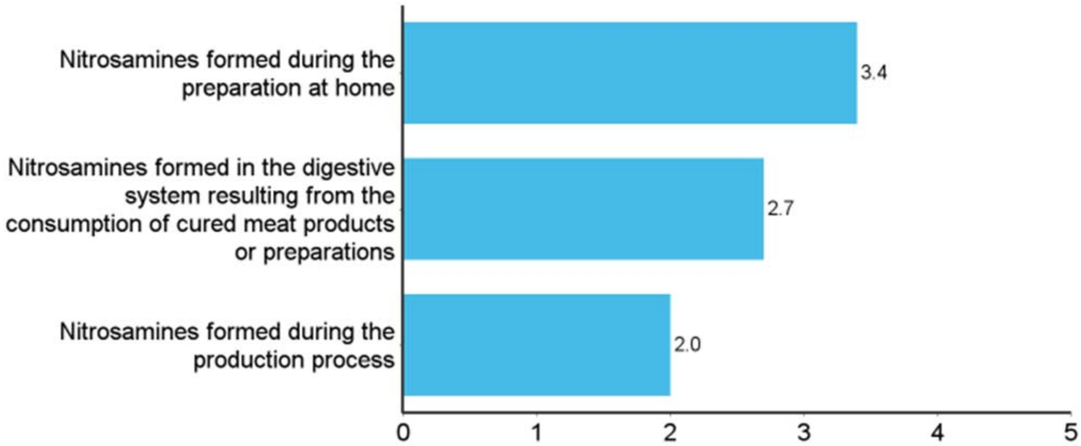
Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=8. This question was only asked to respondents from research institutes/universities.

As the figure shows, there was no consensus among the small sample of researchers that answered to this question (8) concerning the balance achieved by the current maximum amounts. While a quarter of the respondents to this question selected 0 (not at all appropriate), 38% selected 4, with all other researchers selecting a value between 0 and 4. The average of responses provided to this question was 2.3, or slightly below the midpoint of 2.5.

In a related question, researchers were asked to assess the relevance for human exposure to nitrosamines caused by cured meat products and preparations, by considering three options: nitrosamines formed during the production process (*in situ* nitrosamine formation), nitrosamines formed during preparation at home (e.g. when cured meat products or preparations are cooked or barbecued) and nitrosamines formed in the digestive system resulting from the consumption of cured meat products and preparations (*in vivo* nitrosamine formation). For each option, researchers were asked to provide an assessment on a scale of 0 to 5, with 0 indicating that the option is not at all relevant for human exposure to nitrosamines, and 5 indicating that it is very relevant.

The results for this question are presented in the figure below.

Figure 29: "According to your knowledge, how relevant for human exposure to nitrosamines caused by cured meat products and preparations do you consider …"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=8/6/8. This question was only asked to respondents from research institutes/universities.

The figure above shows that researchers who answered this question considered the formation of nitrosamines during preparation of products at home (e.g. when cured meat products or preparations are cooked or barbecued) as the most relevant source of human exposure to nitrosamines caused by cured meat products and preparations, with an average rating of 3.4. The *in vivo* and *in situ* formation of nitrosamines were considered to be less relevant, though the former still received an average rating of 2.7, or slightly above the midpoint of 2.5.

8.2. **Results of literature research**

The following table presents the results of the literature research relating to the formation of nitrosamines.

Name of author(s)	*Archer, Douglas L.*
Title of publication	**Evidence that Ingested Nitrate and Nitrite Are Beneficial to Health**
Year	2002
Source/Organization	Journal of Food Protection, Vol. 65, Issue 5, 2002.
Type of document	Journal article
Topics covered	Nitrosamines
Abstract	The literature was reviewed to determine whether ingested nitrate or nitrite may be detrimental or beneficial to human health. Nitrate is ingested when vegetables are consumed. Nitrite, nitrate's metabolite, has a long history of use as a food additive, particularly in cured meat products. Nitrite has been a valuable antibotulinal agent in cured meats and may offer some protection from other pathogens in these products as well. Nitrite's use in food has been clouded by suspicions that nitrite could react with amines in the gastric acid and form carcinogenic nitrosamines, leading to various cancers. Nitrate's safety has also been questioned, particularly with regard to several cancers. Recently, and for related reasons, nitrite became a suspected developmental toxicant. A substantial body of epidemiological evidence and evidence from chronic feeding studies conducted by the National Toxicology Program refute the suspicions of detrimental effects. Recent studies demonstrate that nitrite, upon its ingestion and mixture with gastric acid, is a potent bacteriostatic and/or bactericidal agent and that ingested nitrate is responsible for much of the ingested nitrite. Acidified nitrite has been shown to be bactericidal for gastrointestinal, oral, and skin pathogenic bacteria. Although these are in vitro studies, the possibility is raised that nitrite, in synergy with acid in the stomach, mouth, or skin, may be an element of innate immunity.
Key information relevant	About 7% of ingested nitrite comes from food and 93% from nitrate in saliva (which is converted to nitrite by oral cavity microorganisms). As the vast majority of nitrate intake comes from vegetables, it might appear that vegetable consumption contributes indirectly to carcinogenesis. However, there is no evidence for this relationship. Studies in Canada, Italy, Sweden, and Germany have failed to show an association or have demonstrated a negative association between estimated nitrate intake and gastric cancer, perhaps precisely because nitrate intake primarily comes from vegetables. In regard to nitrite, there is evidence that it have a number of health benefits, specifically by acting in synergy with acid as a barrier to gastrointestinal pathogens and playing a role in the defence of the skin, teeth, and gums from pathogenic bacteria.

Name of author(s)	*Corpet, Denis E*
Title of publication	**Red meat and colon cancer: should we become vegetarians, or can we make meat safer?**
Year	2011
Source/Organization	Meat Science, Vol. 89, Issue 3, 2011, pp. 310-6.
Type of document	Journal article
Topics covered	Nitrosamines
Abstract	The effect of meat consumption on cancer risk is a controversial issue. However, recent meta-analyses show that high consumers of cured meats and red meat are at increased risk of colorectal cancer. This increase is significant but modest (20-30%). Current WCRF-AICR recommendations are to eat no more than 500g per week of red meat, and to avoid processed meat. Moreover, our studies show that beef meat and cured pork meat promote colon carcinogenesis in rats. The major promoter in meat is heme iron, via N-nitrosation or fat peroxidation. Dietary additives can suppress the toxic effects of heme iron. For instance, promotion of colon carcinogenesis in rats by cooked, nitrite-treated and oxidized high-heme cured meat was suppressed by dietary calcium and by α-tocopherol, and a study in volunteers supported these protective effects in humans. These additives, and others still under study, could provide an acceptable way to prevent colorectal cancer.
Key information relevant	Experiments in rats show that red meat and processed meat can increase colon carcinogenesis. It is hypothesised that this is due primarily to fat peroxidation and the formation of N-Nitroso-compounds. The risk of cancer can be reduced by the use of antioxidant and antinitrosant additives, or by removing oxygen and nitrite from meat. Other measures to reduce risk include the consumption of calcium carbonate supplements or α-tocopherol.

Name of author(s)	*De Mey, Eveline*
Title of publication	**N-Nitrosamines in dry fermented sausages: occurrence and formation of N-Nitrosopiperidine**
Year	2014
Source/Organization	Katholieke Universiteit Leuven
Type of document	Report
Topics covered	Nitrosamines; In situ; Belgium
Abstract	N/A
Key information relevant	Generally, it is assumed that N-nitrosamines are formed by the nitrosation of a secondary amine with a nitrosating agent, such as sodium nitrite. During the fermentation and ripening of dry fermented sausages, microorganisms can decarboxylate amino acid to biogenic amines. These biogenic amines may be transformed to the secondary amines, which are the direct precursors of N-nitrosamines. Therefore, biogenic amines are considered to be a risk for the formation of N-nitrosamines in dry fermented sausages. However, this hypothesis has not been confirmed experimentally yet. Therefore, the objective of this work was to gain additional insight in the occurrence and formation of N-nitrosamines in relation to nitrite and the accumulation of biogenic amines in dry fermented sausages, focusing in particular on formation of N-nitrosopiperidine (NPIP). The results obtained demonstrated that in general the risk of N-nitrosamine contamination is low. On the one hand, it was proven that the accumulation of biogenic amines, especially with regard to CAD, will not result in the formation of NPIP during the production of dry fermented sausages. On the other hand, NPIP can be formed from PIP, but only when extreme concentrations are present. Common amounts of PIP, which can be introduced by the addition of PIP containing spices, are not a risk for the formation of NPIP. The sporadic occurrence of quantifiable concentrations in commercial dry fermented sausages will probably be attributed to the use of highly NPIP contaminated spice mixtures.

Name of author(s)	*De Mey, Eveline* *De Maere, Hannelore* *Paelinck, Hubert* *Fraeye, Ilse*
Title of publication	**Volatile N-nitrosamines in meat products: Potential precursors, influence of processing and mitigation strategies**
Year	Forthcoming
Source/Organization	Critical Reviews in Food Science and Nutrition
Type of document	Journal article
Topics covered	Nitrosamines; Alternatives to nitrites
Abstract	Meat products can be contaminated with carcinogenic N-nitrosamines, which is ascribed to the reaction between a nitrosating agent, originating from nitrite or smoke, and a secondary amine, derived from protein and lipid degradation. Although in model systems it is demonstrated that many amine containing compounds can be converted to N-nitrosamines, the yield is dependent of reaction conditions (e.g. low pH and high temperature). In this paper the influence of the composition of the meat products (e.g. pH, aw, spices) and processing (e.g. ageing, ripening, fermentation, smoking, heat treatment and storage) on the presence and availability of the amine precursors and the N-nitrosamine formation mechanism is discussed. In addition, this paper explores the current N-nitrosamine mitigation strategies in order to obtain healthier and more natural meat products.
Key information relevant	In general, it is known that N-nitrosamines are formed by the reaction of secondary amines with a nitrosating agent. In meat products, the latter precursor mainly originates from nitrite or NOx compounds in smoke. With regard to the source of secondary amines, various model systems, which differ especially in water and fat content, were used to study the nitrosation potential of several amine containing compounds. Many compounds, which can occur in meat and meat products, were demonstrated to be able to act as precursors for the formation of carcinogenic N-nitrosamines. In the case of amino acids (i.e., proline, ornithine and lysine) and biogenic amines (i.e., putrescine and cadaverine) an intensive heat treatment (above 160°C) was often necessary to obtain substantial amounts of carcinogenic N-nitrosamines (e.g., NPYR and NPIP) in vitro. In meat products, proteins and lipids can be degraded to amine precursors during the ageing, fermentation, ripening and storage. In the case of dry fermented sausages, especially free amino acids and biogenic amines are formed. However, due to the very mild acidic conditions and low water activity, the abundant presence of these compounds is not a substantial risk for the formation of N-nitrosamines. The necessary deamination and cyclization is thermally catalyzed and takes mainly place during baking and grilling. During mild heating processes (under 160°C), such as pasteurisation and sterilisation, the formation of N-nitrosamines is limited. Moreover, as long as GMP conditions are respected and fresh meat materials, which contain low levels of lipid and protein degradation compounds, are used for the industrial preparation of heated meat products, the N-nitrosamine formation is restricted. However, in the interest of public health it may be opportune to investigate the possible formation of N- nitrosamines during the barbecuing

and baking of foods containing processed meat products (i.e. pepperoni pizza). It can be expected that a combination of processed meats, which contain amine precursors, and an intense heating process, often in combination with uncontrolled smoking, may result in an increased risk of N-nitrosamine formation. In addition, secondary amines, like piperidine (from pepper) can be, although slowly, nitrosated without the necessity of heat treatments. Therefore, the use of alkaloid and nitrate containing spices and herbs can be considered as an additional source of N-nitrosamines in meat products.

Besides the presence of amine precursors, the highest risk on the formation of N-nitrosamines is caused by the use of nitrite in meat products. Due to the many technological advantages of nitrite, the main mitigation strategy in the past to combat the N-nitrosamine formation in meat products is the limitation of the added amount of nitrite to 150mg/kg and the use of anti- oxidants such as ascorbate as nitrite scavenger. Although this approach causes a significant reduction of N-nitrosamines, still traces and occasionally high levels can be detected. Therefore current research is challenged to the further reduction (e.g. 60 mg/kg as imposed by the Danish regulation) and even elimination of nitrite. Gamma irradiation can reduce N- nitrosamines, as well as both precursors (nitrite and biogenic amines). However, the main draw back in Europe is the consumer's resistance towards this technology. In order to meet the needs of consumers for more natural meat products, the current research is mainly focused on the application of natural antioxidants, preferably from sustainable sources such as fruit and vegetable by-products. Nevertheless, the ultimate approach to obtain healthier and more natural meat products implies the total elimination of nitrite. As a consequence, the future challenge is to develop appropriate meat processing technologies such as the natural reddening by zinc protoporphyrin. In this way safe and attractive meat products without the use of chemical additives can be obtained.

Name of author(s)	*Domańska, Katarzyna* *Kowalski, Bogdan*
Title of publication	**Effect of Different Storage Conditions on N-Nitrosamine Content in Polish Edible Offals Processed Meat Products**
Year	2002
Source/Organization	Bulletin of the Veterinary Institute in Pulawy
Type of document	Journal article
Topics covered	Nitrosamines
Abstract	N/A
Key information relevant	The experiment was intended to follow how different storage conditions influence the N-nitrosamines content in edible offals processed meat products. The chosen storage conditions were intended to reflect these ones which could occur in the routine food management in shop or kitchen (i.e.72 h of storage at 4-8°C - storage of products during a few day in the open chilled display unit or refrigerator, additional 24 h of storage at 22-26°C - broken refrigerator or open chilled display unit, temporary lack of electricity etc.). Edible offals processed meat products are very popular meat products in Poland and many different types of them are described. Among the most representative meat products are “salceson” (headchees) and “pasztetowa” (liver sausage). These products can be defined as the mixture of plucks, pork, beef, veal, sheep’s meat and fat, with addition of salt, garlic, onion, paprika and other spices and herbs, in case of “pasztetowa” also semolina, mixed and inserted into natural or artificial casings, which undergo brewing and smoking process. Other edible offals processed meat product is “kaszanka” (blood sausage), manufactured with blood, onion, pork fat and spices, with addition of buckwheat groats and put into natural or artificial casings. Most of these meat products contain corned or salted compounds (lung tissue, liver, mask, tongue, etc., all cut into pieces and minced), however some of them contain non-cured materials. The study proved that fresh samples contained NDMA only sporadically and at a very low concentration. Storage conditions may markedly change the occurrence and concentration of N-nitrosamines. Changes in the levels of other N-nitrosamines (NDBA, NPIP, NPYR and NMOR) were also observed as the results of applied storage conditions. There are several factors which may influence the appearance of nitrosamines. Starting materials for nitrosamine formation are nitrate, nitrite and primary, secondary and tertiary amines and amides, proteins, peptides and amino acids or precursors of these, which are transformed into nitrosamine precursors by microbial action (26). It seems that all these compounds could be present in analyzed meat products.

Name of author(s)	*Drabik-Markiewicz, Gabriela*
Title of publication	**Chromatographic study on the factors influencing generation of selected N-nitrosamines in the course of heating cured meat**
Year	2010
Source/Organization	The University of Silesia, Institute of Chemistry
Type of document	Ph.D Thesis
Topics covered	Use levels; Nitrosamines
Abstract	N/A
Key information relevant	The most widespread exposure to N-nitrosamines is through an intake of food and drinks, but there are also other sources, like tobacco and cosmetics. Endogenous synthesis of N-nitrosamines in the body is yet another important source of N-nitrosamines. N-Nitrosamines are formed in the reaction between a nitrosating agent and a substance having an amino group, and their formation can be the result of a chemical and/or microbial reaction. Micro-organisms can take part in the formation of N-nitrosamines in various different ways, e.g., by reduction of nitrates to nitrites, by degradation of proteins to amines and amino acids, and by production of enzymes carrying out nitrosation and formation of a suitable pH for nitrosation. For the aforementioned reasons, formation of N-nitrosamines is a complex process and appearance of these compounds in meat products depends on various different parameters associated with preparation, storage, and thermal processing of meat. The concentration of volatile nitrosamines grows with elevated temperatures and time. Therefore, heat treatment of meat (like pasteurization, sterilization, cooking, and baking) can be responsible for the formation of N-nitrosamines. Moreover, the presence of sodium nitrate and sodium nitrite, the nitrosamine precursors or catalysts, enhances growth of the nitrosamine concentration. Various precursors of NPYR have been suggested, including proline, collagen, and pyrrolidine. Proline seems to be the most significant precursor for N-nitrosopyrrolidine, which is formed from proline by nitrosation followed by decarboxylation at elevated temperatures, or by the decarboxylation of proline in the first step with the formation of pyrrolidine followed by nitrosation. Putrescine, spermidine and spermine can be also the N-nitrosopyrrolidine precursors. Putrescine is obtained by decarboxylation of ornithin, which after deamination and cyclization gives pyrrolidine. The latter one can be transformed to NPYR in the reaction with a nitrosating agent. It has also been suggested that N-nitrosopiperidine can be formed from cadaverine. Upon the performed statistical evaluation of the experimental results presented in this study, the following conclusions can be drawn: (1) Higher concentrations of NaNO2 and higher working temperatures resulted in higher yields of the three detected *N*-nitrosamines (i.e., NDMA, NPYR and NPIP) in the processed meat samples. In most cases, the effect of NaNO2 was more significant than that of the temperature. However, formation of *N*-nitrosamines does not seem problematic when the concentration level of the added NaNO2 is within the legally prescribed limits (150 mg kg-1). (2) Addition of proline did not affect formation of NDMA, while it had a significant influence on formation of NPYR. (3) Addition of hydroxyproline induced a slight increase of the NDMA yields (although with a borderline non-significance). In the case of NPYR, no influence of hydroxyproline on its formation could be detected. (4) Addition of pyrrolidine induced minor increase of the NDMA yields (also with a borderline significance only), yet it significantly affected the NPYR yields. (5) Addition of putrescine did not have a measurable influence on concentrations of *N*-nitrosamines. (6) Addition

	of cadaverine also did not influence the formation of NDMA, although it had a significant effect on the NPIP yields. (7) Addition of spermidine caused a significant increase in both, the NDMA and the NPIP yields, compared with the blank situation. (8) No influence of spermine was established on the *N*-nitrosamines formation. In this study, the importance of amino acids and biogenic amines, which are naturally present in raw meat as precursors of the selected *N*-nitrosamines, was confirmed.

Name of author(s)	*European Commission*
Title of publication	**Reports of the scientific committee for food (thirty-eighth series)**
Year	1997
Source/Organization	European Commission
Type of document	Report
Topics covered	Use levels; Nitrosamines
Abstract	N/A
Key information relevant	Analysis of foods for nitrate and nitrite ions remains somewhat problematic, with various methods applied in different laboratories. Average estimates for intakes of nitrate range from 52 to 156 mg/day in various European countries, while estimates of nitrite intake range from 0.7 - 4.2 mg/day. Dietary levels of carcinogenic N-nitrosocompounds have been estimated to be in the range of 0.3- 0.5µg/day, with these low levels representative of major recent efforts to detect sources of contamination and to achieve prevention. Many nitrosamines and nitrosamides have been shown to be potent carcinogens, and no safe level can be determined. For carcinogens that are also genotoxic, it is generally assumed that there is no threshold dose below which no tumour formation would occur. However, the Committee concluded there was no clear evidence to indicate that nitrate or nitrite are per se carcinogenic, or for the endogenous formation of carcinogenic N-nitrosocompounds after exposure to realistic levels of nitrate and N-nitrosatable precursors. It reiterated its previous opinion that exposure to preformed nitrosamines in food should be minimised by appropriate technological practices such as the lowering of levels of nitrate and nitrite added to foods to the minimum required to achieve the necessary preservative effect and to ensure micro biological safety. It concluded that more research is needed regarding the possible endogenous formation of N-nitrosocompounds after exposure to realistic dietary levels of nitrate.

Name of author(s)	*Hebels, D.* *Jennen, D.* *van Herwijnen, M.* *Moonen, E.* *Pedersen, M.* *Knudsen, L.* *Kleinjans, J.* *de Kok, T.*
Title of publication	**Whole-genome gene expression modifications associated with nitrosamine exposure and micronucleus frequency in human blood cells**
Year	2011
Source/Organization	Mutagenesis Advance Access, Vol. 26, Issue 6, 2011.
Type of document	Journal article
Topics covered	Nitrosamines
Abstract	N-nitroso compounds (NOCs) are suspected human carcinogens and relevant in human exposure. NOCs also induce micronuclei (MN) formation in vivo. Since lymphocytic MN represent a validated biomarker of human cancer risk, establishing a link between NOC exposure and MN frequency in humans and concurrently investigating associated transcriptomic responses may provide crucial information on underlying molecular mechanisms that predispose to carcinogenicity. We used lymphocytes, from adult females participating in the pan-European bio- marker research project NewGeneris, as a surrogate tissue for analysing such potentially carcinogenic gene expression and MN formation events in target organs. To assess NOC exposure, urine samples were analysed for marker nitrosamines. NOC excretion levels and MN frequency were subsequently linked to peripheral blood transcriptomics. We demonstrated a significant association between MN frequency and urinary NOCs (r 5 0.41, P 5 0.025) and identified modifications in among others cytoskeleton remodelling, cell cycle, apoptosis and survival, signal transduction, immune response, G-protein signalling and development pathways, which indicate a response to NOC- induced genotoxicity. Moreover, we established a network of genes, the most important ones of which include FBXW7, BUB3, Caspase 2, Caspase 8, SMAD3, Huntingtin and MGMT, which are involved in processes relevant in carcinogenesis. The modified genetic processes and genes found in this study may be of interest for future investigations into the potential carcinogenic risk associated with NOC exposure in humans.
Key information relevant	Despite policy measures that have significantly decreased the level of N-nitroso compounds (NOCs) in cured meat products, NOCs may also be formed endogenously in the stomach and colon out of the reaction between nitrate and amines or amides. In the 1960s, it was shown that many NOCs are carcinogenic in rats, and most NOCs have been classified as probable or possible human carcinogens by the International Agency for Research on Cancer. It remains difficult, however, to assess the actual human cancer risk as human exposure is relatively low and information on the possible (pre)

	carcinogenic effects of NOCs in humans is sparse. Although there have been numerous reports on genotoxic and mutagenic properties of NOCs in vitro, this does not necessarily imply a carcinogenic risk for intact humans. In this study, the authors evaluated the relationship between human NOC exposure and micronuclei (MN) formation in relation to human carcinogenesis. It identified a number of modifications indicating a response to NOC-induced genotoxicity, and a network of genes that are involved in processes relevant in carcinogenesis.

Name of author(s)	*Herrmann, S.S.* *Duedahl-Olesen, L.* *Granby, K.*
Title of publication	**Occurrence of volatile and non-volatile N-nitrosamines in processed meat products and the role of heat treatment**
Year	2015
Source/Organization	Food Control, Vol. 48, pp. 163-169.
Type of document	Journal article
Topics covered	Nitrosamines; In situ; Denmark; Belgium
Abstract	Most of the available data on the occurrence of N-nitrosamines (NA) in processed meat products have been generated in the 1980s and 1990s and especially data on the occurrence of non-volatile NA (NVNA) are scarce. Therefore we have studied the levels of volatile nitrosamines (VNA) and NVNA in processed meat products on the Danish market (N=70) and for comparison also products on the Belgian market (N=20).The effect of heat treatment on the NA levels, in selected samples, was also studied, in order to enable an evaluation of how preparation before consumption affects the levels of NA. For the Danish products the mean levels of the VNA were generally low (<0.8 µg kg-1), whereas the mean levels of the NVNA were considerably higher (<118 µg kg-1). Slightly higher mean levels were indicated for the Belgian products (i.e. VNA <1.5 µg kg-1 and NVNA <270 µg kg-1). The sums of VNA were higher than 10 mgkg-1 for one Danish sample and two Belgian samples. Levels of up to 2000 and 4000 µg kg-1 of N-nitroso-thiazolidine-4-carboxylic acid (NTCA) an NVNA occurred in the Danish and the Belgian samples, respectively. The majority of the Danish processed meat products contain NVNA but also VNA occur. The levels of NA are comparable with those reported in previous and recent studies; however the frequency in which they are found may be lower and thereby also the mean contents. The levels of N-nitrosopiperidine (NPIP) increased by frying and baking, whereas varying impacts were observed for N- nitrosoproline (NPRO), N-nitrosodimethylamine (NDMA), N-nitrosopyrrolidine (NPYR), N-nitrosodiethylamine (NDEA) and N-nitrosomethylaniline (NMA) depending on the type of product and/or the heat treatment. The levels of the NVNA, NTCA and N-nitroso-2-methyl-thiazolidine 4-carboxylic acid (NMTCA) decreased after frying and baking.
Key information relevant	Several publications report a link between meat intake and colorectal cancer risk. According to an evaluation of the studies in this area, published in 2010, the risk of cancer was estimated to increase by 29% with a daily consumption of 100g red meat and by 21% with a daily consumption of 50g of processed meat. While the mechanisms linking the consumption of red meat and processed meat to cancer are still unclear, it is understood that compounds known as N-nitrosamines are produced in nitrite/nitrate preserved meat products. Many of these are carcinogenic, which may explain why observed adverse health effects are more pronounced for processed meat than for meat in general. Several studies have indicated that there is a positive correlation, though not necessarily linear, between the amount of nitrite added and the amount of NA formed. As maximum levels of nitrite allowed by legislation are lower in Denmark than the rest of the EU, it could therefore be predicted that levels of NA found in meat products on the Danish market are also lower. However, no clear difference between the levels of NA in the products from the Danish and the Belgian markets was found in this study. In terms of the effect of heat treatment on NA concentration, the levels of NPIP increased by frying and baking, whereas varying impacts

	were observed for NPRO, NDMA, NPYR, NDEA and NMA depending on the type of product and/or the heat treatment. The levels of the NTCA and NMTCA decreased with frying and baking.

Name of author(s)	*Herrmann, Susan Strange*
Title of publication	**N-nitrosamines in processed meat products: analysis, occurrence, formation, mitigation and exposure**
Year	2014
Source/Organization	Danish National Food Institute
Type of document	Report
Topics covered	Nitrosamines; In situ; Denmark; Belgium
Abstract	N/A
Key information relevant	There is a large amount of literature on N-nitrosamines (NA) in meat products already available, but the focus has been on volatile NA (VNA), rather than non-volatile NA (NVNA). The aim of this study was to investigate the role of various factors (e.g. ingoing nitrite, fat content, heat treatment) on the formation of both VNA and NVNA. The levels of several NAs were found to be positively related to the ingoing amount of nitrite, although this was not the case for NDMA and NPYR (of which the levels remained low even when 350 mg kg-1 nitrite was added). This may indicate that the relevant precursors are not present. Studies by others have indicated the formation of NDMA to depend more on other factors (e.g. duration of storage). Besides ingoing nitrite, the presence of erythorbic acid was also found to affect levels of NA strongly, and levels of the individual NA were reduced by up to 20-75%. No additional protection against NA formation was obtained by also adding ascorbyl palmitate, a fat soluble antioxidant. Sodium chloride was found to have minor effects on the NA levels. Black pepper significantly increased the levels of NPIP, and Fe(III) increased the levels of NHPRO, NMTCA and NTCA, whereas haem had no effect. The results of heat treatment varied according to the particular NA and heat level. In general, the study showed that there was a low exposure risk from VNA in the surveyed meat products. For NVNA exposure was higher, but it is not possible to assess the risk because data concerning the toxicological relevance of these compounds are lacking.

Name of author(s)	*Honikel, Karl-Otto*
Title of publication	**The use and control of nitrate and nitrite for the processing of meat products**
Year	2008
Source/Organization	Meat Science
Type of document	Journal article
Topics covered	Use levels; Effect on colour; Nitrosamines
Abstract	Nitrate and nitrite are used for the purpose of curing meat products. In most countries the use of both substances, usually added as potassium or sodium salts, is limited. Either the ingoing or the residual amounts are regulated by laws. The effective substance is nitrite acting primarily as an inhibitor for some microorganisms. Nitrite added to a batter of meat is partially oxidized to nitrate by sequestering oxygen - thus it acts as an antioxidant - a part of nitrite is bound to myoglobin, forming the heat stable NO-myoglobin, a part is bound to proteins or other substances in meat. Nitrate may be reduced to nitrite in raw meat products by microorganisms. As oxidation and reduction may occur, the concentrations of nitrite plus nitrate in a product has to be controlled and measured especially if the residual amounts are regulated. This sum of both compounds is important for the human body. Intake of nitrate with food leads to its absorption over the digestive tract into the blood. In the oral cavity nitrate appears again where it is reduced to nitrite. With the saliva the nitrite is mixed with food, having the same effect as nitrite in a batter (inhibiting growth of some pathogenic microorganisms) and swallowed. In the stomach nitrite can eventually form carcinogenic nitrosamines in the acidic environment.
Key information relevant	In the last decades ascorbic acid or ascorbate, respectively, isoascorbate (erythorbate) is used in cured meat baters. There is a reaction of ascorbate with oxygen discussed forming dehydroascorbate and thus reducing the amount of nitrite which could be oxidized to nitrate. But ascorbate seems also to react with nitrite (nitrous acid or NO). Dahl, Loewe, and Bunton (1960), Fox and Ackerman (1968) and Izumi et al. (1989) show that ascorbate also reacts with ‘‘nitrite’’ and binding the resulting NO. The bound NO seems to be able to react as NO with other meat ingredients. Ascorbate is also added to reduce the formation of nitrosamines. The sequence of reactions of ascorbate preventing nitrosamine formation has not been fully elucidated. It may be due to the reduction of residual nitrite in meat products by ascorbate (EFSA, 2003) or the binding of NO to ascorbate and its retarded release. Furthermore, ascorbate in batters reduces the toxin production by proteolytic clostridium botulinum types A and B together with nitrite and salt (Robinson, Gibson, & Roberts, 1982). (…) Nitrite was added to meat products sometimes in too high amounts and e.g. in Germany some people died in the 3rd decade of the 20th century due to intoxication by nitrite in meat products. Germany solved the problem in 1934 with the Nitrit-Pokelsalz-Gesetz (nitrite curing salt law). It enforced that the

use of nitrite in meat products is only allowed in premixes with table salt; its content should be 0.5% and must not exceed 0.6%. Only nitrate could be added directly to meat batters. 0.5% means that with 20 g nitrite curing salt/kg of batter (2%) 100 mg nitrite/kg batter (100 ppm) would be added. In the 1950s, the Fleischverordnung (meat regulation) limited the residual amount to 100 mg sodium nitrite/kg in ready-to-eat meat products. In raw hams 150 mg NaNO2/kg were permitted. Also nitrate restrictions were applied. In the Fleischverordnung of 1982 nitrate was limited to some non-heated products with ingoing amounts of 300, respectively, 600 mg/kg and residual amounts of 100– 600 mg/kg product. (…)

The oxidation of nitrite to nitrate in meat also explains why in meat products to which only nitrite has been added nitrate will be found in considerable concentrations. In Figs. 5 and 6, the nitrite and nitrate concentrations of German meat products are shown. The emulsion type and cooked sausages and cooked hams are manufactured with nitrite only but they contain a mean of 20–30 mg nitrate/kg as also shown in Table 3 in a very recent survey. Nitrite is in most cases lower than nitrate in the finished product with concentration below 20 mg nitrite/kg in the median value. Only a few samples of cooked and raw sausages and raw ham exists above 60 mg nitrite/kg which also have higher nitrate concentrations. In the raw products nitrate may have been added. It could be assumed that the concentration of nitrate in a sausage where only nitrite is added is related to the nitrite content. Fig. 7 shows that with emulsion type sausages (only nitrite curing salt is used) the residual amounts of nitrite and nitrate exhibit no relationship above 20 mg residual nitrite/kg. There is no generally recognizable increase of nitrate with increasing residual amounts of nitrite. Without nitrite addition a residual amount of nitrate up to 30 mg/kg is probably due to the added drinking water and spices into the batter (0–50 mg nitrate/l).

When does the nitrite disappear in the product? Table 4 shows results from Russian colleagues (Kudryashow, 2003). The largest decrease is observed during the manufacturing up to the end of the heating process. This early loss amounts usually to about 65% independent of the ingoing concentrations. Within 20 days of cold storage the concentrations drop further to a third of the concentration after heating. The disappearance continues until 60 days of cold storage. Table 5 confirms the results. It furthermore shows that a higher pH value retards the disappearance of nitrite. It also confirms the results of Table 3 that nitrate concentrations are already high at day 0 after heating. Nitrate also falls in concentrations with time of storage. The reduction during storage is slower with increasing pH. Table 6 shows the influence of different heat treatment inmeat homogenates. To muscles with different pH, 100 mg nitrite/kg was added and the homogenate was either mildly heated (pasteurized) or sterilized. The nitrite and nitrate concentrations immediately after heating and 12 days of storage were measured. The results were: The higher the heating, the greater is the loss of nitrite. The formation of nitrate is also reduced. The residual nitrite plus nitrate added at no time of measurement to 100 mg/kg. Immediately after pasteurization both added to about 75 mg/kg. Sterilisation and storage reduced the added concentrations even further. Both compounds seem to react with other ingredients and are no longer analytically measured as inorganic nitrite or nitrate. The addition of ascorbate and polyphosphate show that the disappearance of nitrite is accelerated by ascorbate in the raw batter (Table 7). Heating for 7 min to 80°C leads to a slower loss of nitrite. Heating for additionally 1 h at 70°C retards the loss even longer. This is probably due to the inactivation of microorganisms and inactivation of enzymes by heating. With ascorbate and even more by polyphosphates the retarding by heating is also observed. Nitrite in all cases described here is partially oxidized to nitrate. In many experiments (see Tables 5 and 6) about 10–40% of the nitrite is oxidized to nitrate. This is known since decades. Already in 1978 Cassens et al. postulated that nitrite is bound to various meat constituents.

The red colour of cured meat products is one of the important effects of nitrite in meat products. The red colour is developing in a number of complicated reaction steps until NO-myglobin (Fe2+) is formed. Myoglobin exists in a muscle in three states, in which the cofactor haem, a porphyrin ring with an iron ion in its centre binds different ligands or in which the iron exists in the Fe2+ or Fe3+ state. In the native myoglobin, the porphyrin moiety (Fig. 8) is supported in the ligand binding by amino acids of the protein in the neighbourhood. In the “original’’ state myoglobin with Fe2+ in the porphyrin cofactor does not bind any ligand maybe a water molecule. In the presence of oxygen the myoglobin can bind an O2 molecule and it becomes bright red. The iron ion is in the Fe^{2+} state. But oxygen and other oxidizing agents like nitrite can oxidize the Fe^{2+} to Fe^{3+}. The formed metmyoglobin (MetMb) is brown. The ‘‘original’’ myoglobin (Mb), the oximyoglobin (MbO_2) and the metmyoglobin are occurring together in meat. In a muscle in a live animal there is very little metmyoglobin which increases post-mortem with the disappearance of oxygen except when meat is MAP-packed with high oxygen content. The three states of myoglobin have three characteristics absorbance spectra between 400 and 700 nm. As the three are in a kind of equilibrium to each other, the spectra have an isosbestic point at 525 nm where all three absorption curve cross which each other. The absorbance of this wave- length can be used for detecting the percentage of each form in meat. Nitrosomyoglobin has a spectrum which has similar maximum wavelength like oximyoglobin (Fig. 9). Oxygen and NO are biatomic molecules. A similar biatomic molecule CO also binds to myoglobin and also very tight. In some countries (e.g. USA and Norway) MAP packaging of meat with 1–2% CO is permitted. By reducing enzymes or chemical reactions with reducing agent like ascorbate the Fe^{3+} is reduced to Fe^{2+}. The NO formed from N_2O_3 can bind to the myoglobin (Fe^{2+}) and forms a heat stable NO-myoglobin. Oximyoglobin is not heat stable and dissociates. The meat turns grey or brown. On heating the NO-myoglobin the protein moiety is denatured but the red NO-porphyrin ring system (called often nitroso-myochromogen) still exists and is found in meat products heated to 120°C. This heat stable red colour will change on bacterial spoilage and it fades on UV light. The first one is advantageous as the consumer recognizes spoilage like in fresh meat which also changes colour on spoilage. In most recent years the riddle about the red colour of cured raw hams like Parma ham without added nitrite or nitrate has been solved. Various authors could show and proof that the Fe^{2+} in the porphyrin ring is exchanged with Zn^{2+} which gives the products a pleasant red colour. Nitrite addition prevents the exchange.

(…) As heated meat products are produced from fresh meat (chilled or frozen) no amines are available. In raw nitrate- cured meat products the nitrite concentration is rather low. Thus the formation of NO^+ is rather unlikely. In products heated above 130°C nitrosamines can be formed. Bacon frying, cured sausage grilling or frying of cured meat products as pizza toppings may experience such conditions that nitrosamines are formed. Table 9 shows the results of an investigation by Deierling, Hemmrich, Groth, and und Taschan (1997). In German foods only beer and pizza exhibited dimethyl-nitrosamine in detectable amounts. Thus nitrosamines occur only in small amounts and they are easily avoidable by proper frying, grilling and pizza baking. A data base for nitrosamines in foods together with other processing related residues are published by Jakszyn et al. (2004). Besides amines also amides and unsaturated fatty acids or derivatives of the latter can react with nitrite or its derivatives. Fatty acids or its derivatives can form alkylnitrites. About their concentrations very little are known about their presence in meat products. To the database Jakszyn et al. (2004) is referred. In this context, it should be mentioned that nitrosamines can be present in elastic rubber nettings for meat products which may contaminate the edible parts of e.g. cooked ham.

Name of author(s)	*Hustad, G. O.* *Cerveny, J. G.* *Trenk, H.* *Deibel, R. H.* *Kautter, D. A* *Fazio, T.* *Johnston, R. W.* *Kolari, O. E.*
Title of publication	**Effect of sodium nitrite and sodium nitrate on botulinal toxin production and nitrosamine formation in wieners**
Year	1973
Source/Organization	Applied Microbiology
Type of document	Journal article
Topics covered	C. botulinum, Effect on colour, Effect on taste, Nitrosamines
Abstract	Wieners were formulated and processed approximating commercial conditions as closely as possible. Twenty-four batches of product were made with the addition of six levels of sodium nitrite (0, 50, 100, 150, 200, and 300 µg/g), four levels of sodium nitrate (0, 50, 150, and 450 mug/g), and two levels of Clostridium botulinum (0 and 620 spores/g). After formulation, processing, and vacuum packaging, portions of each batch were incubated at 27°C or held for 21 days at 7°C followed by incubation at 27°C for 56 days. The latter storage condition approximated distribution of product through commercial channels and potential temperature abuse at the consumer level. Samples were analyzed for botulinal toxin, nitrite, and nitrate levels after 3, 7, 14, 21, 28, and 56 days of incubation. When nitrite was not added, toxic samples were detected after 14 days of incubation at 27°C. At the lowest level of nitrite added (50 µg/g), no toxic samples were observed until 56 days of incubation. Higher levels of nitrite completely inhibited toxin production throughout the incubation period. Nine uninoculated samples, representing various levels and combinations of nitrite and nitrate, were evaluated organoleptically. The flavor quality of wieners made with nitrite was judged significantly higher (P = 0.05) than of wieners made without nitrite. The nine samples were negative for 14 volatile nitrosamines at a sensitivity level of 10 ng/g. The results indicated that nitrite effectively inhibited botulinal toxin formation at commercially employed levels in wieners and that detectable quantities of nitrosamines were not produced during preparation and processing of the product for consumption.
Key information relevant	The development of toxin in the wiener samples was markedly influenced by the level of nitrite added to the meat (Table 3). Only two samples containing 50 µg of added nitrite per g became toxic after 56 days storage at 27°C. Nitrite concentrations above this level completely suppressed toxin formation in all samples. Toxin was present in 79 of 220 nitrite-free samples. Eighty-one of the 1,320 samples examined were toxic. Toxin was not

detected until the product was incubated at 27°C for at least 14 days. A factor that may govern growth and toxin production is the relatively uniform distribution of nitrite in the product. The probability of spore contact with nitrite, or some reaction product of nitrite, would be enhanced in this finely comminuted, well-mixed product, as compared to a coarsely comminuted or larger particle-type product that is not thoroughly mixed. Although residual levels of nitrite were gener ally low during storage (Table 1), toxin was not detected in inoculated product initially formulated to contain 100 µg or more of nitrite per g. The level of nitrite at the time of manufacture rather than the level of residual nitrite is the key protective factor in inhibiting toxin production.

Characteristic cured meat color was absent in the nitrite-free samples. No differences were observed in the color of wieners containing the various levels of nitrite. The color of wieners made without nitrite but smoked with hickory sawdust has been described as brown of varying intensity on the surface and grey in the interior. Smoke apparently contains ,sufficient oxides of nitrogen to react with myoglobin to form small amounts of the nitroso meat pigment on the surface of the product. In the study reported herein, liquid smoke imparted a characteristic reddish-brown surface color to the wieners made with added nitrite; nitrite-free wieners had a light brown surface color. The flavor quality of wieners containing 50 to 300 µg of nitrite per g (Table 4) was judged significantly higher (P = 0.05) than for wieners made without nitrite. Flavor quality was not affected by nitrate. Similar data on the effect of nitrite and nitrate on flavor have been reported. Taste panel scores for tenderness and juiciness were not affected by either nitrite or nitrate.

Nine samples containing various levels of nitrite and nitrate were analyzed for 14 volatile nitrosamines. Each wiener sample was analyzed before heating, after water heating for 7 min, and after pan frying. The 27 results were negative for nitrosamines. This is in agreement with a recent study concerning the effect of sodium nitrite concentration on N- nitrosodimethylamine formation in wieners.

Name of author(s)	*Hsu, James* *Arcot, Jayashree* *Alice Lee, N.*
Title of publication	**Nitrate and nitrite quantification from cured meat and vegetables and their estimated dietary intake in Australians**
Year	2009
Source/Organization	Food Chemistry, Vol. 115, Issue 1, 2009, pp. 334-339.
Type of document	Journal article
Topics covered	Australia; Use levels; Nitrosamines
Abstract	High dietary nitrate and nitrite intake may increase the risk of gastro-intestinal cancers due to the in vivo formation of carcinogenic chemicals known as N-nitroso compounds. Water and leafy vegetables are natural sources of dietary nitrate, whereas cured meats are the major sources of dietary nitrite. This paper describes a simple and fast analytical method for determining nitrate and nitrite contents in vegetables and meat, using reversed-phase HPLC-UV. The linearity R2 value was >0.998 for the anions. The limits of quantification for nitrite and nitrate were 5.0 and 2.5 mg/kg, respectively. This method is applicable for both leafy vegetable and meat samples. A range of vegetables was tested, which contained <23 mg/kg nitrite, but as much as 5000 mg/kg of nitrate. In cured and fresh meat samples, nitrate content ranged from 3.7 to 139.5 mg/kg, and nitrite content ranged from 3.7 to 86.7 mg/kg. These were below the regulatory limits set by food standards Australia and New Zealand (FSANZ). Based on the average consumption of these vegetables and cured meat in Australia, the estimated dietary intake for nitrate and nitrite for Australians were 267 and 5.3 mg/adult/day, respectively.
Key information relevant	Once in the stomach, nitrite can react with amines and amides, which are organics containing nitrogen such as amino acids, to form a group of carcinogens known as N-nitroso compounds. The stomach is most at risk from endogenous N-nitroso compound synthesis since stomach acid catalyses nitrosation reactions. High nitrate intake has been associated with gastric cancer in England, Colombia, Chile, Japan, Denmark, Hungary and Italy. Exposure to endogenously formed N-nitroso compounds had been associated with increased risks of cancer of the stomach, oesophagus and bladder. The results of this study confirmed the consensus view that the largest source of dietary nitrite is cured meat products. It also established that intake levels in Australia were well below the recommended maximum ADI.

Name of author(s)	*Larsson, Susanna C.* *Bergkvist, Leif* *Wolk, Alicja*
Title of publication	**Processed meat consumption, dietary nitrosamines and stomach cancer risk in a cohort of Swedish women**
Year	2006
Source/Organization	International Journal of Cancer, Vol. 119, Issue 4, 2006, pp. 915-919.
Type of document	Journal article
Topics covered	Nitrosamines; Sweden
Abstract	Processed meat consumption has been associated with an increased risk of stomach cancer in some epidemiological studies (mainly case-control). Nitrosamines may be responsible for this association, but few studies have directly examined nitrosamine intake in relation to stomach cancer risk. We prospectively investigated the associations between intakes of processed meat, other meats and N-nitrosodimethylamine (the most frequently occurring nitrosamine in foods) with risk of stomach cancer among 61,433 women who were enrolled in the population-based Swedish Mammography Cohort. Information on diet was collected at baseline (between 1987 and 1990) and updated in 1997. During 18 years of follow-up, 156 incident cases of stomach cancer were ascertained. High consumption of processed meat, but not of other meats (i.e., red meat, fish and poultry), was associated with a statistically significant increased risk of stomach cancer. After adjustment for potential confounders, the hazard ratios for the highest compared with the lowest category of intake were 1.66 (95% CI = 1.13-2.45) for all processed meats, 1.55 (95% CI = 1.00-2.41) for bacon or side pork, 1.50 (95% CI = 0.93-2.41) for sausage or hotdogs and 1.48 (95% CI= 0.99-2.22) for ham or salami. Stomach cancer risk was 2-fold higher among women in the top quintile of N-nitrosodimethylamine intake when compared with those in the bottom quintile (hazard ratio = 1.96; 95% CI = 1.08-3.58). Our findings suggest that high consumption of processed meat may increase the risk of stomach cancer. Dietary nitrosamines might be responsible for the positive association.
Key information relevant	Prior to this study, 5 case–control studies and only 1 prospective cohort study with a small number of cases (n = 68) had investigated the association between NDMA or nitrosamine intake and stomach cancer risk, with 4 case–control studies showing a positive association. Among the 61,433 women covered by this study, 156 incident cases of stomach cancer were ascertained during 940,770 person-years of follow-up from 1987 through 2004. Increasing consumption of processed meat was statistically significantly associated with increasing risk of stomach cancer. Women in the highest quintile of dietary NDMA intake had a 2-fold higher risk when compared with those in the lowest quintile. The association remained essentially unchanged after additional adjustment for other potential confounders. Because vitamins C and E, polyphenols, and fruit and vegetable juices have been shown to inhibit the formation of N-nitroso compounds in the stomach, the study investigated whether the association of processed meat or NDMA intake with risk of stomach cancer was modified by intake of vitamins C or E, or fruit and vegetables. The association with processed meat intake was slightly stronger among women with low fruit and vegetable consumption than among those with high fruit and vegetable consumption, but a test for interaction was not statistically significant. The association of processed meat or NDMA intake with stomach cancer did not appear to differ according to level of vitamin C or vitamin E intake).

Name of author(s)	*Liu, Chen-Yu* *Hsu, Yi-Hsiang* *Wu, Ming-Tsang* *Pan, Pi-Chen* *Ho, Chi-Kung* *Su, Li* *Xu, Xin* *Li, Yi* *Christiani, David C*
Title of publication	**Cured meat, vegetables, and bean-curd foods in relation to childhood acute leukemia risk: a population based case-control study**
Year	2009
Source/Organization	BMC Cancer, Vol. 9, Issue 15, 2009.
Type of document	Journal article
Topics covered	Nitrosamines; China
Abstract	Background: Consumption of cured/smoked meat and fish leads to the formation of carcinogenic N-nitroso compounds in the acidic stomach. This study investigated whether consumed cured/ smoked meat and fish, the major dietary resource for exposure to nitrites and nitrosamines, is associated with childhood acute leukaemia. Methods: A population-based case-control study of Han Chinese between 2 and 20 years old was conducted in southern Taiwan. 145 acute leukaemia cases and 370 age- and sex-matched controls were recruited between 1997 and 2005. Dietary data were obtained from a questionnaire. Multiple logistic regression models were used in data analyses. Results: Consumption of cured/smoked meat and fish more than once a week was associated with an increased risk of acute leukaemia (OR = 1.74; 95% CI: 1.15–2.64). Conversely, higher intake of vegetables (OR = 0.55; 95% CI: 0.37–0.83) and bean-curd (OR = 0.55; 95% CI: 0.34–0.89) was associated with a reduced risk. No statistically significant association was observed between leukaemia risk and the consumption of pickled vegetables, fruits, and tea. Conclusion: Dietary exposure to cured/smoked meat and fish may be associated with leukaemia risk through their contents of nitrites and nitrosamines among children and adolescents, and intake of vegetables and soy-bean curd may be protective.
Key information relevant	Consumption of cured/smoked meat and fish, which contains N-nitroso precursors, leads to the formation of carcinogenic N-nitroso compounds in the acidic stomach. Antioxidants, such as vitamin C, E, flavones and flavanones in fresh fruits, vegetables, green tea and soybeans have been found to block the nitrosation reaction. Epidemiologic studies have suggested that increased consumption of cured meat is associated with a higher risk of colorectal cancer and stomach cancer, while consumption of fresh fruits and vegetables is associated with a decreased risk of breast, colon, lung, pancreas, bladder, larynx, stomach, esophageal and oral cancers. These results are supported by this study, which demonstrated an association between leukaemia risk and dietary exposure to cured/smoked meat and fish, as well as between reduced risk and consumption of vegetables and soy-bean curd.

	This confirms previous findings of a study conducted in California, although two other previous studies failed to find a significant association between cured/smoked meat consumption and leukaemia risk.

Name of author(s)	*McCutcheon, J.W.*
Title of publication	**Nitrosamines in bacon: a case study of balancing risks**
Year	1984
Source/Organization	Public Health Reports 1984 Jul-Aug; 99(4): 360–364.
Type of document	Journal article
Topics covered	Nitrosamines; USA
Abstract	Nitrite has been used for centuries to preserve, color, and flavor meat. Today, about 10 billion pounds of cured meat products are produced annually, accounting for some one-tenth of the American food supply. Regulators became concerned about the safety of using nitrite in the early 1960s when studies showed the presence of carcinogenic nitrosamines in cured meat products. In the early 1970s, a study at the Massachusetts Institute of Technology implicated nitrite itself as a carcinogen. As studies have raised concern over the safety of nitrite, regulators have had to weigh the potential risk from cancer against nitrite's proven role in protecting consumers from deadly food poisoning bacteria. Today there is little scientific support for the theory that nitrite is a direct carcinogen. To deal with the nitrosamine problem, the U.S. Department of Agriculture (USDA) lowered the permissible amount of nitrite in cured meats to that level considered necessary for botulism protection. Regulators, however, found it necessary to take additional steps with bacon because nitrosamines were found consistently in fried bacon samples. In addition to lowering the amount of nitrite that could be added to "pumped bacon" (cured by injecting liquid curing agents in the pork belly), USDA required the addition of nitrosamine inhibitors and began an intensive monitoring program in processing plants to ensure that fried bacon did not contain confirmable nitrosamines. The cooperative effort between Government and industry resulted in the virtual elimination of confirmable nitrosamines in pumped bacon by 1980. USDA is continuing its efforts to reduce nitrite in meats wherever possible. It is involved in active research programs in the Federal Government, academia, and industry.
Key information relevant	In May 1978, on the basis of USDA and industry data, USDA issued a final regulation, reducing the level of nitrite that could be used in curing bacon from 200 ppm to 120 ppm and requiring that the nitrite be used in combination with 550 ppm of sodium ascorbate or erythorbate. The regulation also contained a significant policy statement. In a major step to ensure the protection of the public health, the Department stated that cooked pumped bacon could not contain confirmable levels of nitrosamines (12). At the same time, USDA proposed further decreasing the level of nitrite in bacon to 40 ppm, used in combination with 0.26 percent potassium sorbate. USDA tests showed that this method of curing bacon resulted in less nitrosamine formation and provided protection against botulism. Sorbate is used in a variety of products and had not been shown to cause adverse effects in toxicity tests. However, the use of potassium sorbate was later ruled out because it caused allergic reactions in some people handling and tasting the fried bacon during taste tests conducted by USDA taste panels (13). Subsequently, several reactive products formed by the combinations of sorbate and nitrite at low pH and high temperatures were found to be mutagenic (14). Today, USDA still enforces the levels required by the May 1978 regulation- 120 ppm of nitrite used with 550 ppm of sodium ascorbate or erythorbate.

Name of author(s)	*Mckeith, Amanda Gipe*
Title of publication	**Alternative Curing**
Year	2014
Source/Organization	Factsheet Pork Information Gateway, June 2014
Type of document	Journal article
Topics covered	Nitrosamines; Use levels; United States; Alternatives to nitrites
Abstract	N/A
Key information relevant	The nitrite controversy in the 1970s led to expanded research efforts in regard to curing, most of which focused on the refinement of improved meat curing practices to minimize the potential for nitrosamine formation, such as prohibiting nitrate and requiring a cure accelerator in bacon. Traditional or conventional meat curing, as we know it today, involves the direct addition of nitrite (typically in the form of sodium nitrite), which allows for a known amount of nitrite to be added to the product. However, meat can also be cured with natural sources of nitrate or nitrite, such as vegetable juice or celery juice powder. The 2006 US Code of Federal Regulations requires such products to be labelled as “uncured”, although they may have similar quality characteristics to sodium nitrite-cured products. At the time of publication, the USDA was considering a petition to remove this regulation, pending more research concerning the ability of natural cure ingredients to inhibit pathogen growth of pathogenic bacteria including Listeria monocytogenes, Clostridium perfringens and Clostridium botulinum. Some ingredients commonly used in alternatively-cured meat products include sea salt, evaporated cane juice, raw or turbinado sugar, lactic acid starter culture, and natural flavorings, such as celery juice, celery juice concentrate, or vegetable juice powder.

Name of author(s)	*Santarelli, Raphaëlle L* *Pierre, Fabrice* *Corpet, Denis E*
Title of publication	**Processed meat and colorectal cancer: a review of epidemiologic and experimental evidence**
Year	2008
Source/Organization	Nutrition and Cancer, Vol. 60, Issue 2, 2008, pp. 131-144.
Type of document	Journal article
Topics covered	Nitrosamines
Abstract	Processed meat intake may be involved in the etiology of colorectal cancer, a major cause of death in affluent countries. The epidemiologic studies published to date conclude that the excess risk in the highest category of processed meat-eaters is comprised between 20% and 50% compared with non-eaters. In addition, the excess risk per gram of intake is clearly higher than that of fresh red meat. Several hypotheses, which are mainly based on studies carried out on red meat, may explain why processed meat intake is linked to cancer risk. Those that have been tested experimentally are (i) that high-fat diets could promote carcinogenesis via insulin resistance or fecal bile acids; (ii) that cooking meat at a high temperature forms carcinogenic heterocyclic amines and polycyclic aromatic hydrocarbons; (iii) that carcinogenic N-nitroso compounds are formed in meat and endogenously; (iv) that heme iron in red meat can promote carcinogenesis because it increases cell proliferation in the mucosa, through lipoperoxidation and/or cytotoxicity of fecal water. Nitrosation might increase the toxicity of heme in cured products. Solving this puzzle is a challenge that would permit to reduce cancer load by changing the processes rather than by banning processed meat.
Key information relevant	Epidemiologic studies suggest that meat intake is associated with CRC risk, although the association is not significant in most studies. Published in 1997, the World Cancer Research Fund authoritative expert report states: "evidence shows that red meat probably increases risk and processed meat possibly increases risk of CRC". Since 2000, three meta-analyses showed that total meat intake is not related to risk, but that red meat intake is a significant risk factor. In addition, the association of CRC risk with processed red meat may be stronger than that with fresh red meat. There are a number of possible causes for this correlation, but those identified by this study as most likely were heme-induced promoters and carcinogenic N-nitroso compounds (NOCs). The endogenous formation of NOCs from nitrite is strikingly increased by the heme from meat. Non-toxic processed meat could potentially be produced either by removing nitrite to reduce NOC formation, or by adding a specific inhibitor (e.g., calcium to block heme in the digestive tract).

Name of author(s)	*Sindelar, Jeffrey J* *Milkowski, Andrew L*
Title of publication	**Sodium Nitrite in Processed Meat and Poultry Meats: A Review of Curing and Examining the Risk/Benefit of Its Use**
Year	2011
Source/Organization	American Meat Science Association White Paper Series, Vol. 3, 2011
Type of document	Journal article
Topics covered	Effect on colour; Effect on taste; Preservation; C. botulinum; Nitrosamines; In situ
Abstract	N/A
Key information relevant	Research conducted since the mid-1980s has suggested that nitrite is a significant molecule important for human health. As a product of enzymatic synthesis in humans, nitric oxide controls blood pressure, immune response, wound repair, and neurological functions. Very little nitrite is needed to induce a cured colour, but higher levels are required to prevent rapid fading and non-uniform curing. Much of the nitrite added during the product manufacturing is either depleted through a series of reactions or physically lost during certain manufacturing steps. Typically, between 10 and 20 percent of the originally added nitrite normally remains after the manufacturing process and those levels decline during storage. Although the chemistry is poorly understood, nitrites are very important for the development of flavour. This may be partially related to the role nitrite plays in retarding lipid oxidation. Nitrite also has many antimicrobial functions. Its effect against C. botulinum has long been known, but it also controls development of other pathogens. Since the 1970s, the presence of nitrosamines in meat products has been massively reduced. While nitrosamines can still be formed endogenously, this is also the case with other foods. The article therefore calls into question the IARC's classification of nitrite ingestion in conditions leading to endogenous nitrosation as probably carcinogenic. An end to the use of nitrites in meat products would have negative effects on both consumers and manufacturers, such as reduction in storage time.

Name of author(s)	*Sindelar, Jeffrey J* *Milkowski, Andrew L*
Title of publication	**Human safety controversies surrounding nitrate and nitrite in the diet**
Year	2012
Source/Organization	Nitric Oxide, Vol. 26, Issue 4, 2012, pp. 259-266.
Type of document	Journal article
Topics covered	Nitrosamines; Use levels; Effect on taste; Effect on colour; Preservation; C. botulinum; In vivo; In situ
Abstract	Nitrate and nitrite are part of the human diet as nutrients in many vegetables and part of food preservation systems. In the 1950s and 1960s the potential for formation of nitrosamines in food was discovered and it ignited a debate about the safety of ingested nitrite which ultimately focused on cured meats. Nitrate impurities in salt used in the drying of meat in ancient times resulted in improved protection from spoilage during storage. This evolved into their deliberate modern use as curing ingredient responsible for 'fixing' the characteristic color associated with cured meats, creating a unique flavor profile, controlling the oxidation of lipids, and serving as an effective antimicrobial. Several critical reports and comprehensive reviews reporting weak associations and equivocal evidence of nitrite human health safety have fostered concerns and debate among scientists, regulators, press, consumer groups, and consumers. Despite periodic controversy regarding human health concerns from nitrite consumption, a building base of scientific evidence about nitrate, nitrite, heme chemistry, and the overall metabolism of nitrogen oxides in humans has and continues to affirm the general safety of nitrate/nitrite in human health. As nitrite based therapeutics emerge, it is important to consider the past controversies and also understand the beneficial role in the human diet.
Key information relevant	The majority of daily nitrite ingestion (93%) is accounted for by human saliva, caused by the chemical reduction of salivary nitrate to nitrite by commensal bacteria in the oral cavity. Cured meats have been reported to comprise only 4.8% of daily nitrite intake. Vegetables constitute the major dietary source of nitrate, which can be reduced to nitrite endogenously. Nitrate is also contained in toothpaste for sensitive teeth. However, there is no public controversy in regard to this. Although a series of epidemiological studies in the 1990s reported that consumption of cured meats was related to brain cancer and childhood leukaemia, on the whole positive associations were weak and not clearly supported by other independent scientific evidence. Ongoing research has focused on the metabolism of nitric oxide, nitrite and nitrate, and appears to reaffirm the general benefits of nitrate/nitrite in human health. Yet disagreement about health impacts of dietary nitrite and nitrate, particularly in cured meats still exist despite changes in meat curing practices that minimize potential for nitrosamine formation.

Name of author(s)	*U.S Department of Health and Human Services*
Title of publication	**Report on Carcinogens**
Year	2013
Source/Organization	U.S Department of Health and Human Services
Type of document	Report
Topics covered	Nitrosamines; In vivo; In situ
Abstract	N/A
Key information relevant	Human exposure to nitrosamines can result from formation of N-nitroso compounds either in food during storage or preparation or *in vivo*, usually in the stomach. Individual nitrosamines are not found in isolation, but occur in mixtures of various nitrosamines. The concentration of nitrosamines tends to increase over time, and their formation is enhanced by high temperatures, such as occur while frying food, and high acidity, such as in stomach acid. Ascorbic acid or its isomers inhibit the formation of nitrosamines and often are added to food preparations to prevent nitrosamine formation. Although food and tobacco products are important sources of external exposure to N-nitrosamines, exposure also occurs from nitrosamines produced internally in the digestive tract (Hotchkiss 1989). About 5% of ingested nitrates are reduced to nitrites in saliva (NRC 1995). These nitrites can subsequently react in solution with secondary and tertiary amines, as well as N-substituted amides, carbamates, and other related compounds, to form N-nitroso compounds within the gastrointestinal tract.

Name of author(s)	*World Health Organization (WHO)*
Title of publication	**Evaluation of Nitrite, Potassium and Sodium Salts**
Year	1974
Source/Organization	World Health Organization (WHO)
Type of document	Report
Topics covered	Nitrosamines; In vivo
Abstract	N/A
Key information relevant	Based on a review of existing studies, this report drew the following conclusions: a) nitrosamines are potent carcinogens in several species of animal; b) nitrosamines can be formed when nitrites and secondary amines are incubated with human gastric juice; c) nitrosamine formation has been detected in vivo studies; d) nitrosamines have been reported in several foods. While there are indications of a dose-response relationship in nitrosamine-induced tumour development, a no-effect level for several nitrosamines has not yet been established. It must be remembered that the possibility of nitrosamine formation in foods or in the animal organism does not depend solely on added nitrite or nitrate. Nitrates occur naturally in many foods and nitrite has been detected in saliva at levels of 5-10ppm. One promising area of future investigation could be the use of ascorbic acid as a blocking agent in nitrosation of amines.

Name of author(s)	*World Health Organization International Agency for Research on Cancer*
Title of publication	**IARC Monographs on the Evaluation of Carcinogenic Risks to Humans**
Year	2010
Source/Organization	World Health Organization International Agency for Research on Cancer
Type of document	Report
Topics covered	Nitrosamines; In vivo; Use levels
Abstract	N/A
Key information relevant	The preservation of foodstuffs by nitrite can be attributed to a large degree to the high concentration of salts that are employed during the curing process. The average dietary exposure of adults in the UK using the 1997 Total Diet Study was estimated to range between 0.74 and 1.3 mg per person per day. The relative contribution of cured meats to total dietary intake of nitrite has decreased substantially over the past 30 years. The addition of ascorbate as an antioxidant is regulated in some countries, in order to prevent the formation of nitrosamines. Whereas nitrate from both vegetables and drinking-water is reduced in the body to nitrite, sources from vegetables probably result in less endogenous formation of N-nitroso compounds because of the presence of inhibitors of nitrosation. Studies on the association between nitrate intake from food (of which vegetables are the primary source) and gastric and oesophageal tumours find either no relationship or associate high intake with lower risk. By contrast, several studies have established a relationship between nitrite intake and increased risk. The risk may be increased further when high nitrite intake is combined with low intake of Vitamin C. Besides limited evidence in humans for the carcinogenicity of nitrite in food, in experimental animals there is sufficient evidence for the carcinogenicity of nitrite in combination with amines or amides, and limited evidence for nitrite per se. Ingested nitrate or nitrite under conditions that result in endogenous nitrosation is assessed as probably carcinogenic to humans.

Name of author(s)	*World Health Organization International Agency for Research on Cancer*
Title of publication	**Carcinogenicity of consumption of red and processed meat**
Year	2015
Source/Organization	Lancet Oncology
Type of document	Journal article
Topics covered	Nitrosamines
Abstract	N/A
Key information relevant	In October, 2015, 22 scientists from ten countries met at the International Agency for Research on Cancer (IARC) in Lyon, France, to evaluate the carcinogenicity of the consumption of red meat and processed meat. These assessments will be published in volume 114 of the IARC Monographs. (…) Meat processing, such as curing and smoking, can result in formation of carcinogenic chemicals, including N-nitroso-compounds (NOC) and polycyclic aromatic hydrocarbons (PAH). Cooking improves the digestibility and palatability of meat, but can also produce known or suspected carcinogens, including heterocyclic aromatic amines (HAA) and PAH. High-temperature cooking by pan- frying, grilling, or barbecuing generally produces the highest amounts of these chemicals. (…) The largest body of epidemiological data concerned colorectal cancer. Data on the association of red meat consumption with colorectal cancer were available from 14 cohort studies. Positive associations were seen with high versus low consumption of red meat in half of those studies, including a cohort from ten European countries spanning a wide range of meat consumption and other large cohorts in Sweden and Australia. Of the 15 informative case-control studies considered, seven reported positive associations of colorectal cancer with high versus low consumption of red meat. Positive associations of colorectal cancer with consumption of processed meat were reported in 12 of the 18 cohort studies that provided relevant data, including studies in Europe, Japan, and the USA. Supporting evidence came from six of nine informative case-control studies. A meta-analysis of colorectal cancer in ten cohort studies reported a statistically significant dose–response relationship, with a 17% increased risk (95% CI 1·05–1·31) per 100 g per day of red meat and an 18% increase (95% CI 1·10–1·28) per 50 g per day of processed meat.12 Data were also available for more than 15 other types of cancer. Positive associations were seen in cohort studies and population-based case- control studies between consumption of red meat and cancers of the pancreas and the prostate (mainly advanced prostate cancer), and between consumption of processed meat and cancer of the stomach. On the basis of the large amount of data and the consistent associations of colorectal cancer with consumption of processed meat across studies in different populations, which make chance, bias, and confounding unlikely as explanations, a majority of the Working Group concluded that there is sufficient evidence in human beings for the carcinogenicity of the consumption of processed meat. (…) Substantial supporting mechanistic evidence was available for multiple meat components (NOC, haem iron, and HAA). Consumption of red meat and processed meat by man induces NOC formation in the colon. High red meat consumption (300 or 420 g/day) increased levels of DNA adducts putatively derived from NOC in exfoliated colonocytes or rectal biopsies in two intervention studies. (…)

	Overall, the Working Group classified consumption of processed meat as “carcinogenic to humans” (Group 1) on the basis of sufficient evidence for colorectal cancer. Additionally, a positive association with the consumption of processed meat was found for stomach cancer.

8.3. Results of expert workshop

The third workshop session centred around the potential formation of nitrosamines resulting from the use of nitrites in meat products and preparations. As mentioned above, Annex II of Regulation (EC) 1333/2008 as amended by Commission Regulation (EU) 1129/2011 seeks to find a balance between the need for microbiological safety and the risk of nitrosamine formation. When asked whether the maximum amounts of nitrites provided in the current legislation achieve this balance, the panel considered that the question was not relevant, noting that there is insufficient data on the relationship between the ingoing amounts of nitrite and nitrosamine formation. Meanwhile, the relationship between nitrite and microbiological safety is clear.

Concerning human exposure to nitrosamines caused by cured meat products and preparations, there was consensus within the panel that nitrosamines formed during **preparation at home** and during **gastrointestinal digestion** are likely to be more relevant routes than nitrosamine formed during the production process. It was underlined that whereas *in situ* formation of nitrosamines can be measured with relative ease, nitrosamine formation in the gastrointestinal tract cannot be directly measured. As a result, the relevance of the in vivo formation of nitrosamines is more difficult to assess. However, as one of the members of the expert panel emphasised, there is considerable evidence linking endogenous nitrosamine formation with processed meat consumption and an increased risk of colorectal cancer.

Furthermore, it was noted by the panel that there is a strong relationship between the **temperature** applied whilst cooking and the formation of nitrosamines in meat products and preparations. This finding explains the relevance of nitrosamine formation during the preparation of meat at home: heat treatment applied in industrial production processes rarely exceeds sterilisation and temperatures typically range between 70 and 80°C, while subsequent preparation (e.g. through frying, barbecuing or baking) exposes products to higher temperatures. This issue is particularly salient when considering products that are intended to be eaten raw and for which high residual amounts are permitted, such as dry cured ham and dry cured loin, but that are subsequently heated at high temperatures (e.g. as topping on a pizza).

In addition, the panel identified several factors that are considered to increase the likelihood of nitrosamine formation, including meat products containing **black pepper** and those intended to **be cooked at high temperatures or barbecued**. Concerning the latter, one expert noted that research has shown that meat pieces to which no nitrite has been added were found to contain high amounts of nitrosamines following barbecuing, due to the nitrosating agents present in smoke.

According to the panel, measures that could be taken by producers to reduce the formation of nitrosamines include good processing practices and the addition of compounds which can scavenge the reactive nitrogen species. Consumers can also decrease their exposure to nitrosamines by **cleaning their pans and barbecue grills after cooking meat.** One expert also mentioned that new methods have been developed to measure the level of nitrosamines in products at the end of the production process; however given that the most relevant nitrosamine formation is considered to occur during the preparation at home and during gastrointestinal digestion, it is doubtful that these methods can help in reducing exposure to nitrosamines.

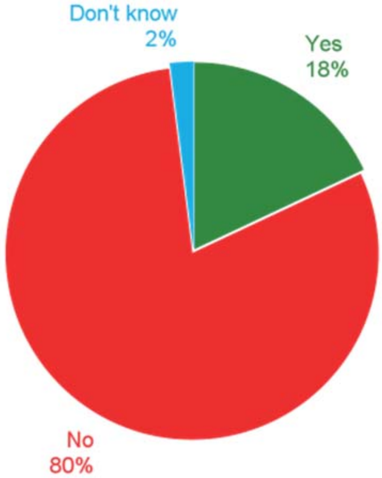
9. POSSIBLE ALTERNATIVES TO THE USE OF NITRITES: DEVELOPMENT, TESTING AND USE IN INDUSTRY

Given the risk of nitrosamine formation related to the use of nitrites in meat products and preparations, in the 1970s and 1980s pressure mounted to reduce nitrate and/or nitrite addition to meat products and even to eliminate them completely.[33] As a result, past and ongoing research has sought to find alternatives for achieving protection against microbiological activity and for inducing the desired colour and flavour in meat products. In some countries, the meat industry has attempted to reduce the levels of nitrites used by replacing them with various natural substances or other additives. Moreover, as discussed in Section 6, survey results suggest that across EU Member States, the meat industry has largely maintained or decreased the levels of nitrites used in the production of meat products and preparations. This section presents the study results concerning the development, testing, and use of possible alternatives to the use of nitrites.

9.1. Survey results

In our survey, producers of meat products and preparations and their organisations were asked whether they or their member companies produce organic meat products or preparations.[34] Given the lower maximum amount of nitrites permitted in products labelled as "organic", producers were also asked which additional measures they take to ensure that products are safe in relation to the possible presence of *Clostridium botulinum*. The following figure presents the results.

Figure 30: "Does your company/do your member companies produce organic meat products/preparations?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=93.

As show in the figure above, nearly one fifth (18%) of producers and organisations that answered this question reported producing organic meat products or preparations. Moreover, those respondents who reported producing organic meat products/preparations were asked whether they take additional measures to ensure microbiological safety of their products. The resulting responses are illustrated in the figure below.

[33] European Food Safety Authority (EFSA), "Opinion of the Scientific Panel on Biological Hazards on the Effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products", The EFSA Journal, Vol. 14, 2003, pp. 1–31.
[34] Commission Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, sets a maximum indicative ingoing amount of nitrites (expressed as $NaNO_2$) at 80 mg/kg.

Figure 31: "If Yes, do you take additional measures to ensure that the products are safe in relation to the possible presence of Clostridium botulinum?"

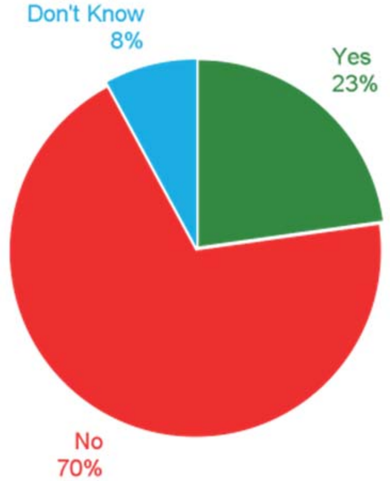
Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=15.

As the figure shows, just over half of respondents (53%) who reported producing organic meat products/preparations affirmed not taking any additional measures, while 27% did not know. On the other hand, three respondents (20%) reported taking additional measures for ensuring microbiological safety. Two of these respondents provided the following comments concerning the additional measures taken:

- "[B]y adding vegetable extracts in combination with lowering the water activity Aw. / Shorter shelf life" *(Organisation of food business operators/meat producers or processors)*;
- "At this moment it is not possible to use alternatives to nitrite to guarantee microbiological safety. If a plant [doesn't] use nitrites [it] must validate [its] manufacturing process to demonstrate the product safety" *(Organisation of food business operators/meat producers or processors).*

A related survey question asked respondents whether their company or member companies produce meat products/preparations *without* the addition of nitrites. The question referred to products typically cured using nitrites. The following figure illustrates the results provided for this question.

Figure 32: "Does your company/do your member companies produce nitrite-free meat products/preparations?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=93.

Nearly a quarter (23%) of meat producers/processors and their organisations who responded to this question reported producing nitrite-free products. Moreover, respondents were asked to specify the products they referred to, and how they safeguard a high level of protection against microbiological activity. The following table presents a selection of responses provided.

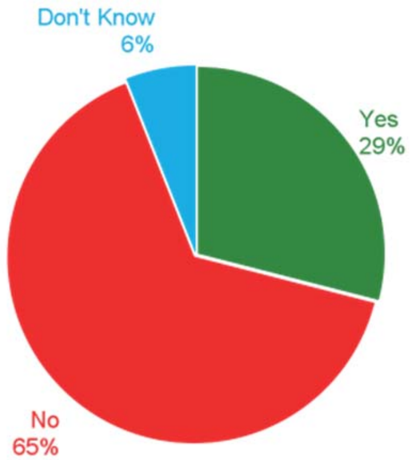
Table 5: Selected survey responses concerning nitrite-free products and measures taken to safeguard a high level of protection against microbiological activity

Member State	Type of operator/ association	Name of nitrite-free product or preparation	Measures taken to safeguard a high level of protection against microbiological activity
Other	Association	:	Extended dry curing or very limited shelf life under very strict chilling conditions
Belgium	Association	[C]ooked ham, cooked sausages	:
Netherlands	Association	[F]ricandeau	Limited shelf life
		BBQ sausage	[S]torage conditions and packaging, frozen and pasteurised and vacuum packed
		Roast beef	[Pasteurisation], low temperature and very short shelf life
Spain	Company	[B]urger, longaniza fresca	[A]dd sulphites
France	Company	[D]ry sausage	[V]ery strong [and] quick fermentation + presence of NaNO3 with [authorised] level (150 mg/Kg). Bacteriological analyses done more frequently.
Belgium	Company	Boudin Blanc	[A] heat treated product containing nearly no red muscular meat (but fat, water and bread). The product has a very short shelf life (typically < 10 days) at 4°C.
Finland	Association	Finnish Christmas Ham	The product is typically sold as frozen or fresh with short [shelf] life and cooked at home.
		[S]ausages made in small volumes	They are for special consumer groups (mostly children) and their [shelf] life is shorter. The safety is secured among [others] with [C]. botulinum stress tests, which are very expensive.
Spain	Company	[Hamburgers] and meat preparations, bratwurst [type] sausage	[Protection] against microbiological activity: extreme [hygienic] practices.
Poland	Company	Pates	High level of protection is ensured by: / a) modified atmosphere packaging / b) freezing / c) other [ingredients] influencing the shelf life stability / d) short shelf-life / e) packaging maintained at high care/risk areas (high sanitary regime)
		Natural roasted turkey breast	
		Chicken wings	
Ireland	Association	Beef, chicken	:
Ireland	Company	[M]eat chops	:
Ireland	Company	[B]eef chops	:
France	Company	Confit de foie de porc + 4 terrines de campagne	[T]hese meats have a very [high] Vp and salt amount that ensure protection against microbiological activity
Norway	Company	[S]ausages […]	:
Sweden	Company	Organic salami.	Low water activity, short shelflife.
Spain	Company	Chorizos, tapas.	Nitrates, paprika, natural sources of nitrates, lactates, acetates

Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders.

More generally, our survey asked all respondents whether they were aware of any alternatives in testing, development or use that could replace nitrites in the production processes of meat products/preparations while fulfilling the same technological needs (microbiological safety, colouring and flavouring). The following figure illustrates the results for this question:

Figure 33: "Are you aware of any alternatives to nitrites that are currently in testing, development or use, that could replace nitrites in the production processes of meat products/preparations while fulfilling the same technological needs (microbiological safety, colouring, flavouring)?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=108.

Of the over one hundred respondents who answered this question, nearly one third (29%) reported that they were aware of alternatives to nitrites in testing, development or use, while the remaining two thirds stated that they were not aware of such alternatives (65%) or that they did not know (6%). Respondents who answered "Yes" most frequently referred to alternatives such as phytochemicals, vegetables extracts, adding nitrates, starter cultures, lactates and acetates. However, a number of respondents also noted that the alternatives only consider a part, and not all, of the technological needs fulfilled by nitrites.

Respondents who answered "No" provided the following explanations:

- "Today no solution can [take] the place of nitrites" *(Organisation of food business operators/meat producers or processors)*;
- "Those that have been proposed all contain nitrates the level of which are variable and ultimately convert to nitrite. The variable and uncontrolled presence of nitrate is not a safe basis on which to base a food safety system. It [i]s far better to add a known amount of nitrite via formulation or residual amount in the traditional product. We have seen no other additive that creates the colour or flavour of cured meats that the UK consumer has come to expect in these types of products" *(Meat producer or processor);*
- "No substitutions for color and caracteristic aroma" *(Meat producer or processor)*;
- "Problem of pink colour for cooked product / Taste ? / Today, No alternative without clostridium botulinum risk" *(Meat producer or processor)*.

9.2. Results of literature research

The following table presents the results of the literature research relating to possible alternatives to the use of nitrites that are currently in development, testing, or use.

Name of author(s)	*Bulambaeva, A.A* *Vlahova-Vangelova, D.B* *Dragoev, S.C* *Balev, D.K* *Uzakov, Y.M*
Title of publication	**Development of New Functional Cooked Sausages by Addition of Goji Berry and Pumpkin Powder**
Year	2014
Source/Organization	American Journal of Food Technology, Vol. 9, Issue 4, 2014, pp. 180-189.
Type of document	Journal article
Topics covered	Alternatives to nitrites
Abstract	An identification of the technological capabilities to develop new functional cooked sausages with ½ reduced content of nitrite, enriched with dried goji berry (Lycium chinense) or powder of butternut pumpkin (Cucurbita moschata) was studied. The experiments were produced with samples containing 5 g kg-1 sodium nitrite and 5 or 10 g kg-1 dried goji berry fruits, respectively 5 or 10 g kg-1 pumpkin powder. The controls with 5 or 10 g kg-1 sodium nitrite only were used. The samples were analyzed on 1d after manufacturing and on 6d after storage at 0-4°C. It was found the addition of 0.5% goji berry or 0.5% pumpkin powder in the most significant extend contributes to preserve the sensory properties and delay the proteolytic processes. The combination of 0.75% goji berry and 0.75% pumpkin powder most preferably preserves the color characteristics of the sausages, but addition of 0.5-1.0% goji berry effectively inhibit the protein oxidation, lipolysis and lipid oxidation was determined. The conclusion was made that the addition of goji berry and pumpkin powder can be used as additives for development new functional meat products with halfway reduced amounts of nitrites. Future experiments are need for optimization the sausage formulation.
Key information relevant	While the use of 0.5g or 1g of dried goji berry fruits or pumpkin powder per kg of meat cannot by itself guarantee good quality and chemical safety of cooked sausages, a combination of 1% goji berry and 0.5% pumpkin powder (in combination with a reduced amount of sodium nitrite) can probably preserve the taste and colour characteristics of the meat, as well as inhibiting hydrolytical and oxidative changes. However, further experimentation was considered necessary to optimise this alternative method of curing.

Name of author(s)	*De Mey, Eveline* *De Maere, Hannelore* *Paelinck, Hubert* *Fraeye, Ilse*
Title of publication	**Volatile N-nitrosamines in meat products: Potential precursors, influence of processing and mitigation strategies**
Year	Forthcoming
Source/Organization	Critical Reviews in Food Science and Nutrition
Type of document	Journal article
Topics covered	Nitrosamines; Alternatives to nitrites
Abstract	Meat products can be contaminated with carcinogenic N-nitrosamines, which is ascribed to the reaction between a nitrosating agent, originating from nitrite or smoke, and a secondary amine, derived from protein and lipid degradation. Although in model systems it is demonstrated that many amine containing compounds can be converted to N-nitrosamines, the yield is dependent of reaction conditions (e.g. low pH and high temperature). In this paper the influence of the composition of the meat products (e.g. pH, aw, spices) and processing (e.g. ageing, ripening, fermentation, smoking, heat treatment and storage) on the presence and availability of the amine precursors and the N-nitrosamine formation mechanism is discussed. In addition, this paper explores the current N-nitrosamine mitigation strategies in order to obtain healthier and more natural meat products.
Key information relevant	In general, it is known that N-nitrosamines are formed by the reaction of secondary amines with a nitrosating agent. In meat products, the latter precursor mainly originates from nitrite or NOx compounds in smoke. With regard to the source of secondary amines, various model systems, which differ especially in water and fat content, were used to study the nitrosation potential of several amine containing compounds. Many compounds, which can occur in meat and meat products, were demonstrated to be able to act as precursors for the formation of carcinogenic N-nitrosamines. In the case of amino acids (i.e., proline, ornithine and lysine) and biogenic amines (i.e., putrescine and cadaverine) an intensive heat treatment (above 160°C) was often necessary to obtain substantial amounts of carcinogenic N-nitrosamines (e.g., NPYR and NPIP) in vitro. In meat products, proteins and lipids can be degraded to amine precursors during the ageing, fermentation, ripening and storage. In the case of dry fermented sausages, especially free amino acids and biogenic amines are formed. However, due to the very mild acidic conditions and low water activity, the abundant presence of these compounds is not a substantial risk for the formation of N-nitrosamines. The necessary deamination and cyclization is thermally catalyzed and takes mainly place during baking and grilling. During mild heating processes (under 160°C), such as pasteurisation and sterilisation, the formation of N-nitrosamines is limited. Moreover, as long as GMP conditions are respected and fresh meat materials, which contain low levels of lipid and protein degradation compounds, are used for the industrial preparation of heated meat products, the N-nitrosamine formation is restricted. However, in the interest of public health it may be opportune to investigate the possible formation of N- nitrosamines during the barbecuing

and baking of foods containing processed meat products (i.e. pepperoni pizza). It can be expected that a combination of processed meats, which contain amine precursors, and an intense heating process, often in combination with uncontrolled smoking, may result in an increased risk of N-nitrosamine formation. In addition, secondary amines, like piperidine (from pepper) can be, although slowly, nitrosated without the necessity of heat treatments. Therefore, the use of alkaloid and nitrate containing spices and herbs can be considered as an additional source of N-nitrosamines in meat products.

Besides the presence of amine precursors, the highest risk on the formation of N-nitrosamines is caused by the use of nitrite in meat products. Due to the many technological advantages of nitrite, the main mitigation strategy in the past to combat the N-nitrosamine formation in meat products is the limitation of the added amount of nitrite to 150mg/kg and the use of anti- oxidants such as ascorbate as nitrite scavenger. Although this approach causes a significant reduction of N-nitrosamines, still traces and occasionally high levels can be detected. Therefore current research is challenged to the further reduction (e.g. 60 mg/kg as imposed by the Danish regulation) and even elimination of nitrite. Gamma irradiation can reduce N- nitrosamines, as well as both precursors (nitrite and biogenic amines). However, the main draw back in Europe is the consumer's resistance towards this technology. In order to meet the needs of consumers for more natural meat products, the current research is mainly focused on the application of natural antioxidants, preferably from sustainable sources such as fruit and vegetable by-products. Nevertheless, the ultimate approach to obtain healthier and more natural meat products implies the total elimination of nitrite. As a consequence, the future challenge is to develop appropriate meat processing technologies such as the natural reddening by zinc protoporphyrin. In this way safe and attractive meat products without the use of chemical additives can be obtained.

Name of author(s)	*Doolaege, Evelyne H. A.* *Vossen, Els* *Raes, Katleen* *De Meulenaer, Bruno* *Verhé, Roland* *Paelinck, Hubert* *De Smet, Stefaan*
Title of publication	**Effect of rosemary extract dose on lipid oxidation, colour stability and antioxidant concentrations, in reduced nitrite liver pâtés**
Year	2012
Source/Organization	Meat Science
Type of document	Journal article
Topics covered	Effect on colour; Effect on taste; Alternatives to nitrites
Abstract	The oxidative stability of liver pâté was investigated in relation to different doses of rosemary extract (RE) and sodium nitrite. Colour stability, lipid oxidation (TBARS) and concentrations of ascorbic acid, α-tocopherol, carnosic acid and nitrite were measured on the batters before cooking and on the cooked liver pâté before and after exposure to light and air for 48 h at 4°C. Results showed that the use of RE significantly reduced lipid oxidation, whereas it had no effect on colour stability. Ascorbic acid and nitrite concentrations were significantly higher and lower respectively when RE was added. RE dose-dependently increased the concentration of carnosic acid. Lower sodium nitrite doses resulted in significantly lower nitrite concentrations and slightly lower TBARS values. It was concluded that in liver pâté sodium nitrite levels may be lowered to 80 mg/kg without negatively affecting colour and lipid stability and that the use of RE may help in maintaining lipid stability.
Key information relevant	The present study only focussed on lipid and colour stability in a reduced nitrite meat product. Nitrite also contributes to the typical flavour of cured meat products. Sensory analyses would be valuable to assess the effects of reducing nitrite and the use of other additives on flavour and consumer acceptability. In addition, the protective effect of nitrite against spore forming bacteria especially Clostridium botulinum needs to be considered. (…) The addition of a rosemary extract to porcine liver pâté had a positive effect on retarding lipid oxidation and maintaining higher concentrations of the antioxidants ascorbic acid, α-tocopherol and carnosic acid. Furthermore, it was found that the sodium nitrite dose, added to the liver pâté, could be reduced from 120mg/kg to 80mg/kg when rosemary extract was added, without negative effects on lipid oxidation, antioxidant level and colour stability.

Name of author(s)	*European Food Safety Authority*
Title of publication	**Opinion of the Scientific Panel on Biological Hazards on the request from the Commission related to the effects of Nitrites / Nitrates on the Microbiological Safety of Meat Products**
Year	2003
Source/Organization	European Food Safety Authority
Type of document	Report
Topics covered	C. botulinum; Preservation; Alternatives to nitrites
Abstract	N/A
Key information relevant	Despite substantial research efforts, no alternative for sodium nitrite has been identified.

Name of author(s)	*J.A. Gallego-Restrepo, O.A. Ochoa and J.A. Pérez-Alvarez*
Title of publication	**Use of celery extract and starter culture (Staphylococcus carnosus) as an alternative sources of sodium nitrite in cooked ham: influence upon colour**
Year	2013
Source/Organization	Journal of Meat Science and Technology
Type of document	Journal article
Topics covered	Alternatives to nitrites
Abstract	The effect of a new source of nitrites from vegetable origin was evaluated. A celery extract (CE) and holding time on the colour, reflectance spectrum, pH and residual nitrite in Medellin-type cooked ham (MCH), as well as effects of the cooking and cooling processes was studied. The was incorporated as a powder at concentrations of 0.2, 0.3 and 0.4%. The holding time was set at 12, 18 and 24 h. The control, to which only nitrite was added, showed a significantly higher residual nitrite content than the other treatments used. Two colour zones were identified in all MCH containing celery extract, the peripheral zone differing significantly from the control values for the colour coordinates of lightness (L*), red-green (a*) and yellow-blue (b*). The reflectance spectrum for the external zone differed between the different experimental treatments and the control, especially for yellow and red wavelengths.
Key information relevant	Using the control formula (0% CE and 24 h holding time) as a base, two different concentrations (0.2% and 0.4% CE) plus an intermediate value (0.3% CE) with two different holding times (12 h and 24 h) with a central time (18 h) were used to evaluate the behaviour of the response variables. The central point was set to verify whether the interaction was statistically significant or, in other words, to establish whether there was a non lineal relationship between concentrations and holding times in the response surface. The starter culture, Staphylococcus carnosus (culture CS 299), was used at 0.02% weight of the formula in all cases where CE (Vegetable Juice Powder Natural NA) was used. Both were provided by CHR Hansen Colombia S.A. […] different treatments of celery extract and resting time (Combinations: Cmb 2 to 6), had no statistically significant effect on the residual nitrite content (p>0.05). The low levels were found when CE is added. These results suggest that new studies are needed to determine the impact of this method of producing Colombian hams on the role of the starter culture in reducing nitrates to nitrites.In combinations 2 to 6, the concentration of 40-50 mg/kg, that are considered sufficient for the technological and microbiological effects sought in most products (USDA, 1995), was not reached. The lightness values (L*) increased in the treatments 2, 3, 4, 5 and 6 with respect to the control, although no statistically significant differences existed between the treatments in which CE as used as regards (L*) in the external zone (P>0.05). However, there was a statistically significant difference (P>0.05) between these treatments and the control, the external zone being lighter in the treatments. For the same coordinate, there were no statistically significant differences (P>0.05) between the treatments. The parameter a* was lower in all the treatments to which CE had been added, while the final product showed higher green components in the external zone. In agreement with Sammel and Claus (2003), lower values indicate less pinkness. Statistically significant differences in a* were observed between the treatments 2-6 and the control but not in the central zone.

Name of author(s)	*Mckeith, Amanda Gipe*
Title of publication	**Alternative Curing**
Year	2014
Source/Organization	Factsheet Pork Information Gateway, June 2014
Type of document	Journal article
Topics covered	Nitrosamines; Use levels; United States; Alternatives to nitrites
Abstract	N/A
Key information relevant	(…) [M]eat can also be cured with natural sources of nitrate or nitrite, such as vegetable juice or celery juice powder. The 2006 US Code of Federal Regulations requires such products to be labelled as "uncured", although they may have similar quality characteristics to sodium nitrite-cured products. At the time of publication, the USDA was considering a petition to remove this regulation, pending more research concerning the ability of natural cure ingredients to inhibit pathogen growth of pathogenic bacteria including Listeria monocytogenes, Clostridium perfringens and Clostridium botulinum. Some ingredients commonly used in alternatively-cured meat products include sea salt, evaporated cane juice, raw or turbinado sugar, lactic acid starter culture, and natural flavorings, such as celery juice, celery juice concentrate, or vegetable juice powder.

Name of author(s)	*Mulvey, Liz* *Everis, Linda* *Leeks, David* *Hughes, Holly* *Wood, Ann*
Title of publication	**Alternatives to Nitrates and Nitrites in Organic Meat Products**
Year	2010
Source/Organization	Camden Technology Limited, for Defra (UK Department for Environment, Food and Rural Affairs)
Type of document	Report
Topics covered	Alternatives to nitrites; Effect on colour; Effect on taste; C. botulinum; Nitrosamines; Preservation; Use levels
Abstract	A requirement of Commission Regulation (EC) 889/2008 (EC 2008a), which laid down detailed rules to further elaborate Council Regulation (EC) 834/2007 (EC 2007a) on organic production and labelling of organic products, is a re-examination of the use of nitrates and nitrites in cured organic meats with a view to withdrawing these additives by the end of 2010. In order to inform Defra of the possible effects of this action in the UK, this Defra funded project (Defra Project Reference OF0389) includes a literature review of alternatives to nitrates and nitrites in meat products, an analysis of the microbiological issues relating to nitrates and nitrites in meat products with regard to shelf life and pathogenic organisms and a consultation with industry about the implications of this legislation.
Key information relevant	The chemistry of nitrite in cured meat is a complex issue as nitrite is a very reactive compound. The intensity of cured meat colour is related to the concentration of nitric-oxide stabilised myoglobin in the muscle, not the nitrite level. The addition of ascorbic acid, ascorbate or erythorbate can increase the conversion of nitrite to nitric oxide and consequently speed up the reaction. Cured meat flavour may be related to prevention of lipid oxidation, although the use of other antioxidants does not result in similar flavour. Nitrite levels in cured meats fall during storage and the level of residual nitrite is usually comparable in a range of products irrespective of in-going amount. It would appear that nitrite can be inhibitory to a range of pathogens at in-going levels of 50mg/kg to 200mg/kg when used in combination with low storage temperature, reduced pH (i.e.<6.0) and increased salt levels (up to 3%). Any change to a single one of these factors will disturb the balance of the preservation system. In order to maintain safety and shelf-life, the formulation of cured meat products may need to be altered to include additional preservative measures such as sorbate or lactate. Overall, there is no single alternative to nitrite available that can produce all the cured characteristics including microbial stability, colour and flavour. Products made without nitrite or suitable alternatives would be expected to have a shorter shelf life, be grey or dark in colour and require very high standards of hygiene during production and distribution, and may not remain safe if abused by the consumer.

Name of author(s)	Sebranek, Joseph Bacus, James
Title of publication	**Natural and Organic Cured Meat Products: Regulatory, Manufacturing, Marketing, Quality and Safety Issues**
Year	2007
Source/Organization	American Meat Science Association White Paper Series, Number 1, March 2007.
Type of document	Journal article
Topics covered	Alternatives to nitrites; Use levels; Nitrosamines; Effect on colour; Effect on taste; Preservation; C. botulinum; United States
Abstract	N/A
Key information relevant	Regulations forbid the addition of nitrite and nitrate to products sold in the US and labelled as “natural” or “organic”. Natural or organic versions of products that are traditionally cured, such as bacon, are therefore also additionally required to be labelled as “uncured” (this is not the case for other products, such as fresh sausage). However, meat processing technology has developed means by which nitrate and nitrite can be indirectly added to these products to achieve very typical cured meat properties. Natural sources of nitrite and/or nitrite that are frequently used include sea salt, raw sugar and vegetable juices/powders (in particular celery juice/powder). Ingredients that might be considered as curing adjuncts for natural or organic processed meats include vinegar, lemon juice solids and cherry powder. When ingredients with naturally occurring nitrate are used, a nitrate reductase enzyme is also necessary to convert the nitrate into nitrite. The use of natural curing ingredients appears adequate to attain conventional cured colour and taste. However, one issue for processed meats that use natural sources of nitrate is that the true amount of nitrite formed is unknown and impossible to measure because nitrite reacts quickly with meat components. Consequently, the microbial safety of processed meats manufactured with natural sources of nitrate is very difficult to assess. Moreover, consumers may be confused that the products are labelled as “uncured” and “no nitrates or nitrites added”, but may in fact contain significant levels of residual nitrate and nitrite.

Name of author(s)	*Stegeman, D.* *Verkleij, T. J.* *Stekelenburg, F. K.*
Title of publication	**Reductie van nitrietgebruik bij biologische vleeswarenbereiding**
Year	2005
Source/Organization	TNO Kwaliteit van Leven / Agrotechnology & Food Innovations (Wageningen UR)
Type of document	Report
Topics covered	Alternatives to nitrites
Abstract	N/A
Key information relevant	No single component is known that can replace nitrite in realising all of its functions (antimicrobial, anti-oxidant, colour and flavour). Nitrite is a very effective preservative and anti-botulinal agent. For several products good manufacturing practice and introducing extra hurdles like low water activity and low pH may be sufficient to end up with a safe product without nitrite that can be stored at low temperature for 2 or 3 month, but some other products probably still require nitrite (albeit in smaller amounts than presently used). There may be alternative sources of the typical pink colour that is associated with nitrite-cured meat, such as fermented red rice, although they cannot be used in organic food products unless they introduce extra functionality. In terms of taste, anti-oxidants may potentially be able to impart the typical cured flavour, as this may be partly due to the role nitrites play in retarding lipid oxidisation. However, some research claims that it is not possible to achieve the correct taste without the use of nitrite. It can be concluded that simply abandoning nitrite in the production of organic meat products is not possible without changes in appearance and controlling product safety. Depending on product characteristics (especially shelf life and product-colour), attention must be paid to processing conditions and temperature conditions in the supply chain, before lowering the amount of nitrite. The exact levels required should be determined case by case. For specific products, under certain conditions, it may be possible to completely abandon the use of nitrite.

Name of author(s)	*Stegeman, D.* *Verkleij, T. J.*
Title of publication	**Reduction of nitrite in the production of organic meat products: a literature survey - part 2/update**
Year	2010
Source/Organization	Wageningen UR Food & Biobased Research
Type of document	Report
Topics covered	Alternatives to nitrites; Organic; Preservation
Abstract	In the production of meat products like cold meats, nitrites and nitrates are used for several reasons: for forming and stabilizing the red, cured meat colour, obtaining a cured aroma, and for antimicrobial and anti-oxidative reasons. The use of nitrite curing salt in organic products, however, is very much subject for debate. Being additional non-organic components, nitrite and nitrate, in principle, are a non-desired components in organic products. However, for safety reasons it is allowed to use nitrites and nitrates at low levels (and thus ending up with low levels of residual nitrite). Another option to circumvent the addition of non-organic components (and thus labelling of these E-numbers) in organic meat products is adding organic nitrate by using plant extracts. This way however, residual nitrite levels - reducing nitrite basically is meant to reduce the residual nitrite content - are not known. To determine the present state of art, a previously performed literature study on reducing the amounts of nitrite in meat products has been updated. This update shows that although internationally several studies have been published on this subject, no significant new insights have been published in the literature over the last years. Several studies on producing nitrite-free organic products have been published concluding from experiments that it is possible to produce safe meat products without using sodium nitrite. However, frequently, even in these studies, it is still advised to use a reduced amount of sodium nitrite as an extra hurdle or a safety precaution. In practice, also products without nitrite addition are sold on the market. However, often it is not clear if nitrate from plant extracts is being used in these products. Several present publications focus on the use of nitrate rich vegetable powders/extracts in combination with starter cultures to replace the addition of nitrite curing salts. Complete systems (vegetable powers in combination with starter cultures) are commercial available nowadays and used by several producers of meat products. Increasingly knowledge is present about the required incubation time and temperature to end up with the desired cured colour for different products. The main reason to reduce ingoing nitrite in meat products is to reduce the residual nitrite level. In contrast to that, rather little attention is given to the amount of residual nitrite in the final meat products prepared this way. Also no studies are found focussing on the effect of this nitrate- nitrite route on survival and outgrowth of Clostridium botulinum or Clostridium perfringens. No real systematic studies have been found on the exact processes that take place when nitrite is replaced by these additives, and only few studies are published on the anti-micro bacterial effects of these kinds of additives. From the different studies showing different results, it may be concluded that still much is unknown about the theory of using nitrate-containing

	vegetable to replace sodium nitrite. Extra research is needed regarding possible required alterations in processing (especially for cooked cured products) when vegetable extracts are used instead of sodium nitrite. Altogether, applying these vegetable systems at present seem premature, and confusing, if not even misleading with the present declaration, for consumers and it may give an unjustified sense of safety.
Key information relevant	Although internationally, several studies have been published on reducing the amounts of nitrite in meat products, no significant new insights have been encountered in the literature of the last years compared to the last literature survey. Studies on producing nitrite-free organic products that conclude form experiments it is possible to produce safe meat products without using sodium nitrite have been published. However, frequently, even in these publications, it is still advised to use a reduced amount of sodium nitrite as an extra hurdle or a safety precaution to prevent botulism. The last years, new studies have been published on the use of nitrate rich vegetable powders/extracts in combination with starter cultures. These products are added to the meat product and during an incubation period of 30 minutes to several hours at about 40 °C, nitrate is reduced to nitrite enabling the meat product to turn pink during further process steps. No real systematic studies have been found on the exact processes that take place when nitrite is replaced by these additives. Increasingly knowledge is present about the required incubation time and temperature to end up with the desired cured colour for different products. However, not many studies are published on the anti-micro bacterial effects of these kinds of additives, especially not on the anti-botulinum effect. From the studies in general, a positive anti-micro bacterial effect of the vegetable powders can not be concluded. For many consumers and producers, colour indicates the safety of the product. When using vegetable extracts to replace nitrite, the right colour of the product, though, still does not guarantee a food safe product. Also not much attention is given to the amount of residual nitrite in the final meat products prepared this way, whereas reducing residual nitrite is the aim of reducing ingoing nitrite content. Some studies indicate that the residual amounts of nitrite are significantly lower than when nitrite containing curing salt is used, while other studies show the opposite. From the different studies showing different results, it may be concluded that still much is unknown about the theory of using nitrate-containing vegetable to replace sodium nitrite. Extra research is needed regarding possible required alterations in processing (especially for cooked cured products) when vegetable extracts are used instead of sodium nitrite. Despite of this, several commercial systems (vegetable powers in combination with starter cultures) are already available on the market. It is known that these systems are used by several German organic meat producers. The exact composition and origin (organic vs. conventional) is not known. Because the way to declare these systems is not clear yet, it is not known how frequently they are used and in what kind of products the systems are applied. Overall, if these vegetable systems are used it may be confusing, if not even misleading with the present declaration, for consumers and it may give them an unjustified sense of safety.

Name of author(s)	*Sullivan, Gary Anthony*
Title of publication	**Naturally cured meats: Quality, safety, and chemistry**
Year	2011
Source/Organization	Iowa State University
Type of document	Report
Topics covered	Alternatives to nitrites; Use levels; United States; Preservation; Effect on colour; Effect on taste
Abstract	N/A
Key information relevant	In terms of antimicrobial activity, nitrite is most well-known for inhibiting Clostridium botulinum but also inhibits other pathogens such as Listeria monocytogenes, which is of great concern in ready-to-eat processed meats. Greater ingoing nitrite concentrations are required to provide antimicrobial activity than the other cured meat characteristics (e.g. taste, colour). To ensure product safety, USDA policy requires a minimum 120 ppm of ingoing nitrite to all "Keep Refrigerated" products unless other preservation processes are verified and implemented to assure safety. The direct addition of nitrite to comminuted products is limited to 156 ppm. For products manufactured with brine added through emersion, massaging, or injection, 200 ppm of nitrite is allowed. The addition of 625 ppm of nitrite is allowed in the manufacture of dry cured products. Bacon has a separate regulation in order to limit N- nitrosamine formation during frying. Injected or brine cured bacon products are produced with the addition of 120 ppm of nitrite, 550 ppm sodium erythorbate or ascorbate, and the use of nitrate is prohibited. Many compounds are added to cured meats for their antimicrobial activity. Organic acids are among the most common, in particular lactate and diacetate. Recently, much evidence has challenged the notion that nitrites are damaging to health. Much work has been conducted to find a substitute for nitrite but no single ingredient can replace all functions of nitrite.

Name of author(s)	*Vossen, Els* *Doolaege, Evelyne H. A.* *Moges, Haile Demewez* *De Meulenaer, Bruno* *Szczepaniak, Slawomir* *Raes, Katleen* *De Smet, Stefaan*
Title of publication	**Effect of sodium ascorbate dose on the shelf life stability of reduced nitrite liver pâtés**
Year	2012
Source/Organization	Meat Science
Type of document	Journal article
Topics covered	Effect on colour; Effect on taste; Alternatives to nitrites
Abstract	The effect of sodium ascorbate (SA; 500, 750, 1000 mg/kg) and sodium nitrite (SN; 40, 80, 120 mg/kg) doses on the shelf-life stability of liver pâtés was investigated in a full factorial design. Clear dose-dependent responses of the added SN or SA were found for the concentrations of nitrite, ascorbic acid and dehydroascorbic acid in the raw batters and in the cooked pâtés before and after 48 h of chilled display. Decreasing the SN dose to 80 mg/kg had no negative impact on the colour stability (a* value) and lipid oxidation (TBARS), and no additional antioxidant effect of SA was noticed. Lowering SN to 40 mg/kg resulted in proper colour formation, but the colour stability was inferior and lipid oxidation increased. Yet, increasing the amount of SA, at this low SN dose, resulted in lower TBARS values. Decreasing the SN dose to 80 or 40 mg/kg had no distinct effect on protein oxidation, which was however only measured by carbonyl content.
Key information relevant	Lowering the use of nitrite in liver pâté to 80 or even 40 mg/kg SN should be possible without facing major problems concerning the oxidative stability of the liver pâtés. Additional research should be done to verify if these lower doses still have a sufficient protective effect against microbiological risks. Also, sensory research on the acceptability of low-nitrite liver pâtés is warranted. Due to the multi- functional roles of nitrite, an approach where several additives are used to replace nitrite will be necessary. Sodium ascorbate is one of these potential additives.

Name of author(s)	Wójciak, K M Dolatowski, Z J Okoń, A
Title of publication	**The effect of water plant extracts addition on the oxidative stability of meat products**
Year	2011
Source/Organization	Acta Scientiarum Polonorum: Technologia Alimentaria
Type of document	Journal article
Topics covered	Alternatives to nitrites
Abstract	N/A
Key information relevant	Natural antioxidants extracted from plants have a lot of antioxidants catechins, epigallocatechins (green tea) rosmariquinone, rosmaridiphenol (rosemary), capsaicinoids (red pepper). They can be used as alternatives to the synthetic antioxidants because of their equivalence or greater effect on inhibition of lipid oxidation and haem pigment (nitrosohemachrome) protection. The aim of the study was to compare the effect of addition of green tea extract, red pepper extract and rosemary extract while curing process on colour and lipid stability during refrigerated storage of meat products. The addition of the plant extracts (pepper, green tea, rosemary) to the pork meat samples does not change significantly the acidity of the samples during chilling storage. All plants extracts effectively reduce lipid oxidation in cooked pork meat compared to the control. Pepper extract was effective in maintaining redness because of its reduction activity (low potential redox value in sample) and low TBARS values in sample during chill- ing storage. Addition of pepper extract and green tea extract in curing meat process helped with nitrosomyoglobin formation and curb prevention of metmyoglobin formation which stabilized the colour of product during chilling storage.

9.3. Results of expert workshop

In the workshop discussion concerning possible alternatives to nitrites, a number of experts provided insight concerning meat products that are produced in their Member State **without the addition of nitrites**. For instance, in Germany several such products exist, which also do not contain organic sources of nitrate such as fermented celery extract. These products have a **shorter shelf-life** and tend to be **vacuum-packed**. In the Netherlands, products without nitrites have been on the market for ten years, without incurring problems related to microbiological safety. Other companies in this country produce organic products with 60 or 80 mg/kg of nitrite added, whose safety is ensured through a shorter shelf life and a **lower storage temperature**. A member of the expert panel clarified that the production of Parma-type dry-cured ham, which does not involve the use of nitrite, uses a specific technology based on refrigeration at a low temperature until water activity (a_w) reaches a value of 0.96, followed by a long maturation period. A combination of these factors ensures that the product is safe.

The panel found that without the presence of nitrites, microbiological safety can be ensured if a **correct combination of key parameters** such as water activity, pH, storage temperature, and shelf life are achieved. **Alternative food additives** such as lactate, diacetate and sorbate may also contribute to ensuring that products are safe in relation to the possible presence of *Clostridium botulinum*. The panel also underlined the importance of packaging for ensuring the microbiological safety of meat products.

However, the panel confirmed that there is **currently no single alternative** that can fulfil all functions ensured by nitrites. A number of existing additives were discussed that aim to achieve microbiological safety (e.g. nisin, ethyl lauroyl arginate and essential oils) or that are added for colouring and flavouring purposes (e.g. lycopene, tomato paste, phytochemicals), but none were found by the panel to produce adequate results. The panel concluded that while there is **no adequate replacement for nitrite** that would allow for the production of the products currently on the market, these alternatives might be helpful in reducing the amount of ingoing nitrite. Examples of alternatives currently under development provided by the panel included phytochemicals and active packaging technology (e.g. plastics containing antioxidants and antimicrobials). The panel considered it unlikely that in the future, a single alternative will be developed that will fulfil the same technological needs as nitrites. Other products based on alternatives to nitrites may be developed but these would have properties differing from existing cured meat products and preparations.

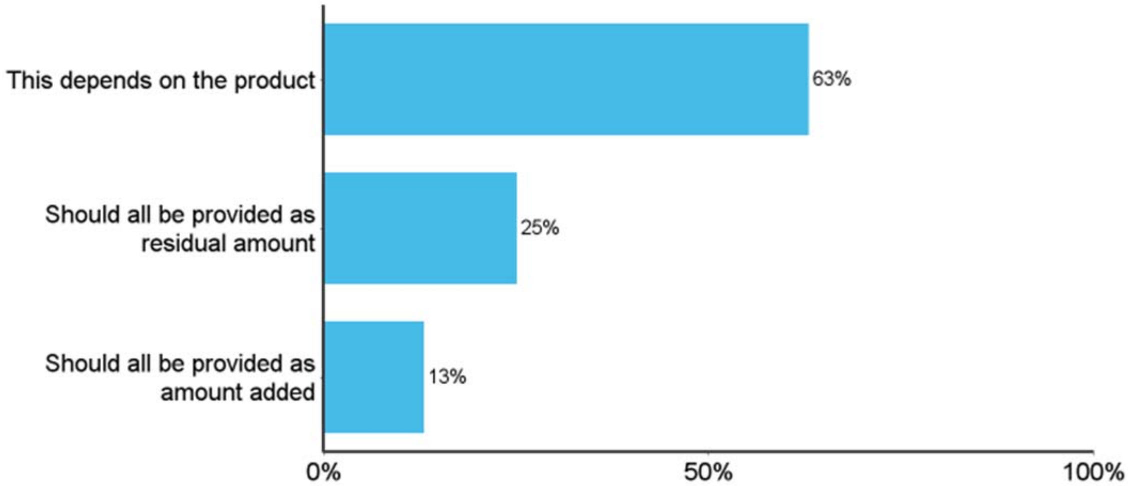
10. POSSIBILITY TO REVIEW THE CURRENT MAXIMUM LEVELS OF NITRITES

This final section presents results concerning the possibility to review the current maximum levels of nitrites authorised in the EU legislation. We first provide the results of the survey questions relevant to this issue, present key results from the literature review, and summarise the discussion held in the expert workshop. Finally, we conclude on the possibility to review the current maximum levels of nitrites, based on the results generated through the three methodological tools used in the course of the study.

10.1. Survey results

The legislation currently in place provides maximum added amounts authorised for non-traditional meat products and preparations, and maximum residual amounts for most traditionally cured meat products. In our survey, respondents from research institutes/universities were asked to provide their assessment whether legislation should provide maximum amounts of nitrites as amount added or as a residual amount. The results are presented in the figure below.

Figure 34: "In your view, should legislation provide maximum amounts of nitrites as amount added or as a residual amount?"



Source: Civic Consulting survey responses from research institutes/universities N=8.

As the figure above shows, there was no consensus among experts who contributed to our survey on this question. While two respondents (25%) considered that maximum amounts should all be provided as residual amounts, one respondent considered they should be provided as amounts added, with the remaining 63% stating that this depends on the product. One of two experts who responded that the legislation should provide all maximum amounts as residual amounts gave the following explanation:

- "For consumers, the residual amount gives more safety. Also the addition of ascorbic acid, ascorbate or similar derivates improve the safety and the red coloring and reduce the formation of nitrosamines".

In contrast, the expert who considered that the legislation should provide maximum amounts of nitrites as an amount added provided the following explanation:

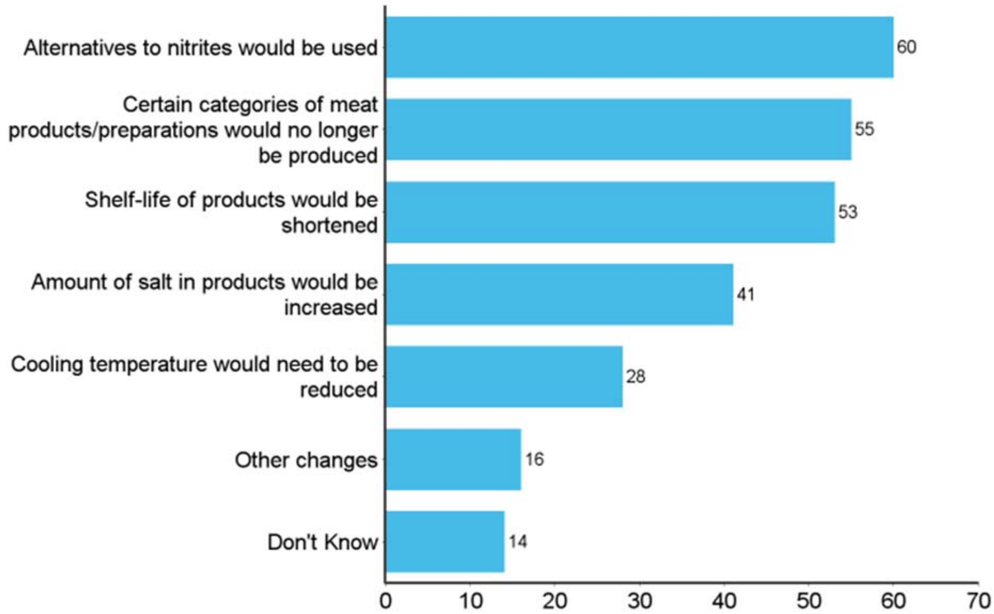
- "As the residual amount of nitrite depends highly on a number of other process parameters and additives, the amount added is most useful to control nitrite levels applied for meat products".

Finally, those experts who considered that this depends on the product in question provided the following comments:

- "In practice easier to apply a restriction of the added amount. However, certainly in un-heated meat products the conversion of nitrate (especially introduced by spices) may play a role in uncontrolled high amounts of residual nitrite amount";
- "The transformation of added nitrite into other products is highly variable depending on the raw material and the processing. In some case it may be unnecessary to include the ingoing given that the amount in the salt use as ingredient (particularly in whole meat products salted with dry salt on the surface, traditional drycured hams for instance can be considerably high in comparison with the final amount diffused into the meat product. Finally, if the purpose of controlling nitrite is mostly the formation of nitrosamines from residual nitrite, we are overlooking other risks derived from the addition of nitrite. Nitrite virtually reacts with all food components (including lipids and proteins) and very little we know about the potential toxicity of nitrated lipids/proteins. More scientific knowledge on this topic should be gathered. While 3 nitrotyrosine is used as marker of nitrosative stress in medicine, it is largely unknown whether this compound is formed or not in cured muscle foods for instance";
- "The efficiency of nitrite is affected by several factors. In particular, factors like water activity, pH, intensity of the heat treatment, initial load of spores, amount of iron, process and storage temperature, and presence of other ingredients like ascorbates influences the needed amount respectively the residual amount. During storage the nitrite concentration will decrease";
- "In labels, the inclusion of maximum added amount or residual amount, could confuse consumers and lead to errors in the selection of such products. Perhaps the application of a "traffic light" type could be useful";
- "The panel of EFSA is of opinion that the ingoing amount of nitrite contributes to the inhibitory activity against C. botulinum rather than the residual amount. So it's important settling the maximum ingoing amounts of nitrite to have the safety. But in many production it's necessary to increase the ingoing amounts of nitrites in order to have a diffusion of nitrite in all parts of the meat. In this case the check of residual is needed".

A final question in our survey asked respondents to consider what changes in production methods and/or types of meat products/preparations produced, if any, would occur if the use of nitrites in meat products and preparations was no longer possible. Respondents could select multiple options, and provided comments concerning other changes they consider to be relevant. The following figure presents the results of this survey question.

Figure 35: "If the use of nitrites in meat products and preparations was no longer possible, how would that change production methods and/or types of meat products/preparations produced?"



Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders. N=101.

As the figure shows, the option selected most frequently by respondents was "Alternatives to nitrites would be used". Respondents also tended to consider that certain categories of meat products/preparations would no longer be produced and that the shelf life of products would be shortened, with more than half of respondents selecting these options. A smaller number of respondents considered that the amount of salt in products would be increased (41) and that the cooling temperature would need to be reduced (28). Those respondents who selected "Other changes" referred, among others, to the changes in colour and flavour that products would undergo and to an increase in microbiological risk.

10.2. **Results of literature research**

The literature research has also provided insight on the possibility of reviewing the current maximum levels of nitrites authorised. While the reports and articles reviewed did not provide an explicit conclusion of whether or not the current levels could be reduced, they present evidence related to the processing conditions under which such a reduction could be achieved and whether the maximum amount authorised should be provided as an amount added or a residual amount. Several documents also suggest levels of nitrites that could be used for certain products. The table below presents key excerpts from the literature research related to the possibility of reviewing the current maximum levels of nitrites as authorised in the legislation.

Title of publication	Author(s)	Year	Key information related to the possibility of reviewing the current maximum levels of nitrites as authorised in the legislation
Potential changes in meat production/processing conditions			
Effect of nitrite on the odourant volatile fraction of cooked ham	Thomas, C., Mercier, F., Tournayre, P., Martin, J-L., Berdagué, J-L.	2013	"Despite its positive features, nitrite use entails an additional health risk for consumers. Several studies suggest that the nitroso compounds generated during cooking (Ferguson, 2010; Loeppky, 1994) are responsible for genetic modifications that may induce gastric or colorectal cancers (Corpet, 2011; Demeyer, Honikel, & De Smet, 2008; Sebranek & Bacus, 2007). In the face of a growing demand for healthier food, the maximum authorised dose in pork products may ultimately have to be reduced. However, given its many useful functions, abruptly banning nitrite from pork products is a difficult step because it would mean replacing a chemical health risk by a microbiological one, and also profoundly changing the organoleptic characteristics of the product."
Vers Une Recommendation de Reduction Du Taux de Nitrites Dans Les Differentes Familles de Charcuterie	IFIP - Institut du Porc	2010	"(…) a reduction [in the level of nitrites], especially if it is major, should be systematically accompanied by a consideration of each company based on an analysis of the microbiological risk, in particular of Clostridium botulinum. It should lead professionals to increase the level of food safety by e.g. using ascorbate, modifying the process to ensure the destruction of Clostridium spores, acidification of the product or a reduction of water activity, and good management of the cold chain during the shelf life of the product."
Effects of Reducing the Amount of Nitrite in Organic Meat Products	Verkleij, T.J., F.K. Stekelenburg, and D. Stegeman	2006	" (…) Complete abandoning of nitrite in the processing of organic meat products is not advisable. This will result in serious color instability of the product compared to conventional products and from this point of view the product doesn't look as consumers expect. By a reduction of the amount of nitrite to an extent of approximately 80 mg/kg ingoing, the color development and stability will be sufficient to reach a shelf life of 65 days."
Reductie van Nitrietgebruik Bij Biologische Vleeswarenbereiding, 2005.	Stegeman, D., Verkleij, T. J., Stekelenburg, F. K.	2005	"(…) Depending on product characteristics (especially shelf life and product-colour), attention must be paid to processing conditions and temperature conditions in the supply chain, before lowering the amount of nitrite. The exact levels required should be determined case by case. For specific products, under certain conditions, it may be possible to completely abandon the use of nitrite."

Opinion of the Scientific Panel on Biological Hazards on the Request from the Commission Related to the Effects of Nitrites / Nitrates on the Microbiological Safety of Meat Products	European Food Safety Authority	2003	"(…) the amount of nitrite necessary to inhibit C. botulinum differs from product to product. With good hygiene, HACCP and realistically short storage times under good temperature control, some meat products can be produced without using nitrites, although these are not strictly "cured meat products". The practices mentioned above are essential whenever levels of nitrites are reduced."
Amount added vs. residual amount			
Practical Use of Nitrite and Basis for Dosage in the Manufacture of Meat Products	Adler-Nissen, J., Ekgreen, M., Risum, J.	2014	"EFSA strongly advocates for specifying the maximum ingoing amount of nitrite instead of residual amount (EFSA 2003). However, there are arguments for not doing this universally. A major argument is that for certain types of production, in particular dry curing of whole meat, it is very difficult to control the amount of nitrite absorbed by the meat during the production, because the curing salt is usually removed again by brushing and/or washing before the curing period has ended (Werth 2009). Furthermore, (…) some dry cured products from South Europe are made with nitrate, which slowly and only partly is converted to nitrite and further to NO during the curing process."
Opinion of the Scientific Panel on Biological Hazards on the Request from the Commission Related to the Effects of Nitrites / Nitrates on the Microbiological Safety of Meat Products	European Food Safety Authority	2003	"The Panel is of the opinion that the ingoing amount of nitrite, rather than the residual amount, contributes to the inhibitory activity against C. botulinum. Therefore, control of nitrite in cured meat products should be via the input levels rather than the residual amounts."
Scope for reducing the maximum levels of nitrites authorised			
Effect of Rosemary Extract Dose on Lipid Oxidation, Colour Stability and Antioxidant Concentrations, in Reduced Nitrite Liver Pâtés	Doolaege, E., Vossen, E., Raes, K., De Meulenaer, B., Verhé, R., Paelinck, H., De Smet, S.	2012	"(…) It was found that the sodium nitrite dose, added to the liver pâté, could be reduced from 120mg/kg to 80mg/kg when rosemary extract was added, without negative effects on lipid oxidation, antioxidant level and colour stability (..)"
Vers Une Recommendation de Reduction Du Taux de Nitrites	IFIP - Institut du Porc	2010	" (…)To continue the control of the bacterium through nitrites, it will be difficult to reduce levels below 80 mg/kg of added sodium nitrite. Based on previous research cited in this

Dans Les Differentes Familles de Charcuterie			document, this quantity seems sufficient to guarantee the development of the colour and aroma specific to meat products (…)”
Reducing the Amount of Nitrites in the Production of Pasteurized Organic Meat Products - Experiments on an Industrial Scale	Stegeman, D., Hulstein, J.,Verkleij, J., Stekelenburg, K.	2007	“It can be concluded that, under practical conditions (production and handling under hygienic conditions, cold storage at temperatures below 7°C and aw in accordance to the shelf life), nitrite content in organic cooked cured ham and Bologna type of sausage can be reduced to 40 ppm ingoing amount.”

10.3. **Results of expert workshop**

The panel concluded that while it would not support abolishing the use of nitrites in meat products and preparations, **it is possible to reduce current maximum levels of nitrites as authorised in the legislation.** For identifying possible lower maximum amounts of nitrites added, one expert emphasised that microbiological safety must be demonstrated before any lower limits can be implemented. The panel suggested that using the experience of countries that currently have lower limits for specific meat categories (Denmark) or had them in the past (Finland and Germany) could be used as a possible benchmark.

The panel suggested prioritising the **focus of the reduction on mainstream products** and to initiate in parallel a process in which specific product (categories) could be identified for which an exception could be made (i.e. for which higher levels of nitrites could be allowed). The panel also agreed that a new categorisation of products should be defined, which should be based on the technology used in the production processes of the relevant meat products and preparations.

More specifically, when asked to consider how meat products and preparation would be affected if the limit was reduced to 100 mg/kg of added nitrite, the panel concluded that this amount would be sufficient for a majority of products, without significant effects on colour, flavour and microbiological safety (which would have to be demonstrated, e.g. by reference to countries in which such limits are or were in place, or other evidence). However, it was also agreed that for some products, a higher concentration of nitrite would be required. Experts considered that e.g. for fermented products, 120 mg/kg could be a more suitable limit.

A panel member reported that in Denmark 50 mg/kg of nitrites added was considered to be sufficient for many products to safeguard a stable shelf life and satisfactory quality, which led to a legal limit of 60 mg/kg for specific meat categories. Although this is considered to work and many producers do not use the current EU maximum amounts of nitrites, the panel suggested that there could be problems if this limit was imposed across product categories uncritically. The panel concluded that a reduction from 150 mg/kg to 60 mg/kg would not be favourable if microbiological safety is not demonstrated, and problems could be encountered for some products in terms of colour formation, colour stability and possibly flavour.

According to the panel, abolishing nitrites would be feasible if the production processes underwent technological changes. This would primarily affect traditional products, for which production processes would need to change so that the product would not remain the same. Cooked and possibly sliced products would also undergo significant changes. Moreover, the microbiological safety of the products could be affected if additional measures (such as increasing salt content or cooking temperature) are not taken. The taste, and possibly the colour of the products would likely also be affected.

An additional question considered by the panel related to the need for regulating the concentration of nitrites present in curing salt. Experts suggested that if a limit is provided in the legislation on the concentration of nitrite allowed, it could be set at 0.6% or 0.9% (for products with a reduced sodium content).

10.4. Possibility to review the current maximum levels of nitrites authorised in the legislation

Through three methodological tools – literature review, survey and expert workshop – this study has collected evidence concerning nitrosamine formation in meat products, the use and use levels of nitrites across the EU and the technological needs for nitrites in meat products and preparations. We present key results and finally conclude on the possibility to review the current maximum levels of nitrites as authorised in the legislation.

10.4.1. *Nitrosamine formation*

Although curing salt containing nitrite has been historically used for preservation purposes and for inducing the desired flavour and colour of cured meat, since the 1970s there has been concern about the formation of nitrosamines resulting from the use of nitrite in meat production.[35] While the link between **ingoing amounts of nitrite and nitrosamine formation** has not been established, previous studies have suggested the correlation is positive, though not necessarily linear.[36] On the other hand, results from the literature review and expert workshop conducted for this study suggest that there is **strong evidence of the link** between the consumption of processed meat, endogenous nitrosamine formation and an increased risk of colorectal cancer.

Three potential routes for nitrosamine formation in meat products have been documented: in the course of the production process (in situ), during the subsequent preparation of meat products at home, as well as in the gastro-intestinal tract (in vivo) following consumption. Although the extent to which nitrosamines are formed in the gastro-intestinal tract is difficult to detect, results of the survey and of the expert workshop suggest that in vivo nitrosamine formation and nitrosamines formed during the preparation of products at home are likely to be more relevant routes than nitrosamines formed in the production process. Moreover, several factors that increase the risk of nitrosamine formation were identified in the expert workshop and literature review: these include **the intense heating of meat products** (e.g. through frying, baking or barbecuing)[37] and the **presence of black pepper**.[38]

As a result, the study has identified several measures that can be taken to **reduce the risk of nitrosamine formation** in meat products and preparations:

[35] European Food Safety Authority (EFSA), "Opinion of the Scientific Panel on Biological Hazards on the Effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products," The EFSA Journal, Vol. 14, 2003, p.12.
[36] Herrmann, S.S., L. Duedahl-Olesen, and K. Granby, "Occurrence of Volatile and Non-Volatile N-Nitrosamines in Processed Meat Products and the Role of Heat Treatment", Food Control, Vol. 48, February 2015, pp. 163–169. http://linkinghub.elsevier.com/retrieve/pii/S0956713514002850.
[37] See e.g. Honikel, Karl-Otto, "The Use and Control of Nitrate and Nitrite for the Processing of Meat Products", *Meat Science*, Vol. 78, No. 1–2, 2008, pp. 68–76. http://www.sciencedirect.com/science/article/pii/S0309174007001994.
[38] See e.g. Herrmann, Susan Strange, "N-Nitrosamines in Processed Meat Products: Analysis, Occurrence, Formation, Mitigation and Exposure", Technical University of Denmark, 2014 and De Mey, Eveline, Hannelore De Maere, Hubert Paelinck, and Ilse Fraeye, "Volatile N-Nitrosamines in Meat Products: Potential Precursors, Influence of Processing and Mitigation Strategies", Critical Reviews in Food Science and Nutrition.

- A **reduction in the use of nitrites** has been suggested in the literature as a way of decreasing exposure to nitrosamines.[39]

- Additional measures that can be taken by **producers** discussed in the literature and expert workshop include avoiding the mentioned risk factors (heat treatment and the use of pepper), following good production practices and adding compounds that can scavenge the reactive nitrogen species, such as ascorbate.

- **Consumers** can also contribute to decreasing their exposure to nitrosamines by avoiding intensive heat treatment of cured products (such as frying of bacon) and by cleaning pans and barbecue grills after cooking meat, according to the expert panel.

10.4.2. *Levels of nitrites currently used in the EU*

Results of our survey of meat business operators, their organisations and other stakeholders show that for many categories of meat products and preparations, the **typical levels used by producers vary widely**: for the same product category, e.g. non-heat treated processed meat derived from minced red meat, reported typical use levels ranged between 15.6 mg/kg and 180 mg/kg of added nitrite, the latter value being significantly above the limit of 150 mg/kg provided in the legislation. According to the experts in the workshop panel, two key reasons can serve to explain this wide variation in reported use levels for non-traditional products and preparations. On one hand, producers may use excessive amounts of nitrite due to a lack of awareness of the legal limits. On the other hand, the results point to the unwillingness of some producers to use lower amounts than provided in traditional recipes or in the legislation. By contrast, country differences are not considered to be relevant in explaining the diverging levels of nitrites used.

The conclusions arising from these findings are threefold: Firstly, there is a need for **raising awareness of producers** concerning the maximum amounts of nitrites authorised in the EU, which should be coupled with a **better enforcement** of the legislation. This double objective could be achieved by providing both producers and inspectors with guidance and tools to allow them to calculate and monitor the use levels of nitrites. Moreover, producers could be required to report the levels used in their production processes and to provide recipes and other documentation, such as amounts and concentrations of curing salt purchased/used in a specified production period, to ensure better enforcement. A **simpler categorisation** of products, based on technological processes, could also contribute to a better alignment of practices with the legal provisions.

Secondly, it can be concluded that at least to some extent, producers may use the legislation as a benchmark for the amount of nitrites they add to their meat products and preparations. This conclusion is supported by the results of the EC's 2013 desk study, which found that for otherwise identical products, companies adapted their use levels depending on whether the product was intended to be delivered to the Danish market for example, or to other EU countries. Thus, in an effort to remain "on the safe side", producers may be hesitant to deviate from the legal limits or from traditional recipes that do not take into account improvements in hygiene practices.

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[39] De Mey, Eveline, Hannelore De Maere, Hubert Paelinck, and Ilse Fraeye, "Volatile N-Nitrosamines in Meat Products: Potential Precursors, Influence of Processing and Mitigation Strategies", Critical Reviews in Food Science and Nutrition.

Finally, evidence from producers typically using nitrite levels at the lower end of the distribution suggests that there is **scope for reducing the amount of nitrites used**. This conclusion is based on the practical experience of producers as observed through survey results, but it is also confirmed to a certain extent by examining the findings concerning the effect of nitrite on meat colour, taste and preservation.

Results from the study relating to the technological need for nitrites confirm that nitrites have an important role in current production processes for achieving the typical cured colour and flavour and for ensuring microbiological safety. For **colouring** purposes, results of the expert panel suggest that levels between 55 to 70 mg/kg of nitrites added is sufficient for colour formation in non-traditional meat products and preparations, with 80 mg/kg of added nitrite a meaningful point of reference for ensuring colour stability. For traditional products, 20 to 30 mg/kg of residual nitrite is according to the panel an appropriate range to ensure colour stability in most traditional meat products (with 40 to 50 mg/kg suggested for some traditional products). Similarly, a range between 50 to 80 mg/kg of added nitrite provides meaningful guidance for safeguarding **taste-related** aspects in non-traditional products and preparations. For traditional products, values between 30 to 50 mg/kg of residual nitrite are considered by the panel to suffice for flavouring purposes.

10.4.3. *Required minimum levels of nitrites to ensure microbiological safety*

Concerning the minimum level of nitrite required to ensure microbiological safety, most members of the expert panel that had an opinion regarding this aspect agreed that the range of 80 to 100 mg/kg of nitrite added would be reasonably safe for a majority of products when used in combination with other hurdles. However, the panel also emphasised that it is **not possible to reach a firm conclusion for all products and all situations**, acknowledging that microbiological safety is dependent upon a large number of factors. The panel concluded that a reduction of maximum levels to 100 mg/kg of added nitrite would be sufficient for a majority of products without significant effects on colour, flavour and microbiological safety (which would have to be demonstrated, e.g. by reference to countries in which such limits are or were in place, or other evidence). For some products, a higher concentration of nitrite would be required, e.g. for fermented products. It is notable that several countries in the past have applied even stricter maximum levels, and nitrite-free processed meat products are on the market in various countries. Abolishing the use of nitrites in meat products and preparations – while not supported by the panel – would be technically feasible if the production processes underwent technological changes. The panel found that without the presence of nitrites, microbiological safety can be ensured if a correct combination of key parameters such as water activity, pH, storage temperature, and shelf life are achieved. The panel also underlined the importance of packaging for ensuring the microbiological safety of meat products. Abolishing nitrites would primarily affect traditional products, for which production processes would need to change so that the product would not remain the same.

10.4.4. *Conclusions*

Taken together, these results of the study indicate that **there is a possibility to review the current maximum levels of nitrites authorised in the legislation**. This conclusion is consistent with the mentioned lower levels authorised in Denmark, as well as the previous experience in countries such as **Finland or Germany,** where stricter maximum levels were applied in the past. If a review of maximum levels were to take place in the EU, the results of the study suggest that it would be beneficial to base new maximum levels on a simpler categorisation of meat products and preparations, preferably related to the technological processes used. Moreover, a revised limit could be introduced that would apply for most products, with a process put in place for industry to identify products for which a higher limit needs to apply due to safety considerations. Assuming that a review of the maximum levels would aim to reduce exposure to nitrite, a key suggestion related to the need for regulating nitrite (NO_3) and nitrate (NO_2) together in order to avoid producers reducing nitrite levels while simultaneously increasing nitrate levels to compensate the reduction.

Besides the conclusions outlined above, a number of areas were identified for which there is a need for further research. For instance, only limited literature was available concerning the effect of reduced nitrite on flavour, colour and consumer acceptability.[40] In particular, sensory analyses could serve to clarify the extent to which consumers can distinguish between products containing varying levels of nitrite. Further research concerning the amounts of nitrite needed and/or alternative measures to prevent the growth of *Clostridium botulinum* and other bacteria under different conditions could also contribute to ensuring a better understanding of the main technological needs, especially regarding microbiological safety. Finally, additional research could help to better understand the relationship between the ingoing amounts of nitrite and nitrosamine formation, and to continue the ongoing efforts to identify alternatives to nitrites which may serve to further reduce the current levels used.

[40] This point is also made in Doolaege, Evelyne H. A., Els Vossen, Katleen Raes, Bruno De Meulenaer, Roland Verhé, Hubert Paelinck, and Stefaan De Smet, "Effect of Rosemary Extract Dose on Lipid Oxidation, Colour Stability and Antioxidant Concentrations, in Reduced Nitrite Liver Pâtés", Meat Science, Vol. 90, No. 4, 2012, pp. 925–31. http://www.sciencedirect.com/science/article/pii/S0309174011003901.

11. ANNEXES

Annex 1: List of literature reviewed

Adler-Nissen, Jens, Maria Helbo Ekgreen, and Jorgen Risum, *Practical Use of Nitrite and Basis for Dosage in the Manufacture of Meat Products*, 2014.

Archer, Douglas L, "Evidence That Ingested Nitrate and Nitrite Are Beneficial to Health", *Journal of Food Protection*, Vol. 65, No. 5, 2002, pp. 872–875.

Barbuti, Silvana, Maria Silvia Grisenti, Maria Angela Frustoli, and Giovanni Parolari, *Validation of the Manufacturing Process of Italian Dry-Cured Ham (Prosciutto) for the Inactivation of Listerai Monocytogenes and Salmonella Spp.*, 2009.

"Bekanntmachung Der Neufassung Der Fleisch-Verordnung Vom 21. Januar 1982", 1982.

Binkerd, E. F., and O. E. Kolari, "The History and Use of Nitrate and Nitrite in the Curing of Meat", *Food and Cosmetics Toxicology*, Vol. 13, 1975, pp. 655–661.

British Meat Processors Association, *Traditional Wiltshire Cure Bacon Production*, n.d.

Bulambaeva, A.A, D.B Vlahova-Vangelova, S.C Dragoev, D.K Balev, and Y.M Uzakov, "Development of New Functional Cooked Sausages by Addition of Goji Berry and Pumpkin Powder", *American Journal of Food Technology*, Vol. 9, No. 4, 2014, pp. 180–189.

Callaghan, Kathryn, "Food Standards Agency Guidance on the Safety and Shelf-Life of Vacuum and Modified Atmosphere Packed Chilled Foods with Respect to Non-Proteolytic Clostridium Botulinum July 2008", No. July, 2008.

"Capture #797 Baisser Les Niveaux de Nitrite Dans Les Produits Hachés Cuits sans Altérer La Couleur I IFIP Institut Du Porc Recherche et Expertise Pour La Filière Porcine - 04-08-2015.pdf", n.d.

Corpet, Denis E, "Red Meat and Colon Cancer: Should We Become Vegetarians, or Can We Make Meat Safer?", *Meat Science*, Vol. 89, No. 3, November 2011, pp. 310–6. http://www.ncbi.nlm.nih.gov/pubmed/21558046.

Danish Chamber of Commerce, "Denmark's National Provisions on Addition of Nitrites to Certain Meat Products", 2010. http://www.danskerhverv.dk/Nyheder/Documents/Nitrite decision 2010.pdf.

Deutsche Forschungsgemeinschaft, *Nitrate and Nitrite in the Diet: An Approach to Assess Benefit and Risk for Human Health*, Bonn, 2014.

Domańska, Katarzyna, and Bogdan Kowalski, "Effect of Different Storage Conditions on N-Nitrosamine Content in Polish Edible Offals Processed Meat Products", *Bull. Vet. Inst. Pulawy*, Vol. 46, No. 26, 2002, pp. 317–324.

Doolaege, Evelyne H. A., Els Vossen, Katleen Raes, Bruno De Meulenaer, Roland Verhé, Hubert Paelinck, and Stefaan De Smet, "Effect of Rosemary Extract Dose on Lipid Oxidation, Colour Stability and Antioxidant Concentrations, in Reduced Nitrite Liver Pâtés", *Meat Science*, Vol. 90, No. 4, 2012, pp. 925–31. http://www.sciencedirect.com/science/article/pii/S0309174011003901.

Drabik-Markiewicz, Gabriela, *Chromatographic Study on the Factors Influencing Generation of Selected N-Nitrosamines in the Course of Heating Cured Meat*, 2010. http://chemia.us.edu.pl/chemia/attachments/article/1315/1315_Drabik-Markiewicz_ksiazeczka_zamkniecie.pdf.

European Commission, "Commission Decision 2008/448/EC", *Official Journal of the European Union*, 2008, pp. 98–107.

European Commission, "Commission Regulation (EU) 257/2010 Setting up a Programme for the Re-Evaluation of Approved Food Additives in Accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on Food Additivies", *Official Journal of the European Union*, No. 257, 2010, pp. 19–27.

European Commission, "Commission Regulation 1129/2011 Amending Annex II to Regulation 1333/2008 of the European Parliament and of the Council by Establishing a Union List of Food Additives", *Official Journal of the European Union*, 2011.

European Commission, "Commission Regulation 601/2014 Amending Annex II to Regulation 1333/2008 of the European Parliament and of the Council as Regards the Food Categories of Meat and Use of Certain Food Additives in Meat Preparations", *Official Journal of the European Union*, No. 853, 2014.

European Commission, *Guidance Document Describing the Food Categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives*, 2013. http://ec.europa.eu/food/food/fAEF/additives/docs/guidance_1333-2008_descriptors_annex2_20131218_en.pdf.

European Commission, *Questionnaire for Desk Study to Monitor the Implementation of Directive 2006/52/EC*, 2011.

European Commission, *Re-Evaluation of Food Additives: Tentative Work Programme 2014-2015*, 2014.

European Commission, *Reports of the Scientific Committee for Food*, 1997.

European Commission (DG SANCO), "Authorisation of Additives", 2011. https://webgate.ec.europa.eu/sanco_foods/main/?sector=FAD&auth=SANCAS&event=substance.view&identifier=77.

European Commission (DG SANCO), "Summary Record of the SCOFCAH: 08/02/2010", 2010.

European Commission (DG SANCO), "Summary Record of the SCOFCAH: 14/12/2006", 2006.

European Commission (DG SANCO), "Summary Record of the SCOFCAH: 19/05/2010", 2011.

European Commission Health and Consumers Directorate-General, *Final Report on a Desk Study to Monitor the Implementation of Directive 2006/52/EC in the EU Member States as Regards the Use of Nitrites by the Industry in the Different Categories of Meat Products and the Organisation of National Controls*, 2013.

European Food Safety Authority, *Mandate of the Four Standing Working Groups of the ANS Panel on the Re-Evaluation of Approved Food Additives*, Parma, 2014.

European Food Safety Authority (EFSA), "Food Additives", 2014. http://www.efsa.europe.eu/en/topics/topic/additives.htm.

European Food Safety Authority (EFSA), "Opinion of the Scientific Panel on Biological Hazards on the Effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products", *The EFSA Journal*, Vol. 14, 2003, pp. 1–31.

European Food Safety Authority (EFSA), *Opinion of the Scientific Panel on Biological Hazards on the Request from the Commission Related to the Effects of Nitrites / Nitrates on the Microbiological Safety of Meat Products*, 2003.

European Food Safety Authority (EFSA), "Scientific Opinion: Statement on Nitrites in Meat Products", Vol. 8, No. 5, 2010, pp. 1–12.

European Parliament and Council of the European Union, "Directive 2006/52/EC of the European Parliament and of the Council", *Official Journal of the European Union*, 2006, pp. 10–22.

European Parliament and Council of the European Union, "Directive 95/2/EC of the European Parliament and Council of the European Union", No. 95, 1998.

Food and Agriculture Organization (FAO), and World Health Organization (WHO), *FAO Roster of Experts for the Joint FAO / WHO Expert Committee on Food Additives (JECFA)*, 2012.

Food Safety Authority of Ireland, "Guidance Document for Nitrate / Nitrite Sampling of Meat Products", *Chemical Factsheet Series*, 2010, pp. 1–11.

Food Standards Agency, *Food Additives Legislation Guidance to Compliance*, 2013. www.multimedia.food.gov.uk.

Glass, Kathleen, Christopher Sawyer, and James Claus, *Minimum Nitrite Levels Required to Control Listeria Monocytogenes on Ready-to-Eat Poultry Products Manufactured with Lactate and Diacetate*, 2008.

Graham, Ann F., David R. Mason, and Michael W. Peck, "Predictive Model of the Effect of Temperature, pH and Sodium Chloride on Growth from Spores of Non-Proteolytic Clostridium Botulinum", *International Journal of Food Microbiology*, Vol. 31, No. 1–3, 1996, pp. 69–85.

Hebels, Dennie G a J, Danyel G J Jennen, Marcel H M van Herwijnen, Edwin J C Moonen, Marie Pedersen, Lisbeth E Knudsen, Jos C S Kleinjans, and Theo M C M de Kok, "Whole-Genome Gene Expression Modifications Associated with Nitrosamine Exposure and Micronucleus Frequency in Human Blood Cells", *Mutagenesis Advance Access*, Vol. 26, No. 6, November 2011, pp. 753–61. http://www.ncbi.nlm.nih.gov/pubmed/21724973.

Heinz, Gunter, and Peter Hautzinger, "Canning/Sterilization of Meat Products", n.d., pp. 277–306.

Heraud, Fanny, Jean-luc Volatier, and Jean-charles Leblanc, "Assessment of Dietary Exposure of Nitrate and Nitrite in France", *Food Additives and Contaminants*, Vol. 25, No. 08, 2009, pp. 971–988.

Herrmann, S.S., L. Duedahl-Olesen, and K. Granby, "Occurrence of Volatile and Non-Volatile N-Nitrosamines in Processed Meat Products and the Role of Heat

Treatment", *Food Control*, Vol. 48, February 2015, pp. 163–169. http://linkinghub.elsevier.com/retrieve/pii/S0956713514002850.

Herrmann, Susan Strange, "N-Nitrosamines in Processed Meat Products: Analysis, Occurrence, Formation, Mitigation and Exposure", Technical University of Denmark, 2014.

Honikel, Karl-Otto, "The Use and Control of Nitrate and Nitrite for the Processing of Meat Products", *Meat Science*, Vol. 78, No. 1–2, 2008, pp. 68–76. http://www.sciencedirect.com/science/article/pii/S0309174007001994.

Hsu, James, Jayashree Arcot, and N. Alice Lee, "Nitrate and Nitrite Quantification from Cured Meat and Vegetables and Their Estimated Dietary Intake in Australians", *Food Chemistry*, Vol. 115, No. 1, July 2009, pp. 334–339. http://linkinghub.elsevier.com/retrieve/pii/S0308814608014209.

Hustad, G. O., J. G. Cerveny, H. Trenk, R. H. Deibel, D. A Kautter, T. Fazio, R. W. Johnston, and O. E. Kolari, "Effect of Sodium Nitrite and Sodium Nitrate on Botulinal Toxin Production and Nitrosamine Formation in Wieners", *Applied Microbiology*, Vol. 26, No. 1, 1973, pp. 22–26. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=379710&tool=pmcentrez&rendertype=abstract.

IFIP - Institut du Porc, *Vers Une Recommendation de Reduction Du Taux de Nitrites Dans Les Differentes Familles de Charcuterie*, 2010.

"Impact Des Nitrites et de Traitement Thermique Sur La Couleur Des Produits Hachés Cuits", 2013, p. 2013.

Kilcast, D, and F Angus, *Reducing Salt in Foods: Practical Strategies*, Elsevier, 2007.

Kok, Theo M C M De, Simone G J Van Breda, and Jacob J Briedé, "Genomics-Based Identification of Molecular Mechanisms behind the Cancer Preventive Action of Phytochemicals : Potential and Challenges", *Current Pharmaceutical Biotechnology*, Vol. 13, 2012, pp. 255–264.

Larsson, Susanna C., Leif Bergkvist, and Alicja Wolk, "Processed Meat Consumption, Dietary Nitrosamines and Stomach Cancer Risk in a Cohort of Swedish Women", *International Journal of Cancer*, Vol. 119, No. 4, 2006, pp. 915–919.

Leistner, L., "Shelf-Stable Edible Meat", n.d.

Leth, Torben, Sisse Fagt, and Steffen Nielsen, "Nitrite and Nitrate Content in Meat Products and Estimated Intake in Denmark from 1998 to 2006", *Food Additives and Contaminants*, Vol. 25, No. 10, 2011.

"Literature Search Botulinum and Nitrite", n.d.

Liu, Chen-Yu, Yi-Hsiang Hsu, Ming-Tsang Wu, Pi-Chen Pan, Chi-Kung Ho, Li Su, Xin Xu, Yi Li, and David C Christiani, "Cured Meat, Vegetables, and Bean-Curd Foods in Relation to Childhood Acute Leukemia Risk: A Population Based Case-Control Study.", *BMC Cancer*, Vol. 9, No. 15, January 2009. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2653540&tool=pmcentrez&rendertype=abstract.

Lund, Barbara M., and Michael W. Peck, "Clostridium Botulinum", in Ronald G. Labbe and Santos Garcia (eds.), *Guide to Foodborne Pathogens*, 2nd ed., John Wiley & Sons, Ltd., 2013, pp. 329–349.

Mckeith, Amanda Gipe, Bowling Green, Jeff Sindlear, and Sindlear Solutions, "Alternative Curing", *Factsheet Pork Information Gateway*, No. June, 2014, pp. 1–6.

De Mey, Eveline, "N-Nitrosamines in Dry Fermented Sausages: Occurrence and Formation of N-Nitrosopiperidine", Katholieke Universiteit Leuven, 2014.

De Mey, Eveline, Hannelore De Maere, Hubert Paelinck, and Ilse Fraeye, "Volatile N-Nitrosamines in Meat Products: Potential Precursors, Influence of Processing and Mitigation Strategies", *Critical Reviews in Food Science and Nutrition*, n.d.

Mulvey, Liz, Linda Everis, David Leeks, Holly Hughes, and Ann Wood, *Alternatives to Nitrates and Nitrites in Organic Meat Products*, 2010.

Ochoa, O. A., J.A. Gallego-Restrepo, and J. A. Perez-Alvarez, "Use of Celery Extract and Starter Culture (Staphylococcus Carnosus) as an Alternative Sources of Sodium Nitrite in Cooked Ham : Influence upon Colour", *Journal of Meat Science and Technology*, 2013, pp. 12–20.

Parolari, G., "Review: Achievements, Needs and Perspectives in Dry-Cured Ham Technology: The Example of Parma Ham", *Food Science and Technology International*, Vol. 2, 1996, pp. 69–78.

Peck, M.W., "Clostridium Botulinum", *Encyclopedia of Food Safety*, Vol. 1, Elsevier Ltd., Waltham, MA, 2014, pp. 381–394. http://linkinghub.elsevier.com/retrieve/pii/B9780123786128000913.

PHYTOME Project, "Phytome Project Newsletter", *PHYTOME PROJECT: : Phytochemicals to Reduce Nitrite in Meat Products*, 2014.

Santarelli, Raphaëlle L, Fabrice Pierre, and Denis E Corpet, "Processed Meat and Colorectal Cancer: A Review of Epidemiologic and Experimental Evidence", *Nutrition and Cancer*, Vol. 60, No. 2, 2008, pp. 131–144.

Sebranek, Joseph, and James Bacus, "Natural and Organic Cured Meat Products: Regulatory, Manufacturing, Marketing, Quality and Safety Issues", *American Meat Science Association White Paper Series*, No. 1, 2007.

Sebranek, Joseph G., and James N. Bacus, "Cured Meat Products without Direct Addition of Nitrate or Nitrite: What Are the Issues?", *Meat Science*, Vol. 77, No. 1 SPEC. ISS., 2007, pp. 136–147.

Sindelar, Jeffrey J, and Andrew L Milkowski, "Human Safety Controversies Surrounding Nitrate and Nitrite in the Diet", *Nitric Oxide*, Vol. 26, No. 4, May 15, 2012, pp. 259–66. http://www.ncbi.nlm.nih.gov/pubmed/22487433.

Sindelar, Jeffrey J, and Andrew L Milkowski, "Sodium Nitrite in Processed Meat and Poultry Meats: A Review of Curing and Examining the Risk/Benefit of Its Use", *American Meat Science Association White Paper Series*, Vol. 3, 2011.

Stegeman, D, J Hulstein, J Verkleij, and K Stekelenburg, *Reducing the Amount of Nitrites in the Production of Pasteurized Organic Meat Products - Experiments on an Industrial Scale*, 2007.

Stegeman, D, and T J Verkleij, *Reduction of Nitrite in the Production of Organic Meat Products: A Literature Survey - Part 2/update*, 2010.

Stegeman, D., T. J. Verkleij, and F. K. Stekelenburg, *Reductie van Nitrietgebruik Bij Biologische Vleeswarenbereiding*, 2005.

Sullivan, Gary Anthony, *Naturally Cured Meats: Quality, Safety, and Chemistry*, 2011.

TNO Kwaliteit van Leven, *Onderzoek Nitriet- En Nitraatgehalte in Nederlandse Vleeswaren*, 2008. https://www.tno.nl/media/1994/bewegen_nederland_2000_2012_tno_gl_l_13_08_1581n.pdf.

Toldra, Fidel, M-Concepcion Aristoy, and Monica Flores, "Relevance of Nitrate and Nitrite in Dry-Cured Ham and Their Effects on Aroma Development", *Grasas Y Aceites*, Vol. 60, No. 3, 2009, pp. 291–296.

U.S Department of Health and Human Services, *Report on Carcinogens*, 2013.

Verkleij, T.J., F.K. Stekelenburg, and D. Stegeman, *Effects of Reduced Nitrite Content on the Development of Listeria Monocytogenes in Pasteurized Meat Products*, *Food Structures and Applications*, n.d.

Verkleij, T.J., F.K. Stekelenburg, and D. Stegeman, "Effects of Reducing the Amount of Nitrite in Organic Meat Products", *Food and Biotechnology Innovations*, 2006.

Vossen, Els, Evelyne H. A. Doolaege, Haile Demewez Moges, Bruno De Meulenaer, Slawomir Szczepaniak, Katleen Raes, and Stefaan De Smet, "Effect of Sodium Ascorbate Dose on the Shelf Life Stability of Reduced Nitrite Liver Pâtés", *Meat Science*, Vol. 91, No. 1, 2012, pp. 29–35. http://www.sciencedirect.com/science/article/pii/S0309174011003998.

Vossen, Els, and Stefaan De Smet, "Protein Oxidation and Protein Nitration Influenced by Sodium Nitrite in Two Different Meat Model Systems", *Journal of Agricultural and Food Chemistry*, Vol. 63, No. 9, 2015, pp. 2550–2556. http://pubs.acs.org/doi/abs/10.1021/jf505775u.

Van Wezemael, Lynn, Wim Verbeke, Marcia D de Barcellos, Joachim Scholderer, and Federico Perez-Cueto, "Consumer Perceptions of Beef Healthiness: Results from a Qualitative Study in Four European Countries", *BMC Public Health*, Vol. 10, No. 342, January 2010. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2893462&tool=pmcentrez&rendertype=abstract.

Wójciak, K M, Z J Dolatowski, and A Okoń, "The Effect of Water Plant Extracts Addition on the Oxidative Stability of Meat Products", *Acta Scientiarum Polonorum : Technologia Alimentaria*, Vol. 10, No. 2, 2011, pp. 175–188.

World Health Organization (WHO), "Evaluation of Nitrite, Potassium and Sodium Salts", 1974. http://www.inchem.org/documents/jecfa/jecmono/v05je15.htm.

World Health Organization International Agency for Research on Cancer, "Carcinogenicity of Consumption of Red and Processed Meat", *Lancet Oncology*, Vol. 2045, No. 15, 2015, pp. 1–2.

World Health Organization International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Vol. 94, Vol. 94, Lyon, 2010.

Zsarnoczay, Gabriella, *Effect of Different Nitrite-Concentrations in Meat Products*, 2011.

Annex 2: Survey questionnaire

CIVIC
CONSULTING

STUDY ON THE USE OF NITRITES BY INDUSTRY IN DIFFERENT CATEGORIES OF MEAT PRODUCTS

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SURVEY OF MEAT BUSINESS OPERATORS, THEIR ORGANISATIONS AND OTHER STAKEHOLDERS

The Directorate General for Health and Food Safety (DG SANTE) of the European Commission has commissioned Civic Consulting of the Food Chain Evaluation Consortium (FCEC) to conduct a study on the use of nitrites by industry in different categories of meat products.

The purpose of the study is to collect technological data about the need for nitrites and information on the use of nitrites in different types of meat products and preparations in the EU. The information and assessments provided in your responses to this questionnaire will be crucial in assessing the possibility of reviewing the current maximum levels of nitrites as established by relevant EU legislation. For this reason we highly appreciate your taking the time to respond to this survey.

This questionnaire is targeted at key stakeholders involved in the production of meat products and preparations – such as meat business operators and their organisations – and research institutes or experts focusing on meat technology, preservation techniques, or research linked to nitrites.

When completing this questionnaire, please consider the following clarifications:

- The meat products and preparations mentioned in this survey, their respective categories and applicable current limits for the use of nitrites are largely based on Annex II to Regulation (EC) No 1333/2008 on food additives and its relevant amendments (e.g. Commission Regulation 1129/2011 and Commission Regulation (EU) No 601/2014); [LINK TO LEGISLATION]
- Please base your answers on your (or your members') experiences in the production of meat products and preparations and the related use of nitrites, or on your research regarding the use of nitrites by meat processors in your country. International or EU-level stakeholders (such as EU organisations of relevant food business operators) should refer to the situation across the EU, and note any limitations in geographic coverage in the final comment field, if needed.

Please note that the results of this consultation will be presented in an aggregated form only (i.e. as total or by stakeholder group); your name and personal details will remain confidential and will not be communicated to any institution or person outside the FCEC. If any of your comments are quoted, this will only be done anonymously. The names of all contributing organisations to the survey will be listed in the final report. All survey respondents will receive an electronic version of the report after publication.

Please also note that in our invitation to the survey we have provided you with a PDF document with the questionnaire to give you an overview of all questions before answering them online. Question numbering may show gaps, as only those questions that are relevant for your stakeholder group are displayed. Please submit the completed questionnaire no later than 1 June 2015.

If you have any further questions, do not hesitate to contact:
Agathe Osinski
nitrites@civic-consulting.de
Phone: +49 30 2196 2287

THIS QUESTIONNAIRE WILL BE IMPLEMENTED ON AN ONLINE PLATFORM. THE TYPES OF QUESTIONS ARE INDICATED AS FOLLOWS:

TF=Text field DD=Dropdown menu CB=Check box

The following display logics apply for the questionnaire:
[ALL]: The question is displayed to all stakeholders
[PROD]: The question is displayed to producers of meat products and/or meat preparations and relevant food business associations.
[RES]: The question is displayed to research institutes and other independent bodies.
[Other]: The question is displayed to other stakeholders.

I. IDENTIFICATION DATA

1. Please identify yourself: *[ALL]*

a) Name of organisation (obligatory) [TF]
b) Type of organisation (obligatory) [CB: Organisation of food business operators/meat producers or processors; Meat producer or processor; Research institute/university, Other] If other, please specify [TF]
c) Country in which organisation is located [DD: List of 28 EU Member States, Other country] If other country, please specify [TF]
d) Contact person (name, position) [TF]
e) Email address (obligatory) [TF]
f) Phone number [TF]

II. USE OF NITRITES IN NON-TRADITIONAL PRODUCTS AND PREPARATIONS

2. For the following categories of meat products/preparations, please indicate the typical, minimum, and maximum amount of nitrites added in practice by your company/your member companies *[PROD]:*

2. *For the following categories of meat products/preparations, please indicate the typical, minimum, and maximum amount of nitrites added in practice by meat producers/processors in your country [RES]:*

Note: The numbers listed for the categories in the table refer to the categorisation provided in Annex II to Regulation (EC) No 1333/2008 on food additives.

Category	**Description/name**			**Amount added in practice (mg/kg)**			**Comments**
				Typical	**Minimum**	**Maximum**	
Meat preparations (8.2)	*Lomo de cerdo adobado, Pincho moruno, Careta de cerdo adobada, Castilla de cerdo adobada* (ES)			[DD: 10; 20; 30 … 200]	[DD: 10; 20; 30 … 200]	[DD: 10; 20; 30 … 200]	[TF]
	Kasseler, Bräte, Surfleisch (DE, AU, LUX)			*As above*	*As above*	*As above*	*As above*
	Toorvorst, Šašlõkk, Ahjupraad (EE)						
	Kiełbasa surowa biała, Kiełbasa surowa metka, Tatar wołowy (danie tatarskie) (PL)						
Non-heat treated processed meat (8.3.1)	Derived from whole pieces of meat, e.g. dried ham		Red meat				
			Poultry meat				
	Derived from minced meat[1] e.g. dried sausage, salami		Red meat				
			Poultry meat				
Heat treated processed meat (8.3.2)	Sterilised meat products	Derived from whole pieces of meat[2], e.g. canned whole pork	Red meat				
			Poultry meat				
		Derived from minced meat, e.g. canned ground beef	Red meat				
			Poultry meat				
	Non-sterilised meat products	Derived from whole pieces of meat e.g. cooked ham	Red meat				
			Poultry meat				
		Derived from minced meat e.g. emulsified sausages	Red meat				
			Poultry meat				
Other meat products for which nitrites are used	Derived from whole pieces of meat *e.g. Filet d'Ardenne,* Swedish Christmas Ham		Red meat				
			Poultry meat				
	Derived from minced meat, e.g. *Papillotes, Blinde vink*		Red meat				
			Poultry meat				

[1] Minced meat is defined as boned meat that has been minced into fragments.
[2] Whole pieces of meat are those which cannot be considered to be minced meat.

3. For the product categories listed in the previous table, do you have information about the <u>minimum amount of nitrites</u> that is required <u>in practice</u> to achieve protection against Clostridium botulinum or for colouring and flavouring purposes? [DD: Yes, No] *[RES + PROD]* [If Yes, go to question 4. If No, go to question 5.]

4. Please indicate the <u>minimum amount of nitrites added</u> that is required <u>in practice</u> to fulfil the following technological needs (in mg/kg of nitrite added): *[ALL]*

Category	**Sub-category**	**Minimum amount added required in practice for <u>protection against Clostridium botulinum</u> (mg/kg):**	**Minimum amount added required in practice for <u>colouring purposes</u> (mg/kg):**	**Minimum amount added required in practice for <u>flavouring purposes</u> (mg/kg):**	**Could the maximum added amount authorised be <u>reduced</u> without compromising microbiological safety?**	**If Yes, to which amount could it be reduced (mg/kg)?**	**Comments:**
Meat preparations (8.2)	Red meat	[DD: 10; 20; 30 … 200]	[DD: 10; 20; 30 … 200]	[DD: 10; 20; 30 … 200]	[DD: Yes, No, Don't Know]	[DD: 10; 20; 30 … 200]	[TF]
	Poultry meat	*As above*	*As above*	*As above*	*As above*	*As above*	*As above*
Non-heat treated processed meat (8.3.1)	Red meat						
	Poultry meat						
Heat treated processed meat – <u>sterilised</u> (8.3.2)	Red meat						
	Poultry meat						
Heat treated processed meat – <u>non-sterilised</u> (8.3.2)	Red meat						
	Poultry meat						
Other meat products for which nitrites are used	Red meat						
	Poultry meat						

5. For the categories listed in the previous table, does your company/do your member companies also measure the <u>residual amount of nitrites</u> in the final products/preparations? [DD: Yes, No, Don't Know] If Yes, which residual amount(s) do you/your members target? [TF] *[PROD]*.

III. USE OF NITRITES IN TRADITIONAL PRODUCTS

6. Does your company/do your member companies produce traditional meat products (listed as categories 8.3.4.1, 8.2.4.2 and 8.3.4.3 in the legislation)? [DD: Yes, No, Don't Know] *[PROD]* [If Yes, go to question 7. If No or Don't Know, go to question 13.]

7. For the following categories of traditional meat products, please indicate: *[PROD]:*

a) the typical, minimum and maximum <u>residual amount of nitrites</u> present in practice in the final products produced by your company/your member companies (for those traditional products for which a <u>maximum residual amount</u> is provided in legislation)

b) the typical, minimum, and maximum <u>amount of nitrites added</u> in practice by your company / your member companies (for traditional products for which a <u>maximum amount added</u> is provided in legislation)

7. For the following categories of traditional meat products, please indicate: [RES]:

a) the typical, minimum and maximum <u>residual amount of nitrites</u> present in practice in the final products produced by meat producers/processors in your country (for those traditional products for which a <u>maximum residual amount</u> is provided in legislation)

b) the typical, minimum, and maximum <u>amount of nitrites added</u> by meat producers/processors in practice in your country (for traditional products for which a <u>maximum amount added</u> is provided in legislation)

a) Traditional meat products for which a <u>maximum residual amount</u> is provided in legislation

Category	Sub-category	Maximum residual amount authorised (mg/kg)	Residual amount in practice (mg/kg)			Comments:
			Typical	Minimum	Maximum	
Traditional immersion cured products (8.3.4.1)	*Wiltshire ham* and similar products	100	[DD: 10; 20; 30 … 200]	[DD: 10; 20; 30 … 200]	[DD: 10; 20; 30 … 200]	[TF]
	Wiltshire bacon and similar products	175	*As above*	*As above*	*As above*	*As above*
	Entremeada, entrecosto, chispe, orelheira e cabeca (salgados), toucinho fumado and similar products	175				
	Cured tongue	50				
	Rohschinken, nassgepökelt and similar products	50				
Traditional dry cured products (8.3.4.2)	*Dry cured bacon* and similar products	175				
	Dry cured ham and similar products	100				
	Presunto, presunto da pa and *paio de lombo* and similar products	100				
	Rohschinken, trockengepökelt and similar products	50				
Other traditionally cured products (8.3.4.3)	*Rohschinken, trocken-/nasgepökelt* and similar products	50				
	Jellied veal and brisket	50				

b) Traditional meat products for which a <u>maximum amount added</u> is provided in legislation

Category	Sub-category	Maximum amount added authorised (mg/kg)	Amount added in practice (mg/kg)			Comments:
			Typical	Minimum	Maximum	
Traditional immersion cured products (8.3.4.1)	*Kylmâsavustettu poronliha/kallrökt renkött*	150	[DD: 10; 20; 30 … 200]	[DD: 10; 20; 30 … 200]	[DD: 10; 20; 30 … 200]	[TF]
	Bacon, filet de bacon and similar products	150	*As above*	*As above*	*As above*	*As above*
Other traditionally cured products (8.3.4.3)	*Vysocina, selsky salam, turisticky trvanlivy salam, polican, herkules, lovecky salam, dunjaska klobasa, paprikas* and similar products	180				

8. For the product categories listed in the previous table, do you have information about the minimum amount of nitrites that is required in practice to achieve protection against Clostridium botulinum or for colouring and flavouring purposes? [DD: Yes, No] [If Yes, go to question 9. If No, go to question 10.] *[RES + PROD]*

9. Please indicate the minimum residual amount of nitrites required in practice to fulfil the following technological needs regarding traditional meat products (in mg/kg) *[ALL]:*

Category	**Maximum residual amount authorised (mg/kg)**	**Minimum residual amount required in practice for protection against Clostridium botulinum (mg/kg):**	**Minimum residual amount required in practice for colouring purposes (mg/kg):**	**Minimum residual amount required in practice for flavouring purposes (mg/kg):**	**Could the maximum residual amount authorised be reduced without compromising microbiological safety?**	**If Yes, to which amount (mg/kg)?**	**Comments:**
Traditional immersion cured products (8.3.4.1)	50-175	[DD: 10; 20; 30 … 200]	[DD: 10; 20; 30 … 200]	[DD: 10; 20; 30 … 200]	[DD: Yes/No/Don't Know]	[DD: 10; 20; 30 … 200]	[TF]
Traditional dry cured products (8.3.4.2)	50-175	*As above*	*As above*	*As above*	*As above*	*As above*	*As above*
Other traditionally cured products (8.3.4.3)	50						

NOTE: Only products for which maximum is given as a residual amount are considered here.

IV. GENERAL QUESTIONS

10. In your view, to what extent do the current maximum amounts regarding the use of nitrites achieve an appropriate balance between ensuring a high level of protection against microbiological activity and preventing the formation of nitrosamines?: [Scale 0-5: Not at all – Very much] *[RES]*

11. In your view, should legislation provide maximum amounts of nitrites as amount added or as a residual amount? [DD: Should all be provided as amount added, should all be provided as residual amount, this depends on the product, Don't know]. Please explain [TF]. *[RES]*

12. According to your knowledge, how relevant for human exposure to nitrosamines caused by cured meat products and preparations do you consider: *[RES]*

a) Nitrosamines formed during the production process (i.e. during meat processing by an operator)? [Scale: 0 (Not at all relevant) – 5 (very relevant)] Comments: [TF]
b) Nitrosamines formed during the preparation at home (e.g. when cured meat products or preparations are cooked or barbecued)? [Scale: 0 (Not at all relevant) – 5 (very relevant)] Comments: [TF]
c) Nitrosamines formed in the digestive system resulting from the consumption of cured meat products or preparations? [Scale: 0 (Not at all relevant) – 5 (very relevant)] Comments: [TF]

13. What is the amount of nitrites present in the nitrite salt used by your company/members for the curing of meat products/preparations? [DD: 0.6%; 0.7%; 0.8%; 0.9%; Other]. If Other, please specify: [TF]. *[PROD]*

14. In recent years, has your company/have your member companies increased, maintained, or decreased the amounts of nitrites used in meat products/preparations [DD: Increased, Maintained, Decreased, Don't Know] Please explain: [TF] *[PROD]*

***14.** In recent years, have meat producers/processors in your country increased, maintained, or decreased the amounts of nitrites used in meat products/preparations? [DD: Increased, Maintained, Decreased, Don't Know] Please explain: [TF] [RES+ OTHER]*

15. Does your company/do your member companies produce organic meat products/preparations? [DD: Yes, No, Don't Know]. If Yes, do you take additional measures to ensure that the products are safe in relation to the possible presence of Clostridium botulinum? [DD: Yes, No, Don't Know]. If Yes, please specify. [TF] *[PROD]*

[Note: Commission Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, sets a maximum indicative ingoing amount of nitrites (expressed as $NaNO_2$) at 80 mg/kg].

16. Does your company/do your member companies produce nitrite-free meat products/preparations? This question refers to products/preparations which are typically produced using nitrites. [DD: Yes, No, Don't Know]. If Yes, which products are you referring to, and how do you ensure a high level of protection against microbiological activity? [TF] *[PROD]*

17. Are you aware of any alternatives to nitrites that are currently in testing, development or use, that could replace nitrites in the production processes of meat products/preparations while fulfilling the same technological needs (microbiological safety, colouring, flavouring)? [DD: Yes, No, Don't Know]. If Yes, please specify. [TF] *[ALL]*

18. If the use of nitrites in meat products and preparations were no longer possible, how would this change production methods and/or types of meat products/preparations produced? [Multiple answers possible - CB: Amount of salt in products would be increased, alternatives to nitrites would be used, shelflife of products would be shortened, cooling temperature would need to be reduced, certain categories of meat products/preparations would no longer be produced, Other changes [TF], Don't Know] *[ALL]*

19. Are you aware of any data sources or scientific studies regarding the use levels of nitrites in meat products/preparations, the technological needs for nitrites, the formation of nitrosamines in the production process, or alternatives to nitrites? [DD: Yes, No, Don't Know]. If Yes, please provide the link or bibliographic data: [TF]. Do you agree to be contacted to provide us with more information on the data sources and analyses you have mentioned? [CB: Yes, No] *[ALL]*

20. Do you have any other comments? [TF] *[ALL]*

Annex 3: Tables showing survey results on the use levels of nitrites in meat products and preparations

Table 6: Reported use levels of nitrites for sub-category: Meat preparations (8.2) > Lomo de cerdo adobado, Pincho moruno, Careta de cerdo adobada, Castilla de cerdo adobada

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Spain	Company	100	140	150	
	Company	150	150	150	
	Association	150	150	150	The [typical, maximum and minimum] amount of nitrites added are authorized by European legislation. If the scientific literature indicates that 150ppm provides microbiological safety, it is risky to propose lower amount
	Company	150	150	150	Food safety levels against Cl. Botulinum
	Company	150	150	150	
	Expert	50	100	150	
	Expert	100	100	150	Due to its characteristics, we understand that these products are cured. In Spain there are similar products (fresh and non-cured meat products) but nitrite is not incorporated in its formulation. (…)
Overall minimum amount (mg/kg)		**50**			
Median typical amount (mg/kg)			**150**		
Overall maximum amount (mg/kg)				**150**	

Table 7: Reported use levels of nitrites for sub-category: Meat preparations (8.2) > Kasseler, Bräte, Surfleisch

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Austria	Company	100	120	120	
France	Company	:	120	:	
Germany	Company	10	20	30	
	Company	120	:	:	[M]ax. 150
	Company	100	120	150	
	Expert	60	100	150	
Luxembourg	Association	70	80	100	Green weight
	Company	60	60	70	Green weight
Spain	Expert	100	100	150	Due to its characteristics, we understand that these products are cured. In Spain there are similar products (fresh and non-cured meat products) but nitrite is not incorporated in its formulation. If in Spain are elaborated, 100 mg / kg as maximum level must be used (…)
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**100**		
Overall maximum amount (mg/kg)				**150**	

Current maximum authorised: 150 mg/kg (amount added)

Table 8: Reported use levels of nitrites for sub-category: Meat preparations (8.2) > Toorvorst, Šašlõkk, Ahjupraad

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Spain	Expert	100	100	150	Due to its characteristics, we understand that these products are cured. In Spain there are similar products (fresh and non-cured meat products) but nitrite is not incorporated in its formulation. (…)
Overall minimum amount (mg/kg)		**100**			
Median typical amount (mg/kg)			**100**		
Overall maximum amount (mg/kg)				**150**	

Current maximum authorised: 150 mg/kg (amount added)

Table 9: Reported use levels of nitrites for sub-category: Meat preparations (8.2) > Kiełbasa surowa biała, Kiełbasa surowa metka, Tatar wołowy (danie tatarskie)

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Poland	Company	90	100	120	
Spain	Expert	100	100	150	Due to its characteristics, we understand that these products are cured. In Spain there are similar products (fresh and non-cured meat products) but nitrite is not incorporated in its formulation. (…)
Overall minimum amount (mg/kg)		**90**			
Median typical amount (mg/kg)			**100**		
Overall maximum amount (mg/kg)				**150**	

Table 10: Reported use levels of nitrites for sub-category: Non heat treated processed meat (8.3.1) > Derived from whole pieces of meat > Red meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Belgium	Company	120	80	150	[O]n fresh meat, before drying - As regard to the amounts given, nitrate is NOT considered.
	Expert	:	120	150	:
Croatia	Company	:	:	80	[D]ried pork neck
	Company	:	:	180	[P]anceta
Czech Republic	Association	120	150	150	Residual amount is [close] to zero.
Denmark	Expert	:	150	150	Making local variants of specific dried ham types, e.g. Parma or Iberian, only uses NaCl as additive. DK regulation allows both nitrite and nitrate to be used in "spegeskinke", up to 150 ppm as a mixture of the two additives.
Finland	Company	70	:	80	60mg for colour and 80 mg [for] bacteria risk
France	Association	:	120	150	:
	Company	110	:	150	Cured smoked bellies, smoked lardoons, cured smoked bacon
	Company	120	140	190	[D]ried pork bellies
	Company	80	100	110	Concerns bacon bits from smoked and non smoked bellies
	Company	100	120	130	Bacon filet
Germany	Company	120	150	150	:
	Company	:	:	50	*Level based on final product. / At the edge Region of more salted ham [compliance] is difficult. / The actual added nitrite Content is unknown, because the nitrite are partially washed away by the dry salted ham.
	Company	10	20	30	:
	Expert	100	120	150	:
Ireland	Company	100	150	150	[I]njected cure in the bag bacon
	Company	150	150	150	Aim and limit is 150mg/kg
	Company	150	150	150	:
	Company	100	120	150	Cured raw meat

	Company	110	150	150	:
	Company	110	120	130	Product used is metex pickle fm200 160g..ingredients. Salt, sodium ascorbate, sodium nitrite.
	Company	100	150	170	[D]ry cured bacon
	Company	150	150	150	Aim and limit is 150mg/kg
Italy	Association	140	150	150	[T]he [minimum amount] can be [estimated] about at 10-15% less than the [maximum] amount. However if you reduce the nitrite amount, it's necessary to increase the nitrate amount.
	Company	:	150	:	[O]n green weight basis
	Expert	:	150	150	:
Luxembourg	Company	:	:	:	[L]ess than 10 mg is the typical amount added in practice / / END PRODUCT as sold (porc) dried ham
	Company	20	20	30	:
Netherlands	Association	150	150	150	[G]reen weight
	Expert	80	150	180	The amount of nitrate is not mentioned, but is used depending on production process.
Norway	Company	30	30	50	We have one type of dried whole pieces of meat, that we can not [measure] the amount we add, only what we have in the final product. It is less than 1,5 mg/kg. Another product we add 5% [nitrite] salt and have about 9-10 mg/kg in the final product.
Other	Association	80	110	150	As regards the minimum content for nitrite, nitrate is not considered.
Romania	Company	50	100	150	Sodium nitrite
Spain	Company	150	150	150	:
	Company	150	150	150	:
	Company	130	150	150	:
	Company	150	150	150	:
	Company	150	150	150	:
	Expert	10	150	200	[Please] consider that in whole pieces of meat (ham, shoulder), the nitrite is dissolved and diffuses into the whole meat of meat. Hence, the ingoing nitrite concentration in the salt (on the surface of the product) is considerable different to the final concentration (ingoing) in the product. The concentration in the marine salt used for salting dry/cured hams can be up to 800 ppm in some cases. Other producers in Spain do not use nitrite at all.
	Expert	10	150	150	Dry-cured meat products 250 mg/kg nitrates (maximum dose added during

					manufacture without added nitrites)
	Company	100	140	150	:
U.K.	Company	20	20	20	21mg/kg added
	Company	80	150	160	:
	Company	100	150	170	:
	Association	:	:	150	This relates to bacon production(cured pork)
	Association	130	150	150	Expressed on the basis of a retail product
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**150**		
Overall maximum amount (mg/kg)				**200**	

Table 11: Reported use levels of nitrites for sub-category: Non heat treated processed meat (8.3.1) > Derived from whole pieces of meat > Poultry meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Germany	Company	10	20	30	:
	Expert	100	120	150	:
Ireland	Company	110	150	150	:
Poland	Company	130	140	150	EXPRESSED ON BASIS OF FOOD AS MARKETED- dried poultry meat product
Spain	Company	150	150	150	:
	Company	30	50	100	:
	Company	150	150	150	:
	Expert	100	150	150	[D]ry-cured duck breast ("jamón de pato") nitrates usually are not added
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**145**		
Overall maximum amount (mg/kg)				**150**	

Table 12: Reported use levels of nitrites for sub-category: Non heat treated processed meat (8.3.1) > Derived from minced meat > Red meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Austria	Company	110	130	150	:
	Company	140	140	150	[E]xpressed on green weight basis
Belgium	Company	110	80	150	[O]n freshmeat, before fermentation & drying - As regard to the amounts given, nitrate is NOT considered.
	Expert	80	120	150	:
Croatia	Company	120	:	150	[D]ried salami
Czech Republic	Association	150	180	180	Residual amount is [close] to zero.
Denmark	Expert	:	100	100	Minimum level of nitrite in salami is 0 ppm as some organic producers make products without nitrite/nitrate.
Finland	Company	70	:	80	60mg for colour and 80 mg [for] bacteria risk
	Association	120	120	150	Calculated from recipe before drying e.g. green weight, / Salami and metwurst type of products
France	Association	:	120	150	[I]dem
	Company	10	100	120	:
	Company	60	130	200	:
Germany	Company	120	130	150	:
	Company	10	20	30	:
	Expert	80	120	150	:
Hungary	Company	110	110	110	:
	Company	100	100	150	:
Italy	Association	140	150	150	[T]he [minimum amount] can be [estimated] about at 10-15% less than the [maximum] amount. However if you reduce the nitrite amount, it's necessary to increase the nitrate amount.
	Company	:	50	:	[O]n green weight basis
	Expert	:	150	150	[E]xpressed on green weight

Luxembourg	Association	80	80	80	[G]reen
	Company	:	160	:	[D]ried sausage, salami
	Company	60	80	110	[Green]
	Company	70	90	110	:
Netherlands	Association	110	130	150	[G]reen weight
	Expert	80	180	200	Depending on type of salami, some fermentation processes with typical micro organism need also nitrate.
Norway	Company	110	110	150	This amount [before] drying.
Other	Association	80	110	150	As regards the minimum content for nitrite, nitrate is not considered.
Poland	Company	100	140	180	:
Romania	Company	50	100	150	Sodium nitrit[e]
Spain	Company	150	150	150	:
	Company	130	150	150	:
	Company	150	150	150	:
	Company	150	150	150	:
	Company	50	130	150	:
	Expert	100	100	150	:
	Company	120	150	150	:
	Expert	100	150	200	200 mg/kg when mechanically deboned meat is added. Nitrates usually are not added
U.K.	Company	20	20	20	15.6mg/kg added
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**120**		
Overall maximum amount (mg/kg)				**200**	

Table 13: Reported use levels of nitrites for sub-category: Non heat treated processed meat (8.3.1) > Derived from minced meat > Poultry meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Germany	Company	10	20	30	:
	Expert	100	130	150	:
	Company	120	130	150	:
Spain	Company	50	130	150	:
	Expert	100	150	200	200 mg/kg when mechanically deboned poultry meat is added. Nitrates usually are not added
	Company	30	100	100	:
	Company	150	150	150	:
	Company	150	150	150	:
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**130**		
Overall maximum amount (mg/kg)				**200**	

Table 14: Reported use levels of nitrites for sub-category: Heat treated processed meat (8.3.2) > Sterilised meat products > Derived from whole pieces of meat > Red meat

Current maximum authorised: 100 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Belgium	Company	50	70	100	:
Czech Republic	Association	100	120	150	:
Denmark	Expert	150	150	150	:
France	Association	20	60	100	:
Germany	Expert	60	80	100	:
	Company	:	:	70	:
Ireland	Company	110	150	150	:
	Company	100	100	100	[C]anned meat loaf product
Italy	Association	90	100	100	:
	Expert	:	100	100	[E]xpressed on green weight
Netherlands	Expert	120	150	180	:
	Association	120	140	150	[G]reen weight
Other	Company	50	70	100	:
Poland	Company	80	90	100	:
Spain	Company	40	50	70	:
	Expert	100	100	150	:
	Company	150	150	150	:
	Company	150	150	150	:
	Expert	100	100	150	:
Overall minimum amount (mg/kg)		**20**			
Median typical amount (mg/kg)			**100**		
Overall maximum amount (mg/kg)				**180**	

Table 15: Reported use levels of nitrites for sub-category: Heat treated processed meat (8.3.2) > Sterilised meat products > Derived from whole pieces of meat > Poultry meat

Current maximum authorised: 100 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
France	Association	20	60	100	:
Germany	Expert	60	80	100	:
	Company	10	20	30	:
Hungary	Company	50	60	80	:
Ireland	Company	110	150	150	:
Netherlands	Association	10	10	150	0 ppm minimum/green weight
Poland	Company	80	90	100	:
Spain	Company	30	40	50	:
	Expert	100	100	150	:
	Company	150	150	150	:
	Expert	100	100	150	:
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**80**		
Overall maximum amount (mg/kg)				**150**	

Table 16: Reported use levels of nitrites for sub-category: Heat treated processed meat (8.3.2) > Sterilised meat products > Derived from minced meat > Red meat

Current maximum authorised: 100 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Belgium	Company	50	70	100	:
Czech Republic	Association	100	120	150	:
Denmark	Expert	150	150	150	:
	Company	80	90	90	:
France	Association	20	60	100	:
	Company	80	:	120	Cooked sausage (garlic sausages, Saucisses de Strasbourg, cervelas)
	Company	90	:	150	[R]eformed cooked ham [or] shoulder
Germany	Company	100	120	150	:
	Expert	60	80	100	:
Ireland	Company	110	150	150	:
Italy	Association	90	100	100	:
	Company	:	50	:	[O]n green weight basis
	Expert	:	100	100	[E]xpressed on green weight
Netherlands	Association	120	140	150	[G]reen weight
	Expert	120	150	180	:
Poland	Company	80	90	100	:
Spain	Company	40	50	60	:
	Expert	100	100	150	:
	Company	150	150	150	:
	Company	150	150	150	:
	Expert	100	100	150	:

Overall minimum amount (mg/kg)	**20**			
Median typical amount (mg/kg)		**100**		
Overall maximum amount (mg/kg)			**180**	

Table 17: Reported use levels of nitrites for sub-category: Heat treated processed meat (8.3.2) > Sterilised meat products > Derived from minced meat > Poultry meat

Current maximum authorised: 100 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Denmark	Company	80	90	90	:
Germany	Company	10	20	30	:
	Company	100	120	150	:
	Expert	60	80	100	:
Netherlands	Association	80	130	150	[G]reen weight
	Expert	100	120	150	[L]ower sodium content as red meat.
Other	Company	50	70	100	:
Poland	Company	80	90	100	:
Spain	Company	30	40	50	:
	Expert	100	100	150	:
	Company	150	150	150	:
	Company	150	150	150	:
	Expert	100	100	150	:
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**100**		
Overall maximum amount (mg/kg)				**150**	

Table 18: Reported use levels of nitrites for sub-category: Heat treated processed meat (8.3.2) > Non sterilised meat products > Derived from whole pieces of meat > Red meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Austria	Company	80	100	110	:
	Company	100	110	110	:
Belgium	Company	:	150	:	:
	Company	80	100	150	:
	Expert	80	130	150	:
Croatia	Company	100	:	150	:
	Company	:	:	:	:
Czech Republic	Association	120	150	150	:
Denmark	Expert	:	60	100	Again organic products in this category is made without nitrite. For a special Danish product "rullepølse" 100 ppm nitrite is allowed.
Finland	Company	80	:	100	60 mg for colour and 80 mg [for] bacteriarisk
	Association	120	120	130	Calculated before heat treatment
France	Association	60	120	150	
	Company	100	120	130	[E]xpressed on basis of the food as marketed
	Company	100	50	130	:
	Company	120	150	180	[C]ooked hams and shoulders / for Superior, 1st choice and standard based on french Code des Usages définitions
	Company	50	120	120	:
	Company	80	100	110	Cooked ham superior quality
	Company	80	50	120	Expressed on basis of the food as marketed.
	Company	70	80	100	Expressed on green weight basis
	Company	:	120	:	:
Germany	Company	100	120	150	:

	Expert	60	90	120	:
	Company	:	:	100	:
Hungary	Company	130	140	140	:
	Company	150	100	100	:
Ireland	Company	100	150	150	[P]asteurised hams
	Company	80	100	130	:
	Company	110	140	150	:
	Company	110	150	150	:
	Company	60	150	150	[P]ork & beef products,
Italy	Association	90	100	100	:
	Company	:	150	:	[O]n green weight basis
	Expert	:	150	150	[E]xpressed on green weight
Luxembourg	Association	70	80	90	[G]reen
	Company	60	60	70	GREEN
	Company	40	80	110	:
Netherlands	Company	10	10	10	Produced from cooked ham(not shoulder), which has been cut and freeze dried. / Expresses on basis of the food as marketed
	Association	150	150	150	[G]reen weight
	Expert	80	120	150	:
Norway	Company	:	80	:	The whole pieces for meat is in a brine. There is one type used for [all] red meat products and one type for all poultry products. Typical amount added in [practice] is the residual after processing. There is a residual of 18% of the added in the product for both poultry and red meat products. Only E250 of the [nitrite] salts are added. The E250 salt compromise of mostly regular NaCl. Only about 0,54-0,6 is actual [sodium nitrite]. Amount mentioned is the calculated residual in the product of actual [sodium nitrite].
Other	Company	80	100	150	:
Poland	Company	100	120	150	:
Romania	Company	100	150	150	:
Spain	Expert	150	150	200	:
	Company	150	150	150	:
	Company	150	150	150	:

	Company	150	150	150	:
	Expert	100	100	150	:
	Company	50	130	150	:
	Company	100	150	150	:
Sweden	Company	140	140	140	:
UK	Company	20	20	20	21mg/kg added
	Company	130	140	150	:
	Association	130	150	160	Expressed on the basis of a retail product
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**120**		
Overall maximum amount (mg/kg)				**200**	

Table 19: Reported use levels of nitrites for sub-category: Heat treated processed meat (8.3.2) > Non-sterilised meat products > Derived from whole pieces of meat > Poultry meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Belgium	Company	:	150	:	:
	Company	60	100	120	:
Finland	Company	80	:	100	60mg for colour and 80 mg [for] bacteria[l] risk
	Association	:	:	:	Not specified, but typically amounts of nitrite are the same for poultry due to safety reasons
France	Company	90	100	110	[Chicken] cooked ham superior quality
	Company	70	50	120	Expressed on basis of the food as marketed.
Germany	Company	10	20	30	:
	Company	100	120	150	:
	Expert	70	90	120	:
Hungary	Company	110	110	110	:
	Company	70	80	120	:
	Company	120	130	130	:
Ireland	Company	110	150	150	:
Italy	Company	:	150	:	[O]n green weight basis
Netherlands	Association	80	90	100	[G]reen weight, lower than red meat because of colour
	Expert	50	60	90	[D]ue to a lower sodium and lower myoglobin concentration the amount of nitrite needed is lower.
Norway	Company	:	70	:	Se[e] comment for red meat.
Other	Company	60	80	120	:
Poland	Company	100	110	120	EXPRESSED ON BASIS OF FOOD AS MARKETED- cooked ham
	Company	100	110	150	:
	Company	50	80	110	EXPRESSED ON BASIS OF FOOD AS MARKETED- ham in a block
Romania	Company	100	100	100	:
Spain	Company	60	100	100	:

	Expert	150	150	200	:
	Company	150	150	150	:
	Company	150	150	150	:
	Expert	100	100	120	:
	Company	50	130	150	:
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**100**		
Overall maximum amount (mg/kg)				**200**	

Table 20: Reported use levels of nitrites for sub-category: Heat treated processed meat (8.3.2) > Non-sterilised meat products > Derived from minced meat > Red meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Austria	Company	90	120	130	:
	Company	90	120	130	[E]xpressed on green weight basis
Belgium	Expert	80	120	150	:
	Company	:	150	:	:
	Company	80	90	120	:
	Company	80	100	150	Not considering products in which no nitrite is added such as "boudin blanc". However this type of product is not [representative], as it has only a shelf life of max. 10 days (whereas other cooked meat product have shelf life > 3 - 4 weeks or sometimes longer)
Croatia	Company	90	:	120	:
Czech Republic	Association	120	150	150	:
Denmark	Expert	60	60	60	:
	Company	50	60	60	:
Finland	Company	80	:	100	60mg for colour and 80 mg [for] bacteriarisk
	Association	110	120	130	Calculated before heat treatment
France	Association	60	120	150	:
	Company	100	110	120	[E]xpressed on basis of the food as marketed
	Company	110	130	160	[F]rench pâtés
	Company	80	90	100	Pork sausages
	Company	10	10	20	Expressed on green weight basis
	Association	:	120	:	:
Germany	Company	100	120	150	:
	Expert	50	90	120	:
	Company	:	:	100	:

Hungary	Company	100	100	100	:
Italy	Association	90	100	100	:
	Company	:	150	:	[O]n green weight basis
	Expert	:	150	150	[E]xpressed on green weight
Luxembourg	Company	:	160	:	GREEN / cervelas
	Company	80	90	100	GREEN
Netherlands	Association	10	130	200	0 ppm minimum/green weight
	Expert	120	80	50	:
Norway	Company	:	50	:	Only E250 of the [nitrite] salts are added. The E250 salt compromise of mostly regular NaCl. Only about 0,54-0,6 is actual [sodium nitrite]. Amount mentioned is the calculated residual in the product of actual [sodium nitrite].
Other	Company	:	100	150	[L]ow minimum level only for specific short shelf life products e.g. boudin blanc
Poland	Company	100	120	150	:
Romania	Company	100	150	150	:
Spain	Company	100	150	150	:
	Expert	150	150	200	:
	Company	150	150	150	:
	Company	150	150	150	:
	Company	150	150	150	:
	Expert	100	100	150	:
	Company	50	130	150	:
Sweden	Company	130	130	130	:
U.K.	Company	10	10	10	12 mg/kg added
	Association	150	150	150	Expressed on the basis of a retail product
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**120**		
Overall maximum amount (mg/kg)				**200**	

Table 21: Reported use levels of nitrites for sub-category: Heat treated processed meat (8.3.2) > Non-sterilised meat products > Derived from minced meat > Poultry

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Belgium	Company	:	150	:	:
	Company	60	100	120	:
Denmark	Company	50	60	60	:
	Expert	60	60	60	:
Finland	Association	:	:	:	Not specified, but typically amounts of nitrite are the same for poultry due to safety reasons
France	Association	60	120	50	:
	Company	100	110	120	[E]xpressed on basis of the food as marketed
	Company	80	90	110	Chicken sausages
	Company	:	120	:	:
Germany	Company	10	20	30	:
	Company	100	120	150	:
	Expert	50	90	150	:
Hungary	Company	60	80	100	:
	Company	40	70	100	:
	Company	50	90	120	:
Italy	Company	:	150	:	[O]n green weight basis
Netherlands	Expert	80	60	50	:
Norway	Company	:	60	:	Se[e] comment for red meat.
Other	Company	:	80	120	:
Poland	Company	100	110	150	:
	Company	50	80	100	EXPRESSED ON BASIS OF FOOD AS MARKETED- pates, convienience
	Company	50	90	110	EXPRESSED ON BASIS OF FOOD AS MARKETED- hot dogs, sausages

Spain	Company	70	120	120	:
	Expert	150	150	200	:
	Company	150	150	150	:
	Company	150	150	150	:
	Expert	100	100	150	:
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**95**		
Overall maximum amount (mg/kg)				**200**	

Table 22: Reported use levels of nitrites for sub-category: Other meat products for which nitrites are used > Derived from whole pieces of meat > Red meat

Current maximum authorised: N/A

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Denmark	Expert	60	60	60	Numbers are valid raw smoked pork filet.
Germany	Expert	90	110	150	:
Ireland	Company	50	140	150	:
	Company	50	100	100	Bacon Rib / Expressed on Product as Marketed
	Company	150	150	150	[H]am products, no experience outside of Christmas ham
Netherlands	Association	100	130	150	[G]reen weight
Norway	Company	:	70	:	:
Spain	Company	100	150	150	:
	Expert	100	100	150	:
Sweden	Company	:	20	:	:
Overall minimum amount (mg/kg)		**20**[a]			
Median typical amount (mg/kg)			**105**		
Overall maximum amount (mg/kg)				**150**	

Note: a) For this sub-category, the minimum typical level reported (20 mg/kg) was lower than the lowest minimum level reported (50 mg/kg). The former is reported here as the overall minimum amount.

Table 23: Reported use levels of nitrites for sub-category: Other meat products for which nitrites are used > Derived from whole pieces of meat > Poultry meat

Current maximum authorised: N/A

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Germany	Company	10	20	30	:
	Expert	100	120	150	:
Spain	Company	60	100	100	:
	Expert	100	100	120	:
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**100**		
Overall maximum amount (mg/kg)				**150**	

Table 24: Reported use levels of nitrites for sub-category: Other meat products for which nitrites are used > Derived from minced meat > Red meat

Current maximum authorised: N/A

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Netherlands	Association	150	150	150	[G]reen weight
	Expert	:	:	:	No nitrite added to papillotes, blinde vink, slavink.
Spain	Company	100	150	150	:
	Expert	100	100	150	:
Overall minimum amount (mg/kg)		**100**			
Median typical amount (mg/kg)			**150**		
Overall maximum amount (mg/kg)				**150**	

Table 25: Reported use levels of nitrites for sub-category: Other meat products for which nitrites are used > Derived from minced meat > Poultry meat

Current maximum authorised: N/A

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Netherlands	Expert	:	:	:	No nitrite used. Product can do without nitrite
Spain	Company	60	100	100	:
	Expert	100	100	120	:
Overall minimum amount (mg/kg)		**60**			
Median typical amount (mg/kg)			**100**		
Overall maximum amount (mg/kg)				**120**	

Table 26: Reported use levels of nitrites for sub-category: Traditional meat products > Traditional immersion cured products > Cured tongue

Current maximum authorised:50 mg/kg (residual amount)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Belgium	Expert	10	30	80	:
Germany	Expert	10	30	40	:
Netherlands	Association	10	20	50	[M]inimum 0-10, typical 15
	Expert	10	20	40	:
Spain	Expert	50	50	50	The producer normally uses for this meat speciality a “closed formula
UK	Association	:	30	50	For cured tongue, ingoing amounts of nitrite are calculated to ensure a residual level on finished product analysis of 10mg/kg to 30mg/kg (Max 50mg/kg) are achieved. / We would want to retain the derogation for traditional products that allows compliance to be controlled by residual amount rather than the in-going quantity.
	Association	10	50	50	Cured canned tongue is marketed as a solid pack for slicing and sale from delicatessen and other counters, or for slicing for sale in a pre-packaged form, is a product unique to the UK. The food is sold in a pressed form, with few or no gaps between the cooked tongues in the pack. The use of a unique pre-cooking stage prior to packing characteristically results in apparent meat contents greater than 100%. / The canned product is marketed as a commercially sterile canned cured meat (although not meat as presently re-defined), suitable for distribution and storage at ambient temperatures without deterioration for the duration of its’ stated shelf-life, which may be up to four years. / Ox-tongue and pork tongue are also produced as refrigerated slice pre-packed product as an alternative to canning. /
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**30**		
Overall maximum amount (mg/kg)				**80**	

Table 27: Reported use levels of nitrites for sub-category: Traditional meat products > Traditional immersion cured products > Rohschinken, nassgepökelt and similar products

Current maximum authorised: 50 mg/kg (residual amount)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Germany	Company	20	20	30	:
	Company	:	:	50	*Level based on final product. / At the edge Region of more salted ham [compliance] is difficult. / The actual added nitrite Content is unknown, because the nitrite are partially washed away by the dry salted ham.
	Expert	10	20	40	:
	Expert	10	10	200	[T]he measured minimum amount was 1 mg/kg in 3590 samples
Spain	Expert	50	50	50	The producer normally uses for this meat speciality a "closed formula"
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**20**		
Overall maximum amount (mg/kg)				**200**	

Table 28: Reported use levels of nitrites for sub-category: Traditional meat products > Traditional immersion cured products > Wiltshire ham and similar products

Current maximum authorised: 100 mg/kg (residual amount)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Germany	Expert	20	30	40	:
Ireland	Company	20	50	70	:
	Company	90	100	100	:
	Company	30	70	70	40-70 range is typical from last review
Spain	Company	120	150	170	:
	Association	100	100	100	The typical, minimum and maximum amount are the same as those authorized by European legislation. / / If the scientific literature indicates that these amounts provide microbiological safety, it is risky to propose lower amounts /
	Expert	100	100	100	The producer normally uses for this meat speciality a "closed formula"
U.K.	Company	40	60	100	:
	Association	10	50	100	The use of "cover" brines provides a vehicle whereby a distinctive product can be created, dependent on the ingredients used in combination with the length of maturation. Manufacturers would like the UK derogation to be maintained on this to enable them to produce and sell traditional speciality and regional British hams in the premium sector of the market.
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**70**		
Overall maximum amount (mg/kg)				**170**	

Table 29: Reported use levels of nitrites for sub-category: Traditional meat products > Traditional immersion cured products > Wiltshire bacon and similar products

Current maximum authorised: 175 mg/kg (residual amount)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Denmark	Expert	100	150	150	Danish regulation mentions nothing about residual levels. Thus, numbers are based on maximum added amount.
Germany	Expert	20	40	80	:
Hungary	Company	100	100	170	:
Ireland	Company	170	120	170	:
	Company	60	130	150	Bacon Rib / Expressed on Product as Marketed
	Company	150	170	170	:
Spain	Company	150	180	200	:
	Association	170	170	170	The typical, minimum and maximum amount are the same as those authorized by European legislation. / / If the scientific literature indicates that these amounts provide microbiological safety, it is risky to propose lower amounts /
	Expert	100	150	150	The producer normally uses for this meat speciality a "closed formula
UK	Company	30	50	80	:
	Association	:	:	180	This should read 175 mg/kg. / We would want to retain the derogation for traditional products that allows compliance to be controlled by residual amount rather than the in-going quantity.
	Association	10	50	180	Maximum residual amount in practice 175mg/kg
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**130**		
Overall maximum amount (mg/kg)				**200**	

Table 30: Reported use levels of nitrites for sub-category: Traditional meat products > Traditional immersion cured products > Entreamada, entrecosto, chispe, orelheira e cabeca (salgados), toucinho fumado and similar products

Current maximum authorised: 175 mg/kg (residual amount)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Germany	Expert	20	40	80	:
Spain	Company	150	180	200	:
	Company	150	150	150	[According] to EU Legislation and [aligned] with the Food Safety Authorities of the Member States. Scientific literature [shows] 150 ppm as a [guarantee] for not developing Cl. botulinum
	Expert	100	150	150	The producer normally uses for this meat speciality a “closed formula
Overall minimum amount (mg/kg)		**20**			
Median typical amount (mg/kg)			**150**		
Overall maximum amount (mg/kg)				**200**	

Table 31: Reported use levels of nitrites for sub-category: Traditional meat products > Traditional immersion cured products > Kylmâsavustettu poronliha/kallrökt renkött

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Spain	Expert	100	150	150	The producer uses “closed formula”. This “own” formula is obtained from specialized food additives industries.
Overall minimum amount (mg/kg)		**100**			
Median typical amount (mg/kg)			**150**		
Overall maximum amount (mg/kg)				**150**	

Table 32: Reported use levels of nitrites for sub-category: Traditional meat products > Traditional immersion cured products > Bacon, filet de bacon and similar products

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Belgium	Expert	100	120	150	:
Croatia	Company	:	:	180	:
Denmark	Expert	150	150	150	Danish regulation allows a mix of nitrite and nitrate to be used. The maximum allowed limit (Sum of both) is 150 ppm.
Finland	Company	30	:	40	:
France	Association	90	120	150	Max 150
	Company	120	130	140	:
Germany	Company	20	20	30	:
	Expert	20	40	80	[A]scorbates/ascorbic acid in addition to nitrites
Ireland	Company	150	150	150	:
	Company	60	130	150	Bacon Rib / Expressed on Product as Marketed
Netherlands	Association	100	130	150	[G]reen weight
	Expert	150	200	200	[W]hen 3.5% cured salt is added, the amount of nitrite is 200 mg/kg or even higher. Depending on the storage time and curing process, nitrate is also used.
Spain	Association	150	150	150	The typical, minimum and maximum amount are the same as those authorized by European legislation. / / If the scientific literature indicates that these amounts provide microbiological safety, it is risky to propose lower amounts /
	Company	150	150	150	:
	Company	110	110	150	:
	Expert	100	150	150	The producer uses “closed formula”. This “own” formula is obtained from specialized food additives industries.
Overall minimum amount (mg/kg)		**20**			

Median typical amount (mg/kg)		**130**		
Overall maximum amount (mg/kg)			**200**	

Table 33: Reported use levels of nitrites for sub-category: Traditional meat products > Traditional dry cured products > Rohschinken, trockengepökelt and similar products

Current maximum authorised: 50 mg/kg (residual amount)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Austria	Company	:	10	20	[T]ypical residual nitrite values are <10 mg/kg
Germany	Expert	10	20	40	:
	Company	:	:	50	*Level based on final product. / At the edge Region of more salted ham [compliance] is difficult. / The actual added nitrite Content is unknown, because the nitrite are partially washed away by the dry salted ham.
Italy	Company	:	200	:	[O]n green weight basis
Netherlands	Association	10	20	50	[E]xpressed on basis of the food as marketed in NaNo3 and not in NO3
Spain	Company	50	50	50	:
	Expert	50	50	50	The producer normally uses for this meat speciality a “closed formula
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**35**		
Overall maximum amount (mg/kg)				**200** [a]	

Note: a) For this sub-category, the overall maximum amount reported (50 mg/kg) was lower than the maximum typical amount reported (200 mg/kg). The latter is reported here as the overall maximum amount.

Table 34: Reported use levels of nitrites for sub-category: Traditional meat products > Traditional dry cured products > Dry cured ham and similar products

Current maximum authorised: 100 mg/kg (residual amount)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Austria	Company	:	10	20	[T]ypical residual nitrite values are <10 mg/kg
Finland	Company	20	:	40	:
Germany	Expert	10	20	50	:
Italy	Association	:	:	100	Some enterprises produce "similar product" - / the name of the product are: Speck and Bresaola. / For Bresaola the maximum residual is 50 mg/kg / for speck 100 mg/kg. / / we don't have [average] date for typical or minimum amount.
	Expert	10	:	70	[E]xpressed on basis of the food as marketed
Netherlands	Expert	10	40	:	[D]epending on age the amount can be reduced between 2 and 10 mg/kg
Spain	Company	100	120	120	:
	Company	100	100	100	:
	Expert	10	10	50	The residual amount is very low. We have analyzed residual amount of nitrite in dry/cured ham and almost never goes higher than 1 mg/kg.
	Company	10	20	100	:
	Association	100	100	100	The typical, minimum and maximum amount are the same as those authorized by European legislation. / / If the scientific literature indicates that these amounts provide microbiological safety, it is risky to propose lower amounts /
	Company	100	100	100	:
	Expert	100	150	150	:
	Company	10	50	90	:
UK	Association	20	50	100	:
Overall minimum amount (mg/kg)		**10**			

Median typical amount (mg/kg)		**50**		
Overall maximum amount (mg/kg)			**150**	

Table 35: Reported use levels of nitrites for sub-category: Traditional meat products > Traditional dry cured products > Presunto, presunto da pa and paio do lombo and similar products

Current maximum authorised: 100 mg/kg (residual amount)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Germany	Expert	10	20	50	:
Spain	Company	100	120	120	:
	Company	100	100	100	:
	Expert	100	150	150	:
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**110**		
Overall maximum amount (mg/kg)				**150**	

Table 36: Reported use levels of nitrites for sub-category: Traditional meat products > Traditional dry cured products > Dry cured bacon and similar products

Current maximum authorised: 175 mg/kg (residual amount)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Austria	Company	:	10	20	[T]ypical residual nitrite values are <10 mg/kg
Croatia	Company	:	:	10	:
Germany	Expert	10	20	70	:
Ireland	Company	170	150	170	:
	Company	:	:	50	< 50ppm results
Netherlands	Association	10	30	40	[G]reen weight
	Expert	10	40	:	[D]epending on age the amount can be reduced between 2 and 10 mg/kg
Spain	Company	150	180	200	:
	Association	170	170	170	The typical, minimum and maximum amount are the same as those authorized by European legislation. / / If the scientific literature indicates that these amounts provide microbiological safety, it is risky to propose lower amounts /
	Company	170	170	170	:
	Company	110	110	170	:
	Expert	100	150	150	:
UK	Company	30	50	80	:
	Association	:	:	180	This should read 175 mg/kg. / We would want to retain the derogation for traditional products that allows compliance to be controlled by residual amount rather than the in-going quantity.
	Association	10	20	180	Dry cure[d] products as described in the attachments are produced by different methods than the European "dried" hams. The products require a significant time period in contact with curing compound to effect a cure, and incur significant physical losses of curing compound from surfaces used in equipment for achieving the cure (massagers/tumblers. Maximum residual amount in practice- 175mg/kg

Overall minimum amount (mg/kg)	**10**			
Median typical amount (mg/kg)		**80**		
Overall maximum amount (mg/kg)			**200**	

Table 37: Reported use levels of nitrites for sub-category: Traditional meat products > Other traditionally cured products > Rohschinken, trocken/nasgepökelt and similar products

Current maximum authorised: 50 mg/kg (residual amount)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Austria	Company	:	10	20	[T]ypical residual nitrite values are <10 mg/kg
Germany	Company	10	20	40	:
	Expert	10	20	40	:
Hungary	Company	50	50	50	:
Spain	Company	50	50	50	:
	Expert	50	50	50	The producer normally uses for this meat speciality a “closed formula
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**35**		
Overall maximum amount (mg/kg)				**50**	

Table 38: Reported use levels of nitrites for sub-category: Traditional meat products > Other traditionally cured products > Jellied veal and brisket

Current maximum authorised: 50 mg/kg (residual amount)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Germany	Company	10	20	30	:
	Expert	10	20	40	:
Spain	Expert	50	50	50	The producer normally uses for this meat speciality a “closed formula
UK	Association	:	50	50	Both products are canned, pre-cooked cured meat products and at this time unique to the UK. Brisket and veal are used throughout the world but as far as is known it is only canned in the UK. The cans are shelf stable at ambient temperatures and are only chilled prior to opening. The products are sliced and presented for sale on delicatessen counters. The F0 value used in the canning process is comparatively low but the shelf stability relies on the presence of salt and sodium nitrite. It is only in the UK that the cured meat is pre-cooked prior to canning.
Overall minimum amount (mg/kg)		**10**			
Median typical amount (mg/kg)			**35**		
Overall maximum amount (mg/kg)				**50**	

Table 39: Reported use levels of nitrites for sub-category: Traditional meat products > Other traditionally cured products > Vysočina, selský salám, turistický trvanlivý salám, poličan, herkules, lovecký salám, dunjaská klobása, paprikás and similar products

Current maximum authorised: 180 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount (mg/kg)	Typical amount (mg/kg)	Maximum amount (mg/kg)	Comments provided by respondents
Austria	Company	130	150	180	:
Czech Republic	Association	150	180	180	:
Finland	Company	30	:	40	:
Hungary	Company	100	100	150	:
Spain	Expert	100	150	150	The producer uses “closed formula”. This “own” formula is obtained from specialized food additives industries.
Overall minimum amount (mg/kg)		**30**			
Median typical amount (mg/kg)			**150**		
Overall maximum amount (mg/kg)				**180**	

Annex 4: Tables showing survey results on the minimum amount of nitrites necessary for achieving the technological needs

Table 40: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Meat preparations > Red meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Czech Republic	Association	120	40	30	No	:	It highly depends on a type of product - there are meat preparations with no nitrites added, but these have very limited shelf life and must be stored accordingly.
Finland	Company	80	60	:	Yes	100	:
France	Association	120	:	:	Don't Know	10	Not [independent] of others physico-chemical conditions. So regarding Roberts et al model, with 2 % salt at pH=5,4, we need 50 ppm of no dissociated nitrite to control Clostridium botulinum. we need more if, for ex, there is iron in the product
Germany	Company	:	:	120	No	:	:
	Expert	60	50	50	Don't Know	:	[A]scorbates/ascorbic acid in addition to nitrites / minimum level normally 45 mg/kg for coloring and flavoring process
Ireland	Company	120	10	10	Don't Know	:	Product used metex pickle fm 200 160g [Ingredients:] salt sodium ascorbate sodium nitrite

Netherlands	Expert	50	40	80	Don't Know	:	In several cases a higher amount of nitrite is necessary to fulfill the microbiological safety during the total shelf life.
Poland	Company	100	50	30	Don't Know	:	:
Spain	Other	150	150	150	No	:	[P]incho moruno
	Other	150	150	150	No	:	:
	Expert	80	80	80	Don't Know	:	:
	Other	:	150	:	Yes	:	:
U.K.	Company	20	20	20	No	:	21mg/kg added
	Company	:	150	150	Don't Know	:	:
Median		**100**	**55**	**80**			

Table 41: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Meat preparations > Poultry meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Finland	Company	80	60	:	Yes	100	:
France	Association	120	:	:	Don't Know	120	Not [independent] of others physico-chemical conditions. So regarding Roberts et al model, with 2 % salt at pH=5,4, we need 50 ppm of no dissociated nitrite to control Clostridium botulinum. we need more if, for ex, there is iron in the product
Germany	Company	:	:	120	No	:	:
	Expert	60	50	60	Don't Know	:	[A]scorbates/ascorbic acid in addition to nitrites / minimum level normally 45 mg/kg for coloring and flavoring process
Netherlands	Expert	50	20	80	Don't Know	:	Less myoglobin so less needed for colouring. 80 mg/kg needed for warm over flavor.
Poland	Company	100	50	30	Don't Know	:	:
Spain	Other	150	150	150	No	:	:
	Expert	80	80	80	Don't Know	:	:
Median		**80**	**55**	**80**			

Table 42: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Non-heat treated processed meat > Red meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Austria	Company	140	:	:	:	:	[A]ccording to A. Stiebing in H.-J. Sinell, H. Meyer: HACCP in der Praxis, Behr's Verlag, Hamburg 1996.
Belgium	Company	80	60	60	Don't Know	:	:
Czech Republic	Association	120	40	30	No	:	It highly depends on a type of product - there are non-heat treated processed meats with no nitrites added, but these have very limited shelf life and must be stored accordingly.
Denmark	Expert	:	20	:	Yes	:	:
Finland	Company	80	60	:	Yes	100	:
France	Association	120	:	:	Don't Know	120	Not [independent] of others physico-chemical conditions. So regarding Roberts et al model, with 2 % salt at pH=5,4, we need 50 ppm of no dissociated nitrite to control Clostridium botulinum. we need more if, for ex, there is iron in the product. Depend too of the use or not of nitrates
	Company	120	120	120	Yes	120	According to code des usages de la charcuterie

	Company	:	:	40	Yes	120	Bacon bits
Germany	Expert	90	70	70	Don't Know	:	[A]scorbates/ascorbic acid in addition to nitrites /
Hungary	Company	100	100	100	Yes	80	:
Italy	Association	150	:	:	:	:	We don't have data regarding the [minimum] amount required in practice for each function. / Our [entreprises] for microbiological safety use the [maximum] amount permitted. / We know that [research] institutes also [collaborating] with our enterprises are [working] on that but It is not possible to generalize [because] the reduction it is related to the [specific production/product]. In Italy we have many many different products.
	Expert	150	:		:	:	The minimum amount for colouring and flavouring depends on the manufacturing processes. There is the EFSA Opinion (2003) for the safety issue.
Netherlands	Association	10	50	30	No	:	[T]he amount added is between 110-150 ppm. 130 ppm is typical. Green weight. Nitrite makes product more safe during fermentation
	Expert	80	40	40	Yes	80	Nitrate not included.
Other	Association	80	60	60	Don't Know	:	We do not know as there are hardly any studies available - process parameters (eg [heterogeneity] in curing of whole pieces, residual water activity) needs be taken into account
Poland	Company	100	50	30	No	:	:
Romania	Company	50	50	50	Don't Know	50	:
Spain	Other	150	150	150	No	:	:
	Other	150	150	150	No	:	:

	Expert	80	100	100	Don't Know	:	:
	Other	:	150	:	No	:	:
U.K.	Company	20	20	20	No	:	15.6mg/kg added
	Company	100	100	100	Yes	100	:
	Other	140	:	:	Don't Know	:	In a salami type of product it is possible to make a safe product, but it will be depending on sufficient pH drop and levels of NaCl
Median		**100**	**60**	**60**			

Table 43: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Non-heat treated processed meat > Poultry meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
France	Association	120	:	:	Don't know	:	Not [independent] of others physico-chemical conditions. So regarding Roberts et al model, with 2 % salt at pH=5,4, we need 50 ppm of no dissociated nitrite to control Clostridium botulinum. we need more if, for ex, there is iron in the product. Depend too of the use or not of nitrates
Germany	Expert	90	70	70	Don't know	:	[A]scorbates/ascorbic acid in addition to nitrites /
Poland	Company	100	50	30	No	:	:
Romania	Company	50	50	50	Don't Know	50	:
Spain	Other	150	150	150	No	:	:
	Expert	80	100	100	Don't Know	:	:
Median		**95**	**70**	**70**			

Table 44: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Heat treated processed meat > Sterilised > Red meat

Current maximum authorised: 100 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Belgium	Company	50	40	40	Don't know	:	:
Czech Republic	Association	100	40	30	No	:	:
Denmark	Company	90	50	50	No	:	:
France	Association	:	:	:	Don't Know	:	Not [independent] of others physico-chemical conditions. So regarding Roberts et al model, with 2 % salt at pH=5,4, we need 50 ppm of no dissociated nitrite to control Clostridium botulinum. we need more if, for ex, there is iron in the product
Germany	Expert	60	50	50	Yes	60	[A]scorbates/ascorbic acid in addition to nitrites
Italy	Association	100	:	:	:	:	We don't have data regarding the [minimum] amount required in practice for each function. / Our [entreprises] for microbiological safety use the [maximum] amount permitted. / We know that [research] institutes also [collaborating] with our enterprises are [working] on that but [it]t is not possible to generalize [because] the reduction it is

							related to the [specific production/product]. In Italy we have many many different products.
	Expert	100	:	:	:	:	The minimum amount for colouring and flavouring depends on the manufacturing processes. There is the EFSA Opinion (2003) for the safety issue.
Netherlands	Association	120	80	10	Yes	80	[G]reen/80 ppm and F0>3
	Expert	150	40	80	No	:	[S]torage at ambient temperature gives risk for development Clostridium spores and formation of toxin.
Other	Association	50	40	40	Don’t know	:	:
Poland	Company	90	50	30	Don’t know	:	:
Spain	Other	100	100	100	No	:	:
	Other	100	100	100	No	:	:
	Expert	80	80	80	Don’t know	:	:
Median		**100**	**50**	**50**			

Table 45: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Heat treated processed meat > Sterilised > Poultry meat

Current maximum authorised: 100 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Denmark	Company	90	50	50	No	:	:
France	Association	:	:	:	Don't Know	:	Not [independent] of others physico-chemical conditions. So regarding Roberts et al model, with 2 % salt at pH=5,4, we need 50 ppm of no dissociated nitrite to control Clostridium botulinum. we need more if, for ex, there is iron in the product
Germany	Expert	60	60	60	Yes	60	[A]scorbates/ascorbic acid in addition to nitrites /
Netherlands	Association	120	10	10	Yes	10	[G]reen/0 ppm and F0>6
	Expert	150	20	80	No	:	:
Poland	Company	90	50	30	Don't Know	:	:
Spain	Other	100	100	100	No	:	:
	Expert	80	80	80	Don't Know	:	:
Median		**90**	**50**	**60**			

Table 46: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Heat treated processed meat > Non sterilised > Red meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Belgium	Company	100	50	:	:	:	:
	Company	80	60	60	Don't Know	:	:
Czech Republic	Association	120	40	30	No	:	It highly depends on a type of product - there are heat treated processed meats (non-sterilised) with no nitrites added, but these have limited shelf life, grey colour and must be stored accordingly.
Denmark	Company	60	50	50	No	:	:
	Expert	:	20	:	:	:	:
Finland	Company	80	60	:	Yes	100	:
France	Association	120	:	:	Don't Know	:	Not [independent] of others physico-chemical conditions. So regarding Roberts et al model, with 2 % salt at pH=5,4, we need 50 ppm of no dissociated nitrite to control Clostridium botulinum. we need more if, for ex, there is iron in the product
	Company	120	120	120	Yes	120	According to code des usages de la charcuterie
	Company	120	100	100	No	:	[E]xpressed on basis of the food as marketed

	Company	80	40	40	Yes	100	[M]inimum given by biblio
	Company	50	50	50	Yes	100	Expressed on basis of the food as marketed.
Germany	Company	:	:	120	No	:	:
	Expert	60	70	70	Don't Know	:	[A]scorbates/ascorbic acid in addition to nitrites / minimum level normally 45 mg/kg for coloring and flavoring process
Hungary	Company	100	100	100	Yes	80	:
Ireland	Company	80	80	100	Don't Know	:	With ever reducing salt requirements being demanded by competent authorities/retailers the nitrite requirement becomes increasingly important for food safety. More work to understand the salt/nitrite absolute minimum levels would be required to determine food safety impact.
	Company	60	20	60	No	:	[I]mportant hurdle in food safety, especially with lower salt requirements from consumers
Italy	Association	150	:	:	:	:	We don't have data regarding the [minimum] amount required in practice for each function. / Our [enterprises] for microbiological safety use the [maximum] amount permitted. / We know that [research] institutes also [collaborating] with our enterprises are [working] on that but [i]t is not possible to generalize [because] the reduction it is related to the [specific production/product]. In Italy we have many many different products.
	Expert	100	70	70	:	:	The minimum amount for colouring and flavouring depends on the manufacturing processes. There is the EFSA Opinion (2003) for the safety issue.
Netherlands	Expert	80	50	50	Yes	80	:
Norway	Company	:	50	:	:	:	:

Other	Association	80	60	60	No	:	:
Poland	Company	100	50	30	Don't Know	:	:
Romania	Company	100	100	100	Don't Know	100	:
Spain	Other	150	150	150	No	:	:
	Other	150	150	150	No	:	:
	Expert	80	80	80	Don't Know	:	:
	Other	:	150	:	Don't Know	:	:
U.K.	Company	10	10	10	No	:	12mg/kg added
	Company	120	40	40	No	:	[Will] vary depending on salt level.
	Other	150	:	:	Don't Know	:	:
	Association	50	120	100	No	:	Minimum 100mg/kg with appropriate partial quality control program, (indicative minimum levels from research papers). In America cooked bacon is required to have a minimum of 120 mg/kg
Median		**100**	**60**	**70**			

Table 47: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Heat treated processed meat > Non sterilised > Poultry meat

Current maximum authorised: 150 mg/kg (amount added)

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Belgium	Company	100	50	:	:	:	:
	Company	60	40	40	Don't know	:	:
Denmark	Company	60	50	50	No	:	:
EU	Association	60	40	60	No	:	:
Finland	Company	80	60	:	Yes	100	:
France	Association	120	:	:	:	:	:
	Company	50	50	50	Yes	100	Expressed on basis of the food as marketed.
Germany	Company	:	:	120	No	:	:
	Expert	60	70	70	Don't Know	:	[A]scorbates/ascorbic acid in addition to nitrites / minimum level normally 45 mg/kg for coloring and flavoring process
Ireland	Company	60	10	60	No	:	[A]s above,
Netherlands	Expert	80	40	40	Yes	80	[L]ess needed for coloring due to lower myoglobin content

Poland	Company	100	50	30	Don't know	:	:
Romania	Company	100	100	100	Don't know	100	:
Spain	Other	150	150	150	No	:	:
	Expert	80	80	80	Don't know	:	:
Median		**80**	**50**	**60**			

Table 48: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Other meat products for which nitrites are used > Red meat

Current maximum authorised: N/A

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Finland	Company	80	60	:	Yes	100	:
France	Association	120	:	:	:	:	:
Germany	Company	:	:	120	No	:	:
	Expert	60	50	50	Yes	60	E.g. Liver sausages / ascorbates/ascorbic acid in addition to nitrites
Hungary	Company	100	100	100	Yes	80	:
Netherlands	Expert	80	50	50	Yes	80	Beef meat needs more nitrite compared to pork or poultry for colouring red after heating.
Poland	Company	100	50	30	Don't know	:	:
Spain	Other	180	180	180	No	:	:
	Expert	80	80	80	Don't know	:	:
Median		**90**	**60**	**80**			

Table 49: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Other meat products for which nitrites are used > Poultry meat

Current maximum authorised: N/A

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Finland	Company	80	60	:	Yes	100	:
France	Association	120	:	:	:	:	:
Germany	Company	:	:	120	No	:	:
	Expert	60	50	50	Yes	60	E.g. Liver sausages / ascorbates/ascorbic acid in addition to nitrites
Netherlands	Expert	80	40	40	Yes	80	:
Poland	Company	100	50	30	Don't Know	:	:
Spain	Other	180	180	180	No	:	:
	Expert	80	80	80	Don't Know	:	:
Median		**80**	**55**	**65**			

Table 50: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Traditional products > Traditional immersion cured products

Current maximum authorised: 50 – 175 mg/kg (Maximum residual amount)

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Germany	Expert	10	10	10	Don't know	:	[A]scorbates/ascorbic acid in addition to nitrites
Ireland	Other	50	50	50	No	:	:
	Company	60	60	60	Don't know	:	Don't believe we are qualified to make assessment regarding reducing max. amounts permitted.
Netherlands	Expert	20	10	10	:	:	The residual amount at the end of the shelf life can be very low. When a product has a high sodium content, (compared with low aw) and a low storage temperature, there is no risk of developing of C. bot.
Spain	Other	170	170	170	No	:	:
	Expert	100	80	80	Don't know	:	:
	Other	:	:	:	Don't know	:	:
U.K.	Company	10	10	10	No	:	Residual levels of nitrite become depleted during storage , typically from 75ppm eventually reaching the same level , for any given residual level there is a greater anti botulinum effect when the ingoing level is higher.
	Company	50	50	50	Yes	100	:
	Association	10	10	20	No	:	:

Median		**50**	**50**	**50**			

Table 51: Reported minimum levels of nitrites necessary to achieve technological needs for sub-category: Traditional products > Traditional dry cured products

Current maximum authorised: 50 – 175 mg/kg (Maximum residual amount)

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Germany	Expert	10	10	10	Don't know	:	[A]scorbates/ascorbic acid in addition to nitrites
Netherlands	Association	30	30	:	No	:	[G]reen weight
	Expert	20	10	10	:	:	The residual amount at the end of the shelf life can be very low. When a product has a high sodium content, (compared with low aw) and a low storage temperature, there is no risk of developing of C. bot.
Spain	Other	170	170	170	No	:	:
	Expert	10	50	30	Yes	50	:
	Expert	100	80	80	Don't know	:	:
	Other	:	:	:	Don't know	:	:
U.K.	Company	50	50	50	Yes	100	:
	Other	10	:	:	Don't know	:	:
	Association	10	10	20	No	:	:
Median		**20**	**40**	**30**			

Table 52: Traditional products > Other traditionally cured products

Current maximum authorised: 50 mg/kg (Maximum residual amount)

Member State	Type of operator/ association	Minimum amount required in practice for protection against C. botulinum	Minimum amount required in practice for colouring purposes	Minimum amount required in practice for flavouring purposes	Could the maximum amount authorised be reduced without compromising microbiological safety?	If Yes, to which amount could it be reduced?	Comments provided by respondents
Germany	Expert	30	10	10	Don't know	:	:
Netherlands	Association	30	30	:	No	:	[G]reen weight
	Expert	20	10	10	:	:	The residual amount at the end of the shelf life can be very low. When a product has a high sodium content, (compared with low aw) and a low storage temperature, there is no risk of developing of C. bot.
Spain	Other	150	150	150	No	:	[S]alchichón y chorizo tradicionales de larga curación
	Other	50	50	50	No	:	:
	Expert	80	80	80	Don't know	:	:
	Other	:	:	:	Don't know	:	:
U.K.	Other	10	:	:	Don't know	:	:
Median		**30**	**40**	**50**			

Annex 5: Comments provided by survey respondents (Question 13)

Member State	Type of operator/ association	What is the amount of nitrites present in the nitrite salt used by your company/members for the curing of meat products/preparations? If Other, please specify:
Austria	Company	0,6% and 0,9%
	Company	0,6% for production of minced meat products (heat treated and non-heat treated) [,] 0,9% (sea salt) for dry salted and cured products and Rohschinken-type products
Belgium	Company	Concentration between 0.6 % and 3.2% are available. Normally, curing salt with 0.6% nitrite is used. However, on using presalted meat(preparation) and/or on reducing salt (health programs), it may be necessary to use higher %-ations of nitrite to respect the minimum concentrations needed for food safety and quality. Such higher levels are used under strict control of HACCP. […] In general, on reducing salt in products, higher levels of nitrite are necessary to keep product safe
Czech Republic	Association	0.6 % is the amount of nitrites present in the nitrite salt used by our members for heat-treated meat products.
Finland	Association	Concentrations of nitrites in salt are from 0,6 % up depending on the techniques used in nitrite application.
France	Association	[S]ome more concentrated salt 0.9% can be used for reduced salt/products
	Company	[F]or some applications 0.8%
	Company	[S]alt with 0.85% NO2
Germany	Company	0,45 %
	Company	0,4 - 0,5 %
	Company	0,4 - 0,5 % or 0,5 - 0,6 %
	Company	[R]aw ham: 0,9 - 1,0% nitrite salt - usually nitrate will be added too sometimes; / raw sausages: 0,4 - 0,5% nitrite salt; / cooked sausages: 0,4 - 0,5% nitrite salt
Hungary	Company	<0,6%
	Company	[G]enerally 0,45 %
	Company	0,5 %
Ireland	Company	[W]e use nitrite, not nitrite salt
	Company	0.13
	Company	Don't know
	Company	N/A
	Company	Many of our dry ingredients used for Brine/curring contains Nitrite
	Company	Not relevant for our products (Pasta products with some meat in filling or cooked sauces with meat)
	Company	We do not use nitrites
	Company	[W]e are not using a nitrite salt combination, we are using 100 Sodium nitrite in tiny amounts
	Company	[U]se a complete preblend, add our own salt with no nitrite in it
	Company	[N/A] to our process
	Company	Fibricure 2, Sodium Nitrite 6.0%, Sodium Nitrate 4.0% [.] Cure [recipe]: Water - 552 litres [,] Salt - 80 Kg [,] Fibricure 2 - 6.0 Kg
	Company	Metex 160g add to 10.5kg of water / Salt Pickeled Mix pack to 18.5kg of water

	Company	No Percentage given
	Company	Mix of Metex, Mix of salt and water pound of water per pack of salt up to indicated level in drum
	Company	Cure Mix Kerry Foods, 2 Packets
	Company	Packet of Cure 11 Mix 250g net with water
	Company	Metex Mix of sachet and water
	Company	94% Salt content 6% Nitrites
	Company	[D]ont know
	Company	0.5-0.6%
	Company	[N]on applicable
Italy	Association	[No specific] limit and no average data.
Luxembourg	Association	0,4 - 0,5 %
	Company	0,4 à 0,5 %
	Company	0,45%
Netherlands	Company	[U]nknown
	Association	0,6%, 0,9% , 3%
	Company	[C]uring of meat is not practised by [this company]
Poland	Company	0,5-0,6%
	Company	0,40 - 0,55 %
Romania	Company	0.013
	Company	0,4 and 0,9
Italy	Company	0.005
	Company	Between 6-8%
	Company	We prepare the mix of salt and nitrite. The amount of nitrites depends on each product.
UK	Company	[N/A]
	Company	Nitrite-salt blend (50% salt / 50% nitrite) for use in curing systems.
	Company	This is the minimum level - we have various curing salts used for different products that vary between 0.7 - 2.0%
	Company	N/A
	Association	3-5% with typically a salt/nitrite blend of 50% salt and 50% sodium nitrite
Other	Association	Historically 0.6% was applied - in some Member States this level is still laid down in the national legislation. However, to allow salt reduction programs and/ or to allow the use of presalted meat (without jeopardizing food safety), derogations are sometimes granted under the application of good HACCP principles (to avoid the accidental use of curing salts containing up to 3.2 % nitrites).

Source: Civic Consulting survey of meat business operators, their organisations and other stakeholders.

Annex 6: Workshop summary notes

DISCLAIMER: The following summary of the expert workshop is preliminary in nature and may be edited in the final version of the report to reflect changes suggested by members of the expert panel.

Introduction

This document presents the summary notes of the workshop held on 8 September 2015. The workshop was organised in the context of the study on the monitoring of the implementation of Directive 2006/52/EC as regards the use of nitrites by industry in different categories of meat products conducted by the Food Chain Evaluation Consortium (FCEC) for the European Commission Directorate-General for Health and Food Safety.

Session 1: The use of nitrites in meat products and preparations

Table 1: Survey results for non-traditional meat products and preparations

Main category	Whole/ minced	Additional criteria	Legal limit (mg/kg)	Overall minimum (mg/kg)	Median typical amount (mg/kg)	Overall maximum (mg/kg)
Meat preparations	N/A	*Lomo de cerdo adobado, Pincho moruno, Careta de cerdo adobada, Castilla de cerdo adobada*	150	50	**150**	150
		Kasseler, Bräte, Surfleisch		10	**100**	150
		Toorvorst, Šašlõkk, Ahjupraad		100	**100**	150
		Kiełbasa surowa biała, Kiełbasa surowa metka, Tatar wołowy		90	**100**	150
Non-heat treated processed meat	Whole	Red meat	150	10	**150**	200
		Poultry meat		10	**145**	150
	Minced	Red meat		10	**120**	200
		Poultry meat		10	**130**	200
Heat treated processed meat (sterilised)	Whole	Red meat	100	20	**100**	180
		Poultry meat		10	**80**	150
	Minced	Red meat		20	**100**	180
		Poultry meat		10	**100**	150
Heat treated processed meat (non-sterilised)	Whole	Red meat	150	10	**120**	200
		Poultry meat		10	**100**	200
	Minced	Red meat		10	**120**	200
		Poultry meat		10	**95**	200
Other meat products for which nitrites are used	Whole	Red meat	N/A	20	**105**	150
		Poultry meat		10	**100**	150
	Minced	Red meat		100	**150**	150
		Poultry meat		60	**100**	120

1. The table above presents results of the survey on use levels for the following categories of meat preparations and non-traditional meat products:

   - Meat preparations;
   - Non-heat treated processed meat products;
   - Heat treated processed meat products (sterilised);
   - Heat treated processed meat products (non-sterilised);
   - Other meat products for which nitrites are used.

   For each of these categories:

   - *Do you consider the survey results regarding 'typical amounts' for this category to be representative of the wider market in your country/in the EU?*
   - *If not: why not? And: In this case what would you consider to be broadly representative 'typical amounts' used for this category? On which research/data source would you base your suggestion?*

   It was clarified that use levels of nitrites are expressed as sodium nitrite ($NaNO_2$). Most members of the expert panel who expressed an opinion considered that for meat preparations and non-traditional meat products, the survey results reflect the current practices of industry. However, it was emphasised that reported maximum levels were very high, and there is little information available regarding why there are these different levels, as there is no technological basis for this variation. It was also pointed out that producers often determine their use levels based on traditional recipes, which do not take into consideration improvements in hygiene practices. As one panel member put it: "Meat industry is very traditional and won't change anything if not necessary. To me, this shows very clearly that people have not realised how much better hygiene is today than in older times. The survey results are telling the real situation in the meat industry."

   - *How important are country differences in 'typical amounts' used for this category, compared to other factors (such as type of meat, type of product/preparation)?*

   The panel considered that there are no clear country differences in the typical amounts used by industry for non-traditional meat products and preparations, with the exception of Denmark (where different limits apply) and for some specific products such as Parma ham (in which nitrite is not used).

2. In some categories of non-traditional meat products and preparations some producers report to use higher levels of nitrites than authorised in the legislation (most notably for sterilised meat products, where approximately half of respondents reported typical amounts higher than 100 mg/kg). *What would you think are reasons for this? In your experience, how frequent are use levels higher than the amounts authorised in the legislation?*

   According to the panel, factors that may explain why producers use higher levels of nitrites than are authorised in the legislation include a lack of knowledge of the legal limits and a strong emphasis of "being on the safe side" using traditional approaches.

3. *How relevant is the category 'Other meat products for which nitrites are used' in your country/the EU? Which maximum amounts are considered to apply for this category according to your experience?*

   The panel concluded that this category is of little relevance. In this context it was emphasised that the current categorisation of meat products and preparations is overly complicated and should be replaced by a categorisation based on the technology used in the production process.

Table 2: Survey results for traditional meat products and preparations

Main category	Product	Legal limit (mg/kg)	Overall minimum (mg/kg)	Median typical amount (mg/kg)	Overall maximum (mg/kg)
Traditional immersion cured products	*Cured tongue*	50 (residual)	10	**30**	80
	Rohschinken, nassgepökelt and similar products		10	**20**	200
	Wiltshire ham and similar products	100 (residual)	10	**70**	170
	Wilshire bacon and similar products	175 (residual)	10	**130**	200
	Entremeada, entrecosto, chispe, orelheira e cabeca (salgados), toucinho fumado and similar products		20	**150**	200
	Kylmâsavustettu poronliha/kallrökt renkött	150 (added)	100	**150**	150
	Bacon, filet de bacon and similar products		20	**130**	200
Traditional dry cured products	*Rohschinken, trockengepökelt* and similar products	50 (residual)	10	**35**	200
	Dry cured ham and similar products	100 (residual)	10	**50**	150
	Presunto, presunto da pa and paio do lombo and similar products		10	**110**	150
	Dry cured bacon and similar products.	175 (residual)	10	**80**	200
Other traditionally cured products	*Rohschinken, trocken/nasgepökelt* and similar products	50 (residual)	10	**35**	50
	Jellied veal and brisket	50 (residual)	10	**35**	50
	Vysočina, selský salám, turistický trvanlivý salám, poličan, herkules, lovecký salám, dunjaská klobása, paprikás and similar products	180 (added)	30	**150**	180

4. The table above presents results of the survey on use levels for the following categories of traditional meat products:

    - Traditional immersion cured products;
    - Traditional dry cured products;
    - Other traditionally cured products.

    For each of these categories:

    - *Do you consider the survey results regarding 'typical amounts' for this category to be representative of the wider market in your country/in the EU?*
    - *If not: why not? And: In this case what would you consider to be broadly representative 'typical amounts' used for this category? On which research/data source would you base your suggestion?*
    - *How important are country differences in 'typical amounts' used for this category, compared to other factors (such as type of meat, type of product)?*

    For traditional meat products – for which legal limits are mainly based on residual amounts –, the panel highlighted the difficulty for producers to accurately report residual amounts of nitrite in their products at the end of the production process. This is because the depletion of nitrite throughout the production process depends on a large number of factors, including the type of product, fat content, pH, temperature, the use of nitrates, and the size of the product. Using the example of dry cured ham, a panel member that had conducted relevant measurements considered 20 mg/kg to 50 mg/kg residual amount to be realistic, while 150 mg/kg was considered to be a very high value. The panel concluded that the median of reported values, rather than the range of values, could be used as a realistic indication of the levels used in practice. One panel member added a caveat to this conclusion: "Using the median value is fine, but we also should not forget about the high values." [As some producers may indeed use very high ingoing amounts, leading to high residual levels.]

5. In several categories of traditional meat products some producers report to use higher levels of nitrites than authorised in the legislation (most notably Wiltshire ham, Rohschinken, dry cured ham, Presunto). *What would you think are reasons for this? In your experience, how frequent are use levels higher than the amounts authorised in the legislation? Do you consider that a maximum residual amount of 175 mg/kg, e.g. for dry cured bacon, is a realistic limit?*

    Again, the panel discussed reasons such as producers' lack of knowledge about the maximum authorised limits and the use of traditional methods as possible explanations for reported values exceeding legal limits. People who produce meat have very different backgrounds: some may use traditional recipes, others have a scientific background and they try to find ways to reduce the amount of nitrites and nitrates used.

    In the answer to the next question, the panel considered that a maximum residual amount of 175 mg/kg for traditional meat products was too high, and proposed 50 mg/kg as a more realistic limit.

6. Survey results for many categories of meat products and preparations (both non-traditional and traditional) indicate a wide variation of reported minimum and maximum use levels of nitrites. *What can explain the wide range of values reported by different producers? In your view, are differences in use levels more due to differing technological needs for different products, or are they due to differing practices of different producers independent from technological needs (for example with some producers trying to minimise use of nitrites, and others continuing to use traditional recipes)?*

   As indicated before, a possible explanation for the variation in values reported brought forward by the panel relates to the different approaches adopted by producers: while some try to minimise the use of nitrites in their products, others continue to use traditional recipes or maximum amounts “to be on the safe side”. In some cases, the country for which the product is marketed may influence nitrite levels. One participant expert mentioned the EC’s 2013 report; which found that producers use lower levels of nitrite when targeting the Danish market than when producing for other EU countries, for the same product.[41] This suggests that levels of nitrites used in practice may be a reaction to the limit provided in the legislation. Another possible reason for the variation in reported values relates to the different levels of nitrates used by producers, which influences the residual amount of nitrite as measured at the end of the production process.

7. In light of reported use levels that are sometimes higher than authorised in the legislation: *How are current maximum amounts in the legislation enforced in your country/the EU? Does the definition of maximum amounts as amount added or residual amount influence the degree to which they are enforceable?*

   The panel considered that for most products, it is possible to calculate the ingoing amount and that defining the maximum limit as an added amount is preferable. However, a clear caveat in defining limits as ingoing amounts is that it is not possible to control the amounts added in practice by producers, making enforceability a challenge. Moreover, the panel noted that for some products – in particular traditional dry cured or immersion cured products – it is difficult to calculate the ingoing amount.

   Problems with using residual amounts as maximum limit are that in this case it remains not known which amounts of nitrite have been added, and residual amounts of nitrite remaining at the end of the production process depends on a large number of factors (e.g. pH, temperature, amount of lean meat exposed to the nitrite).

   After an extensive discussion, the panel concluded that legislation should continue to define maximum levels as amounts added. In addition, guidance documents and tools could be provided to producers and inspectors to facilitate the calculation of ingoing amounts, with reporting requirements regarding the use of nitrites and checks of recipes being options for better enforcement. Moreover, the panel emphasised that the categorisation of different products and preparations should be clear and simple, including as few categories as possible (see below).

   Finally, the panel pointed out that if the objective is to reduce exposure to nitrite, NO_3 and NO_2 should be regulated together, to avoid producers reducing nitrite levels while simultaneously increasing nitrate levels to compensate the reduction.

8. There appear to be few academic articles or research reports available concerning the use and use levels of nitrites in meat products and preparations in the EU.

[41] European Commission Health and Consumers Directorate-General, Final Report on a Desk Study to Monitor the Implementation of Directive 2006/52/EC in the EU Member States as Regards the Use of Nitrites by the Industry in the Different Categories of Meat Products and the Organisation of National Controls, 2013, p. 2.

Could you recommend additional literature for data in this regard, that could be included in our overview?

A number of members of the expert panel have provided additional articles, which have been screened and presented in the relevant sections of the report.

Session 2: The effect of nitrites on meat colour, taste and preservation

1. Results of the survey regarding the reported minimum amounts added that are required in practice for colouring purposes for non-traditional meat products and preparations are provided in the table below:

Table 53: Overview of reported minimum amounts of nitrites added that are required in practice for colouring purposes (non-traditional meat products and preparations)

Main category	Additional criteria	Minimum amount (mg/kg)	Median amount (mg/kg)	Maximum amount (mg/kg)
Meat preparations	Red meat	10	**55**	150
	Poultry	20	**55**	150
Non-heat treated processed meat	Red meat	20	**60**	150
	Poultry	50	**70**	150
Heat treated processed meat (sterilised)	Red meat	40	**50**	100
	Poultry	10	**50**	100
Heat treated processed meat (non-sterilised)	Red meat	10	**60**	150
	Poultry	10	**50**	150
Other meat products for which nitrites are used	Red meat	50	**60**	180
	Poultry	40	**55**	180

In light of these results:

- *Do you consider the survey results regarding minimum amounts added that are required in practice for colouring purposes for non-traditional meat products and preparations to be broadly reflecting the current knowledge, also considering your own research (where applicable) and research results in literature?*
- *If not: why not? And: In this case what would you consider to be relevant minimum amounts added? On which research/data source would you base your suggestion?*
- *Would the range of median values reported across the different categories (55 to 70 mg/kg added) be an appropriate point of reference*?
- *Is there a need to differentiate this value for the different categories listed above (or between red meat and poultry meat)*?

The panel considered that the range of median values reported (55 to 70 mg/kg added) is sufficient for colour formation in non-traditional meat products and preparations, although these levels may not be enough to ensure colour stability throughout the product shelf life, particularly for cooked or sliced products. 80 mg/kg was suggested as a level that would suffice to ensure colour stability.

2. Results of the survey regarding the reported residual amounts that are required in practice for colouring purposes for traditional meat products are provided in the table below:

Table 54: Overview of reported residual amounts that are required in practice for colouring purposes (traditional meat products)

Main category	Minimum amount (mg/kg)	Median amount (mg/kg)	Maximum amount (mg/kg)
Traditional immersion cured products	10	**50**	170
Traditional dry cured products	10	**40**	170
Other traditionally cured products	10	**40**	150

In light of these results:

- *Do you consider the survey results regarding residual amounts that are required in practice for colouring purposes for traditional meat products to be broadly reflecting the current knowledge, also considering your own research (where applicable) and research results in literature?*
- *If not: why not? And: In this case what would you consider to be relevant minimum residual amounts? On which research/data source would you base your suggestion?*
- *Would the range of median values reported across the different categories 40 to 50 mg/kg residual amount) be an appropriate point of reference?*
- *Is there a need to differentiate this value for the different categories listed above*?

Expressing its opinion on the amount of nitrite necessary for colour formation for traditional meat products, the panel noted that the colour of the product mainly depends on the ingoing amount of nitrite rather than the residual amount remaining at the end of the production process. At the same time, however, it was emphasised that a higher residual amount of nitrite leads to a more stable colour. A majority of members of the expert panel agreed that 20 to 30 mg/kg of residual nitrite is an appropriate range to ensure colour stability in most traditional meat products, with 40 to 50 mg/kg of residual nitrite needed for some products to safeguard colour stability.

Another conclusion concerning colour formation in traditional products noted by the panel related to the lower levels of nitrite needed for products undergoing injection, in comparison with the outward application of nitrite for larger pieces of meat.

3. Results of the survey regarding the reported minimum amounts added that are required in practice for flavouring purposes for <u>non-traditional meat products and preparations</u> are provided in the table below:

Table 55: Overview of reported minimum amounts of nitrites added that are required in practice for flavouring purposes (non-traditional meat products and preparations)

Main category	Additional criteria	Minimum amount (mg/kg)	Median amount (mg/kg)	Maximum amount (mg/kg)
Meat preparations	Red meat	10	**80**	150
	Poultry	30	**80**	150
Non-heat treated processed meat	Red meat	20	**60**	150
	Poultry	30	**70**	150
Heat treated processed meat (sterilised)	Red meat	10	**50**	100
	Poultry	10	**60**	100
Heat treated processed meat (non-sterilised)	Red meat	10	**70**	150
	Poultry	30	**60**	150
Other meat products for which nitrites are used	Red meat	30	**80**	180
	Poultry	30	**65**	120

In light of these results:

- *Do you consider the survey results regarding <u>minimum amounts added</u> that are required in practice for flavouring purposes for non-traditional meat products and preparations to be broadly reflecting the current knowledge, also considering your own research (where applicable) and research results in literature?*
- *<u>If not</u>: why not? And: In this case what would you consider to be relevant minimum amounts added? On which research/data source would you base your suggestion?*
- *Would the range of median values reported across the different categories (50 to 80mg/kg added) be an appropriate point of reference*?
- *Is there a need to differentiate this value for the different categories listed above (or between red meat and poultry meat)*?

Concerning flavouring purposes, the panel confirmed that nitrites contribute to the typical flavour of cured meat products and preparations. Members of the expert panel considered that the range of median values reported (50 to 80 mg/kg of added nitrite) provides meaningful guidance for safeguarding taste-related aspects, while acknowledging differences in products and consumer expectations. The panel emphasised that the use of additives should focus mainly on food safety, and that there is no indication that higher levels of nitrites are required for flavouring purposes than for ensuring microbiological safety.

4. Results of the survey regarding the reported residual amounts that are required in practice for flavouring purposes for traditional meat products are provided in the table below:

Table 56: Overview of reported residual amounts that are required in practice for flavouring purposes (traditional meat products)

Main category	Minimum amount (mg/kg)	Median amount (mg/kg)	Maximum amount (mg/kg)
Traditional immersion cured products	10	**50**	170
Traditional dry cured products	10	**30**	170
Other traditionally cured products	10	**50**	150

In light of these results:

- *Do you consider the survey results regarding <u>residual amounts</u> that are required in practice for flavouring purposes for traditional meat products to be broadly reflecting the current knowledge, also considering your own research (where applicable) and research results in literature?*
- *<u>If not</u>: why not? And: In this case what would you consider to be relevant minimum residual amounts? On which research/data source would you base your suggestion?*
- *Would the range of median values reported across the different categories (30 to 50 mg/kg residual amount) be an appropriate point of reference?*
- *Is there a need to differentiate this value for the different categories listed above*?

The panel concluded that the range of median values reported (30 to 50 mg/kg of residual nitrite) is a meaningful point of reference across traditional products and across countries for flavouring purposes.

5. Results of the survey regarding the reported minimum amounts added that are required in practice for protection against *Clostridium botulinum* for non-traditional meat products and preparations are provided in the table below:

Table 57: Overview of reported minimum amounts of nitrites added that are required in practice for protection against Clostridium botulinum (non-traditional meat products and preparations)

Main category	Additional criteria	Minimum amount (mg/kg)	Median amount (mg/kg)	Maximum amount (mg/kg)
Meat preparations	Red meat	20	**100**	150
	Poultry	50	**80**	150
Non-heat treated processed meat	Red meat	10	**100**	150
	Poultry	50	**95**	150
Heat treated processed meat (sterilised)	Red meat	50	**100**	150
	Poultry	60	**90**	150
Heat treated processed meat (non-sterilised)	Red meat	10	**100**	150
	Poultry	50	**80**	150
Other meat products for which nitrites are used	Red meat	60	**90**	180
	Poultry	60	**80**	180

In light of these results:

- *Do you consider the survey results regarding <u>minimum amounts added</u> that are required in practice for protection against Clostridium botulinum for non-traditional meat products and preparations to be broadly reflecting the current knowledge, also considering your own research (where applicable) and research results in literature?*
- *<u>If not</u>: why not? And: In this case what would you consider to be relevant minimum amounts added? On which research/data source would you base your suggestion? Would the range of median values reported across the different categories (80 to 100 mg/kg added) be an appropriate point of reference for protection against Clostridium botulinum for non-traditional meat products and preparations? Or could this point of reference even be at the lower end (for example, 80 mg/kg)?*[42]
- *Is there a need to differentiate this value for the different categories listed above (or between red meat and poultry meat)*?
- *In light of these results, could the maximum added amounts of nitrites authorised for the different categories of non-traditional meat products and preparations be reduced without compromising microbiological safety?*

Members of the expert panel led an extensive discussion on the minimum amount of nitrites added required to achieve microbiological safety in non-traditional meat products and preparations. A number of experts considered that the focus on *Clostridium botulinum* should be broadened to include other bacteria, such as *Listeria*, which are also relevant challenges to food safety.

[42] Commission Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, sets a maximum indicative ingoing amount of nitrites (expressed as NaNO2) at 80 mg/kg, which could be used as a point of reference for protection against Clostridium botulinum.

Various members of the expert panel provided insight and current knowledge from their Member State concerning the levels of added nitrite needed to ensure microbiological safety. Most members of the expert panel that had an opinion regarding this aspect agreed that the range of 80 to 100 mg/kg of nitrite added would be reasonably safe for a majority of products, when used in combination with other hurdles to safeguard microbiological safety. However, the panel also emphasised that it is not possible to reach a firm conclusion for all products and all situations, acknowledging that microbiological safety is dependent upon a large number of factors. One panel member highlighted concerns regarding any change of legal limits: "What we presently do appears to be safe, if we are going to change it, we need evidence. Is this median amount [80 to 100 mg/kg of nitrite] enough [to safeguard microbiological safety]? I think probably not. So if the question is: am I prepared to accept the median? No, I am not. Might it be OK in some foods? Yes. But I don't know which ones […]. I think we can reduce nitrite safely in some products, but I don't know which ones. In these foods, safety requires a combination of hurdles and any reduction in the nitrite concentration requires a thorough understanding of the contribution of these hurdles to safety […]."

The panel concluded that a possible point of reference for lowering maximum limits of nitrites while safeguarding microbiological safety could be countries or product categories for which stricter maximum levels already apply or have applied in the past. These include:

- According to the Danish experience, 60 mg/kg of added nitrite is sufficient for most products, with levels of 100 mg/kg and 150 mg/kg necessary for some categories.
- In Finland, former national legislative limits allowed the use of up to a maximum of 120 mg/kg of nitrite.
- The German *Fleischverordnung* previously in force allowed a residual limit of 100 mg/kg of total nitrite and nitrate (calculated as sodium nitrite) for boiled, cooked and raw sausages. For raw ham ("Nussschinken" and Lachsschinken"), a higher level of 150 mg/kg of total nitrite and nitrate was authorised (also calculated as sodium nitrite). For raw ham and long-term ripening raw sausages with the addition of potassium nitrate, other limits were permitted.[43]
- The limit of 80 mg/kg imposed on organic meat products also provides an indication that it may be possible to reduce the use levels of nitrite, without compromising microbiological safety. Also, there are nitrite-free organic meat products on the market in various countries.

It was also suggested that a reduced maximum added amount of nitrites could be foreseen, with a process put in place for industry to identify products for which a higher limit needs to apply because of safety considerations.

[43] The curing salt authorised contained 99.5% sodium chloride and 0.5% sodium nitrite. The total nitrite and nitrate level is the sum of the analysed content of nitrite and nitrate in the fat and meat of a meat product.

6. Results of the survey regarding the reported residual amounts that are required in practice for protection against *Clostridium botulinum* for traditional meat products are provided in the table below:

Table 58: Overview of reported residual amounts that are required in practice for protection against Clostridium botulinum (traditional meat products)

Main category	Minimum amount (mg/kg)	Median amount (mg/kg)	Maximum amount (mg/kg)
Traditional immersion cured products	10	**50**	170
Traditional dry cured products	10	**20**	170
Other traditionally cured products	10	**30**	150

In light of these results:

- *Do you consider the survey results regarding residual amounts that are required in practice for protection against Clostridium botulinum for traditional meat products to be broadly reflecting the current knowledge, also considering your own research (where applicable) and research results in literature?*
- *If not: why not? And: In this case what would you consider to be relevant minimum residual amounts? On which research/data source would you base your suggestion?*
- *Would the range of median values reported across the different categories (20 to 50 mg/kg residual amount) be an appropriate point of reference for protection against Clostridium botulinum for traditional meat products and preparations? Or could this point of reference be lower?*
- *Is there a need to differentiate this value for the different categories listed above*?
- *In light of these results, could the maximum residual amounts authorised for the different categories of traditional meat products be reduced without compromising microbiological safety?*
- *In the 2003 EFSA Opinion, it is stated that "The Panel considered that the ingoing amount of nitrite contributes to the protection against C. botulinum, rather than the residual amount". In light of this opinion, what are the caveats when using residual amounts as benchmark for protection against Clostridium botulinum?*

Again, as for non-traditional products, the panel suggested focusing on protection against other bacteria in addition to Clostridium botulinum.

Concerning the current limits on the maximum residual amounts provided by the legislation for the different (sub-)categories of products, the panel suggested that the varying levels of nitrites are mainly a result of traditional production processes rather than technological or safety considerations.

One expert considered that both the ingoing and residual amount of nitrite contribute to the microbiological safety of meat products. It was emphasised that some amount of residual nitrite is needed for protection against non-proteolytic *Clostridium botulinum*, although the panel could not establish a precise value that would constitute an appropriate point of reference.

It was emphasised that for sterilised meat products, nitrite is not needed to ensure microbiological safety. However, for other products with an Fo value of 3 or less, some residual nitrite is required.

7. Concerning the effect of nitrite on the preservation of meat: *are the spores produced by Clostridium botulinum able to develop when the product is maintained at a cooling temperature below 7°C?*

   The panel noted that non-proteolytic *Clostridium botulinum* is able to grow at 3°C, while proteolytic *Clostridium botulinum* cannot grow at temperatures below approximately 10 to 12°C.

Session 3: The formation of nitrosamines

1. *In your view, to what extent do the current maximum amounts regarding the use of nitrites achieve an appropriate balance between ensuring a high level of protection against microbiological activity and preventing the formation of nitrosamines?*

   The panel considered the question to be irrelevant, given that there is insufficient data on the relationship between the ingoing amounts of nitrite and nitrosamine formation, whilst the relationship between nitrite and microbiological safety is clear.

2. *Considering survey results, your own research (where applicable) and research results in literature: What are possible conclusions concerning how relevant for human exposure to nitrosamines caused by cured meat products and preparations are the following possible routes:*

   - *Nitrosamines formed during the production process (in situ nitrosamine formation)?*
   - *Nitrosamines formed during preparation at home (e.g. when cured meat products or preparations are cooked or barbecued)?*
   - *Nitrosamines formed in the digestive system resulting from the consumption of cured meat products and preparations (in vivo nitrosamine formation)?*

   Concerning human exposure to nitrosamines caused by cured meat products and preparations, there was consensus within the panel that nitrosamines formed during preparation at home and during gastrointestinal digestion are likely to be more relevant routes than nitrosamine formed during the production process. It was underlined that whereas *in situ* formation of nitrosamines can be measured with relative ease, nitrosamine formation in the gastrointestinal tract cannot be directly measured. As a result, the relevance of the in vivo formation of nitrosamines is more difficult to assess. However, as one of the members of the expert panel emphasised, there is considerable evidence linking endogenous nitrosamine formation with processed meat consumption and an increased risk of colorectal cancer.

   Furthermore, it was noted by the panel that there is a strong relationship between the temperature applied whilst cooking and the formation of nitrosamines in meat products and preparations. This finding explains the relevance of nitrosamine formation during the preparation of meat at home: heat treatment applied in industrial production processes rarely exceeds sterilisation and temperatures typically range between 70 and 80°C, while subsequent preparation (e.g. through frying, barbecuing or baking) exposes products to higher temperatures. This issue is particularly salient when considering products that are intended to be eaten raw and for which high residual amounts are permitted, such as dry cured ham and dry cured loin, but that are subsequently heated at high temperatures (e.g. as topping on a pizza).

3. *According to your research (where applicable) and research results in literature, are there specific categories of cured meat products and preparations that most likely to lead to the formation of nitrosamines?*

   The panel identified several factors that are considered to increase the likelihood of nitrosamine formation, including meat products containing black pepper and those intended to be cooked at high temperatures or barbecued.

   Concerning the latter, one expert noted that research has shown that meat pieces to which no nitrite has been added were found to contain high amounts of nitrosamines following barbecuing, due to the nitrosating agents present in smoke.

4. *According to your research (where applicable) and research results in literature, what is the effect of high temperatures during frying/grilling of meat (e.g. salami on a pizza or frying dry cured bacon) on the formation of nitrosamines, in comparison with heat treatment up to 75°C?*

   This issue was already discussed (see Question 2).

5. *What measures, if any, can be taken by producers or consumers to reduce the formation of nitrosamines in cured meat products and preparations?*

   According to the panel measures that could be taken by producers to reduce the formation of nitrosamines include good processing practices and the additionof compounds which can scavenge the reactive nitrogen species.

   Consumers can also decrease their exposure to nitrosamines by cleaning their pans and barbecue grills after cooking meat. One expert also mentioned that new methods have been developed to measure the level of nitrosamines in products at the end of their production process; however given that the most relevant nitrosamine formation is considered to occur during the preparation at home and during gastrointestinal digestion, it is doubtful that these methods can help in reducing exposure to nitrosamines.

Session 4: Possible alternatives to the use of nitrites - development, testing and use in industry

1. *Can the experiences of companies that produce organic meat products or preparations (with lower amounts of nitrites added) and of companies that produce 'nitrites-free' meat products or preparations inform the discussion of maximum amounts and possible alternatives to the use of nitrites? If so, how?*

   A number of experts provided insight concerning meat products that are produced in their Member State without the addition of nitrites. For instance, in Germany several such products exist, which also do not contain organic sources of nitrate such as fermented celery extract. These products have a shorter shelf-life and tend to be vacuum-packed. In the Netherlands, products without nitrites have been on the market for ten years, without incurring problems related to microbiological safety. Other companies in this country produce organic products with 60 or 80 mg/kg of nitrite added, whose safety is ensured through a shorter shelf life and a lower storage temperature.

2. *Some products such as Parma ham or other quality labels are produced without the use of nitrites. For such products, how are the technological needs normally fulfilled by nitrites achieved? What risks, if any, exist in such products (considering that a maximum residual amount of 100 mg/kg is authorised for dry cured ham)?*

   A member of the expert panel clarified that the production of Parma-type dry-cured ham, which does not involve the use of nitrite, uses a specific technology based on refrigeration at a low temperature until water activity (aw) reaches a value of 0.96, followed by a long maturation period. A combination of these factors ensures that the product is safe.

3. *Considering survey results, your own research (where applicable) and research results in literature: Which additional measures to ensure that the products are safe in relation to the possible presence of Clostridium botulinum can or have to be taken if levels of nitrites are reduced or nitrites are fully avoided?*

   The panel found that microbiological safety can be ensured if a correct combination of key parameters such as water activity, pH, storage temperature, and shelf life are achieved. Alternative food additives such as lactate, diacetate and sorbate may also contribute to ensuring that products are safe in relation to the possible presence of Clostridium botulinum. The panel also underlined the importance of packaging for ensuring the microbiological safety of meat products.

4. *Results from the survey and literature research suggest that there is currently no single alternative to nitrites that could replace nitrites in the production processes of meat products/preparations while fulfilling the same technological needs (microbiological safety, colouring, flavouring). Do you agree with this conclusions? Do you consider that several alternatives (e.g. phytochemicals, natural extracts, other additives) used in combination could fulfil these needs? Could the use of other preservatives such as nisin be considered as an alternative to nitrites?*

   In the discussion concerning possibilities for replacing nitrite in the production of meat products and preparations, the panel confirmed that there is currently no single alternative that can fulfil all functions ensured by nitrites. A number of existing additives were discussed that aim to achieve microbiological safety (e.g. nisin, ethyl lauroyl arginate and essential oils) or that are added for colouring and flavouring purposes (e.g. lycopene, tomato paste, phytochemicals), but none were found by the panel to produce adequate results. The panel concluded that while there is no adequate replacement for nitrite that would allow for the production of the products currently on the market, these alternatives might be helpful in reducing the amount of ingoing nitrite. Other products based on alternatives to nitrites may be developed but these would have properties differing from existing cured meat products and preparations.

5. *According to your knowledge, which alternatives to nitrites are currently under development? Are any alternatives likely to fulfill the same technological needs as nitrites in the future?*

   Examples of alternatives currently under development provided by the panel included phytochemicals and active packaging technology (e.g. plastics containing antioxidants and antimicrobials). The panel considered it unlikely that in the future, a single alternative will be developed that will fulfil the same technological needs as nitrites.

   An additional question considered by the panel related to the need for regulating the concentration of nitrites present in curing salt. Experts suggested that if a limit is provided in the legislation on the concentration of nitrite allowed, it could be set at 0.6% or 0.9% (for products with a reduced sodium content).

Session 5: Conclusions

1. *Do you consider that the current maximum levels of nitrites as authorised in the legislation could be reduced? If not, why not? If yes, for which types of meat products and preparations? To which amount could the maximum levels be reduced?*

   The panel concluded that while it would not support abolishing the use of nitrites in meat products and preparations, it is possible to reduce current maximum levels of nitrites as authorised in the legislation. For identifying possible lower maximum amounts of nitrites added, one expert emphasised that microbiological safety must be demonstrated before any lower limits can be implemented. The panel suggested that the experience of countries that currently have lower limits for specific meat categories (Denmark) or had them in the past (Finland, Germany, Belgium) could be used as a possible benchmark.

   The panel suggested prioritising the focus of the reduction on mainstream products and to initiate in parallel a process in which specific product (categories) could be identified for which an exception could be made (i.e. for which higher levels of nitrites could be allowed).

   The panel also agreed that a new categorisation of products should be defined, which should be based on the technology used in the production processes of the relevant meat products and preparations.

2. *Do you consider that the legislation should provide maximum amounts of nitrites as amount added or as a residual amount?*

   This issue was discussed in a previous session.

3. *What is the correlation between the added and residual levels of nitrites in meat products and preparations?*

   The panel considered that the relationship between added and residual amounts of nitrite in meat product and preparations is too complex for a clear answer to this question to be provided.

4. *Considering survey results, your own research (where applicable) and research results in literature: What would be the main change in the production of meat products/preparations if the amount of nitrites authorised was reduced or nitrites were abolished? Which products would be most affected? Are there products which could no longer be produced (and which currently can also not be produced by companies that produce 'nitrites-free' meat products or preparations)?*

   According to the panel, abolishing nitrites would be feasible if the production processes underwent technological changes. This would primarily affect traditional products, for which production processes would need to change so that the product would not remain the same. Cooked and possibly sliced products would also undergo significant changes. Moreover, the microbiological safety of the products could be affected if additional measures (such as increasing salt content or cooking temperature) are not taken. The taste, and possibly the colour of the products would likely also be affected.

5. *In your view, what would be the effect on meat colour, flavour, microbiological safety and the formation of nitrosamines across product categories if:*

   a. *The maximum amount of nitrites authorised were reduced from 150 mg/kg to 100 mg/kg?*

   The panel concluded that 100 mg/kg of nitrites added would be sufficient for a majority of products, without significant effects on colour, flavour and microbiological safety (which would have to be demonstrated, e.g. by reference to countries in which such limits are or were in place, or other evidence). However, it was also agreed that for some products, a higher concentration of nitrite would be required. Experts considered that e.g. for fermented products, 120 mg/kg could be a more suitable limit.

b. The maximum amount of nitrites authorised were reduced from 150 mg/kg to 60 mg/kg?

A panel member reported that in Denmark 50 mg/kg of nitrites added was considered to be sufficient for many products to safeguard a stable shelf life and satisfactory quality, which led to a legal limit of 60 mg/kg for specific meat categories. And although this is considered to work and many [producers] do not use the current EU maximum amounts of nitrites, the panel suggested that there could be problems if this limit was imposed across product categories uncritically. The panel concluded that a reduction from 150 mg/kg to 60 mg/kg would not be favourable if microbiological safety is not demonstrated, and problems could be encountered for some products in terms of colour formation, colour stability and possibly flavour.

[Catalogue num