Practical Use of Nitrite and Basis for Dosage in the Manufacture of Meat Products

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Preface

This report is a review of current practice with respect to the use of nitrite and basis for dosage in the manufacture of meat products. The work was initiated by *Fødevarestyrelsen* (Danish Veterinary and Food Administration) as assignment *Jr. no. 2012-29-24-04600*. A particular purpose of the review is to scrutinise the technological need for the different legal maximum dosages of nitrite in Directive 2006/52/EC versus the Danish legislation as approved in the Danish National Provisions.

The report is based on a study of published literature, including well-known classical studies of the effect of nitrite dating back to the 1970s. To ensure adequate covering of recent literature, a systematic, electronic survey was made using the keyword "nitrite" in the title combined with the keyword "meat" appearing anywhere in the publication. This survey covered the years from 1999 to 2014 and resulted in over 500 publications. Furthermore, the leading German journal in the field of meat technology, *Fleischwirtschaft*, has been systematically surveyed for relevant publications, and about 40 were included for further review. The authors conclude that it is unlikely that few if any publications in English or German of major significance to the study have escaped the literature search and therefore have not been considered when writing the present report.

However, with regard to the many national and regional specialities, the literature is sparse, and what may be available will usually not be in English or German. Furthermore, the publications may be difficult and costly to procure. Some help could be found in the recently issued Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives, 18 december 2013. Within the limitations of the project the authors have searched for photos of the products on the internet, and from these photos it is possible for the professional to assess what type of product it is, and how it is probably produced.

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DTU, July 2014

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Summary

The use of nitrite ($NaNO_2$) in the manufacture of salted (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*. According to an assessment report by the European Food Safety Authority (*The EFSA Journal,* 14, p. 1-134, 2003) all evidence points to that it is the added amount of nitrite rather than the residual amount of nitrite in the product which exerts the antimicrobial effect. Nitrite also has a desirable anti-oxidant activity and contributes to the formation of pleasant flavours.

A systematic literature review on the function and use of nitrite in meat leads to a tentative first conclusion that if the level of nitrite added to meat products is sufficient to protect against possible toxin formation from *C. botulinum*, then the other technological reasons for using nitrite can be accomplished within the range of 50-100 mg/kg added nitrite, as is recommended by European Food Safety Authority (EFSA), see the reference above. A similar conclusion was earlier reached after a large number of experiments were conducted in Denmark in collaboration with the Danish meat manufacturing industry in 1981-1983. Wiltshire bacon and certain canned products largely for export were not investigated in this study, however.

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. This issue is well described in the literature and is not pursued further, as it is not part of the assignment for the report.

In the present report the existing EU legislation on the use of nitrite is reviewed and critically compared with Danish legislation. For *heat sterilised products* the EU limit of 100 mg/kg on added nitrite is identical to the level specified in Danish legislation. This is the only group of products where there is complete agreement between EU and Danish legislation with respect to the use of nitrite in meat.

For *bacon* the EU limit of 175 mg/kg on *residual* nitrite is obviously 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. *However, a strictly quantitative conversion from added to residual amount of nitrite is not possible*.

For *raw fermented sausages*, the EU limit of 180 mg/kg on added nitrite for a number of specified Central European sausages is obviously higher than the DK limit of 100 mg/kg on added nitrite for fermented sausages. Arguments for maintaining this high level are lacking in the available literature, and on the basis of what can be deduced with respect to the manufacturing processes for these products, it is hard to conceive of substantial arguments for the high level of 180 mg/kg.

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. Denmark has specifically exempted the addition of nitrite in liver paste and meat balls, thus specifying a limit of 0 mg/kg for these particular, common products in Danish cuisine.

A major reason for the discrepancies between the EU and DK legislation is that Directive 2006/52/EC in many cases specifies residual amounts, while Denmark specifies added amounts of nitrite. Denmark's position is in accordance with the recommendations by EFSA. However, it should be adduced that assessments of the added amount of nitrite are difficult to state for certain traditional curing processes, such as dry cured hams and traditional immersion curing of whole meat in a vat. The particularities of the production methods make such a quantification rather uncertain. 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. The Danish limitations on the use of nitrate are identical to those of Directive 2006/52/EC.

In conclusion, most of the Danish product categories comply with EFSA's recommended ingoing (added) nitrite level of 50-100 mg/kg. However, there is an issue regarding bacon and some unspecified products where Danish legislation allows 150 mg/kg. With regard to in particular dry cured products there is also an issue on how to specify limits on the use of nitrite in a meaningful way.

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1. The technological function of nitrite in cured meat products

1.1 Historical background

The use of nitrite ($NaNO_2$) in the manufacture of salted (cured) meat products has a long tradition in the industry, dating back to the early twentieth century. Practice developed slowly according to the experience of skilled manufacturers who mastered the traditional salting and curing methods (Binkerd & Kolari 1975; Honikel 2008). Preservation of meat and fish by salting was well-developed already in Antiquity, and the present methods of dry salting, wet salting, and combinations of the two became established through medieval times. During the late 1800s and early 1900s, the curing of meat was widely industrialised, and while conventional wet salting in a vat (immersion or pickle salting) continued to be in use, new variants of wet salting were introduced, such as the use of perforated pumping needles to inject brine into the meat (stitch salting) (Binkerd & Kolari 1975).

The use of nitrite has several technological purposes, of which the formation of a stable red colour in the meat and the inhibition of the growth of *Clostridium botulinum* are particularly important. In addition, nitrite also exerts a desirable anti-oxidant activity and contributes to the formation of pleasant flavours (Lücke 2000; Honikel 2008; Toldrá *et al*. 2009; Skibsted 2011). However, the understanding of the technological effect of nitrite only slowly developed, and for a long period up to the first half of the 1900s, *nitrate* was considered to be the active agent.

1.2 Preservation of colour

Many natural salt deposits contain saltpetre (KNO_3) in varying amounts, and the reddening effect of salting raw meat was recognised already by the Romans (Binkerd & Kolari 1975). Naturally occurring deposits of saltpetre were also utilised purposefully for the curing of meat in ancient China and India (Binkerd & Kolari 1975). During the 19th century it was realized that some salts were better preservatives than others, and that addition of saltpetre to the curing brine could enhance the preserving effect and give a stable red colour to meat products (Binkerd & Kolari 1975; Honikel 2008).

In the late 1800s it was proven that the reddening effect was not caused by saltpetre itself but by bacterial reduction of nitrate (NO_3^-) into nitrite (NO_2^-). In the first decades of the 1900s the chemistry of the red colour formation was elucidated in its basics. In brief, the colour is caused by the reaction of NO with myoglobin to form the bright red nitrosylmyoglobin pigment (Møller & Skibsted 2002; Møller & Skibsted 2008; Skibsted 2011).

It should be added that certain high-value, cured and dried hams (Parma, Iberico) are prepared by dry salting but without the use of nitrite or saltpetre (Parolari 1996). The process takes about a year for Parma ham, and the attractive red colour is due to a slow exchange of Fe with Zn of muscle origin in the myoglobin molecule (Wakamatsu 2009).

The understanding of the role of nitrite in the curing process eventually led industry to fully or partially replacing saltpetre with sodium nitrite in curing brines, resulting in shorter curing periods and better control of colour formation and colour uniformity (Binkerd & Kolari 1975). Because nitrate is acute toxic when ingested in large amounts, legislation was soon introduced

in Germany prescribing that sodium nitrite must only be used as a low-concentrated premix with common salt (NaCl) (Honikel 2008). Today, this is standard practice in the industry, also in countries where it is not compulsory by regulation, and it is also prescribed in the EU Law (Regulation no 1333 (2008)).

Ascorbic acid is commonly used in conjunction with nitrite in curing brines (Honikel 2008). Ascorbic acid reduces NO_2^- to NO and thereby accelerates the curing process (Møller & Skibsted 2008; Parthasarathy & Bryan 2012). A further advantage of using ascorbic acid is that it reduces the formation of nitrosamines (Honikel 2008), see section 1.4 below.

Saltpetre (KNO_3) is permitted within the EU and used as an additive in certain traditional whole meat products and dry fermented sausages (EFSA 2003; Directive 2006/52/EC). Its technological function is to act as a reservoir of nitrite. For example, in the dry curing of ham nitrate diffuses from the surface into the ham and is slowly reduced by bacterial enzymes into nitrite, while nitrite alone would react too rapidly to exert its proper colouring and antimicrobial function inside the ham (Toldrá *et al*. 2009; Armenteros *et al*. 2012). Also dry sausages of the Mediterranean type are reported to obtain a better sensory quality if cured with nitrate instead of nitrite (Sanz *et al*. 1998). This preference for using saltpetre in that kind of products is also reflected in the specifications on the limits of nitrate in Directive 2006/52/EC. It should be noted that in many cases nitrate is only allowed on the condition that nitrite is *not* used.

Denmark has no exception to the EU legislation on nitrate but specifies the same limits as those of Directive 2006/52/EC (Bekendtgørelse nr. 542 (2013)).

1.3 Antimicrobial effect

The antimicrobial effect of nitrite was also for long not well understood, and it was only in the 1950s and 1960s that it became clear that it was nitrite alone and not nitrate that exhibited an antimicrobial effect (EFSA 2003). The microorganism of most concern is *Clostridium botulinum*, and a large study in the USA with artificially inoculated wiener sausages documented that a certain level (50 mg/kg) of added $NaNO_2$ was necessary to prevent toxin formation (Hustad *et al*. 1973). However, the issue becomes complicated when trying to extrapolate from observations in the artificial situations of said study, and the general conclusion is that several factors influence the antimicrobial effect of nitrite, such as the hygienic status, pH, water activity and the concentration of other salts (EFSA 2003). Furthermore, nitrite is degraded during storage of the product, usually by oxidation and/or further reduction to NO (Toldrá *et al*. 2009; Honikel 2008). All evidence points to that it is the in-going amount of nitrite rather than the residual amount of nitrite in the product which exerts an inhibitory effect on *Clostridium botulinum* (EFSA 2003).

The microbial status of the raw material is evidently important; thus, less nitrite is needed if the number of spores is low (Skovgaard, 1992). This is reflected in the levels presented in the report from The Scientific Committee for Food on Nitrate and Nitrite in 1992, where 50-100 mg/kg added nitrite was considered sufficient in most cases for the inhibition of *C. botulinum*, if the producers comply with the Hazard Analysis Critical Control Point (HACCP) regarding process hygiene (Scientific Committee 1992; EFSA 2003).

1.4 Other aspects of the use of nitrite

Nitrite has other positive effects in meat products than the preservation of red colour and the antimicrobial effect. Nitrite has an anti-oxidative effect (Skibsted 2011) and is also responsible for an enhancement of taste and aroma (Hustad *et al*. 1973; Noel *et al*. 1990; Pearson & Gillet 1996, p. 96; Toldrá *et al*. 2009; Parthasarathy & Bryan 2012). The anti-oxidative effect is related to the effect on aroma by delaying the oxidation of lipids; however, the relation is not a simple cause and effect relation (Toldrá *et al*. 2009).

The adverse effects of nitrite can mainly be ascribed to the risk of forming nitrosamines from secondary amines and nitrite during curing, in particular when the cured meat products are heated to high temperatures, typically during frying (Kühne 2003; Honikel 2008; Herrmann et al. 2014). Nitrosamines have been shown to be potent carcinogens in several species, and therefore nitrosamines are likely to be carcinogenic for humans (Parthasarathy & Bryan 2012). It has been pointed out that there is a clear correlation between the level of added nitrite and the formation of volatile nitrosamines (Scientific Committee, 1992). It is primarily the risk of formation of nitrosamines and not nitrite itself which is of public health concern (Scientific Committee 1997; Leth *et al*. 2008; Parthasarathy & Bryan 2012; Bryan *et al*. 2012). However, the subject shall not be pursued further here, as it is not part of the assignment for the present report. In a Danish student report, Helle Hein has addressed the issue of nitrite and nitrosamine formation in more depth (Hein 2013).

For the sake of completeness it should be added that it has recently been suggested that small amounts of nitrite may even be beneficial to health. NO plays an important role in the body as a signalling molecule, and NO insufficiency is detrimental to the cardiovascular system. Intervention studies using nitrite have shown a positive effect on cardiovascular related diseases (Sindelar & Milkowski 2012; Parthasarathy & Bryan 2012). Of course, such findings cannot justify that people of normal health increase their dietary intake of nitrite! It just confirms the dictum of Paracelsus that it is the dose that makes the poison.

1.5 Discussion

The multi-sided effect of nitrite in meat products, and the fact that manufacturing practice and recipes are prescribed by tradition and craftsmanship as much as by a scientific understanding of the role of nitrite in the process, may explain why there seems to be a certain conservatism regarding new possible limitations on the current use of nitrite. This conservatism is evidently difficult to document, however; and there are examples that industry can also be positively engaged into a discussion of a possible lowering of the permitted dosages. For example, the early American study (Hustad *et al*. 1973) mentioned in section 1.3 was carried out in collaboration with industry with the purpose of assessing minimum levels of nitrite in wiener sausages.

An outstanding example of the positive engagement of industry is a large experiment conducted in Denmark from 1981-1983, where the effects of nitrite in commercially prepared Danish cured meat products were investigated (Gry *et al.* 1983). It was found that for most meat products distributed in the cold chain, the technological demand for nitrite was not above 50 mg/kg added; however, for some products the optimum level was 100 mg/kg. Wiltshire bacon and certain canned products largely for export were not investigated. As will be elaborated on later, the Danish 1983 study is fundamental for understanding the Danish National Provisions in the harmonisation of the legislation on the use of nitrite in the European Union. The conclusions drawn from this study comply well with the recommendations by the

EFSA Scientific panel, recommending a range of 50-100 mg/kg added nitrite as minimum for the inhibition of *C. botulinum* (EFSA 2003).

It should be adduced that assessments of the added amount of nitrite cannot meaningfully be stated for certain traditional curing processes, such as dry cured hams and traditional immersion curing of whole meat in a vat. This issue will be resumed later in section 3.5.

Undoubtedly, the overriding concern for minimising the risk of botulism is shared by both industry and public health authorities. Industry is evidently also concerned about keeping the attractive effects of nitrite on quality, primarily stabilisation of the red colour and the particular cured flavour (Lücke 2000; Gøtterup *et al.* 2008).

With regard to stabilisation of colour, concentrations as low as 5-20 mg/kg nitrite are claimed to be sufficient for the formation and stabilisation of the red colour (Belitz *et al*. 2009, p. 454). However, the critical concentration varies much with the type of product, and for turkey or chicken meat the critical concentration is in the range of 1-4 mg/kg nitrite (Heaton *et al*. 2000). Conversely, in products with high iron content, such as liver pâtés, the stabilisation of the colour may need a nitrite dosage of 40 mg/kg or perhaps more (Vossen *et al*. 2012). This is, however, still below the minimum level recommended for protection against toxin formation from *C. botulinum* (EFSA 2003).

With regard to obtaining the particular cured flavour, early studies indicated that a level of 50 mg/kg is sufficient for many products (Hustad *et al*. 1973; Gry *et al*. 1983). This level is also reported in a standard textbook on food chemistry (Belitz *et al*. 2009, p. 454) and by Lücke (2000) in a brief overview of the technological needs for using nitrite. The optimum level might sometimes be higher; for example a recent a study on traditional Turkish dry fermented sausages indicate an optimum level of around 100 mg/kg for this particular product, but also that an acceptable quality was obtained at lower concentrations (Kurt & Zorba 2012). In general, there are few systematic studies aiming at quantifying the effect of nitrite level on the flavour of cured meat products, and we have not come across studies demonstrating that it is necessary in general for proper flavour development to apply nitrite levels *above* the range of 50-100 mg/kg recommended by EFSA (EFSA 2003). There may, of course, be special cases – this will be briefly resumed in sections 4.2 and 4.3.

Thus, a tentative first conclusion is that if the level of nitrite added to meat products is sufficient to protect against possible toxin formation from *C. botulinum*, then the other technological reasons for using nitrite can be accomplished within the range of 50-100 mg/kg recommended by EFSA (EFSA 2003). This is also what can be deduced from the overview by Lücke (2000), who state that in general an added level of 50 mg/kg $NaNO_2$ is sufficient. So, in principle there should be no conflict between the concern for health risks and the concern for quality when it comes to assessing the levels of nitrite in different products.

However, to answer this question more precisely, it is necessary to go into more details on the production of the many different cured meat products in order to investigate, if certain processes and products might imply technological demands for higher levels of nitrite added. This is the subject of section 2.

It should be stressed that the indicated minimum levels above apply for products, such as canned ham and sausages, where the added amount of nitrite can be quantified, while the

situation in the production of other cured products, in particular dry cured hams may be more complicated. However, also for these types of products we have not come across studies demonstrating that proper development of colour and taste demands higher levels of nitrite than what is dictated by the concern for possible toxin formation from *C. botulinum*.

2. Description in principle of manufacturing processes for the different types of meat products listed in Directive 2006/52/EC

The products listed in Directive 2006/52/EC are divided into four categories (the relevant pages 15-17 dealing with nitrite and nitrate are reproduced in Appendix A):

- Sterilised meat products
- Traditional immersion cured meat products (1)
- Traditional dry cured meat products (2)
- Other traditionally cured meat products (3)

The four categories roughly follow the division in curing processes of dry and wet curing, respectively, but with sterilised products as a special category. The processes are briefly described in footnotes to the main categories. A slightly more extensive description is found in Guidance to food categories (2013). Furthermore, the products may be made from pieces of whole meat or of minced/ground meat.

The salts used for curing are normally mixtures of NaCl and $NaNO_2$ (0.4 – 0.9% of the salt) and/or some $NaNO_3$ in certain products. In some rare cases potassium nitrite/nitrate is used.

The different types of products are further specified in 2006/52/EC by a numbering system giving some additional information on the curing process and often also on the maturation period. The numbering system is a sub-system of the numbering system in Guidance to food categories (2013). The numbering system may distinguish standard product types from particular national specialities. For example, (2.1) is dry cured ham, for which it is specified in a footnote that "dry curing is followed by a maturation for at least 4 days". Product group (2.2) consists of *jamón curado* and other Spanish ham products, for which it is specified that after dry curing there is a "stabilisation period of at least 10 days and a maturation period of more than 45 days", see also Guidance to food categories (2013). The different Spanish speciality dry cured hams are protected names in accordance with a quality certification system (Werth 2009). However, there is no difference in the permitted residual level of nitrite (100 mg/kg) between the hams in group (2.1) and (2.2).

Dry cured *bacon* also belongs to group (2.1), but here the permitted residual level of nitrite is 175 mg/kg).

The same levels of residual nitrite are specified for immersion cured ham (1.2) and immersion cured bacon (1.1) as for their dry cured equivalents.

In the following the production methods of the four main categories will be briefly described. Unless otherwise specified the description is based on a leading textbook in meat technology (Pearson & Gillet 1996).

2.1 Sterilised meat products (F_0 > 3.0 min.)

These products can be made both from whole meat and from minced/ground meat. The products made from minced meat are usually low-cost products, which are mixed with salts, spices, potato starch and other water binders. The mix is transferred to cans, which are hermetically closed and heat processed to F_o > 3.0 min. F_o is a measure of the sterilizing effect obtained in the centre of the can, and it is expressed as an equivalent, hypothetical iso-thermal heat treatment at 121,1°C (250°F).

The production of whole meat products is based on salting of whole muscles or cuts of meat (pieces of whole meat) with brine or dry salting, combined with *tumbling*. The tumbling is performed in slowly rotating vessels. Often, vacuum is used to enhance the uptake of salt of the produced brine and avoid the formation of air bubbles in the product. During tumbling the meat produces an exudate that glues the pieces of meat together and promotes an equilibration of salt in the meat. After tumbling the meat is transferred to cans, which are hermetically closed and heat processed to F_o > 3.0 min.

The concentration of salt in all kinds of products within this category is controlled by the added amount of solid salt/brine. No examples of such meat products have been given in the directive 2006/52/EC, but for example luncheon meat, SPAM, or canned restructured pork shoulder are typical products (see the pictures in Appendix B).

2.2 Traditionally immersion cured meat products

The traditional immersion curing is performed in vats by immersing the pieces of meat into brine for a specified time. Even up to a whole side of pig as in traditional Wiltshire bacon can be cured by immersion. The amount of salt absorbed by the meat depends on the characteristic dimensions of the meat and the main process parameters: salt concentration, time, temperature and possible mechanical agitation. The selection of the process parameter values is governed by experience. The transport of Cl^- and NO_2^- into the meat is governed by diffusion, which is slow; therefore the curing time is usually several days.

Today, the production of brine-cured products based on whole meat (e.g. Wiltshire ham and bacon) is, however, often performed by injection of a controlled amount of brine into the meat using multi-stitch equipment with many needles in an array. This procedure ensures a good distribution of brine in the meat and thus a short time for equilibration and makes it possible to control the amount of salt added to the product (Branscheid *et al*. 2003). The injection of brine can sometimes be followed by tumbling.

Combinations processes with stitch salting followed by immersion curing are used for some products, see section 2.4.

2.3 Traditionally dry cured meat products

Production of whole meat products (e.g. dry cured bacon, *Rohschinken* and *Jamón curado*) is normally carried out using the following steps: reception, quality control, trimming, rubbing the surface of the meat with solid salt, curing in solid salt (draining the brine), washing, drying (and perhaps smoking) and maturation. The total loss of weight can be as high as 40% (Werth

2009). The amount of salt retained in the meat depends on the characteristic dimensions of the meat, time of contact with the salt, temperature and air humidity (Anonymous 2002; Troeger *et al*. 2007). As for traditional immersion curing the selection of the process parameter values is based on craftsmanship. The process control consists of measuring temperature and humidity and sometimes also in using controlled temperature and humidity during processing (Anonymous 2002; Troeger *et al*. 2007; Werth 2009; Armenteros *et al*. 2012). Some products may be smoked.

Several of the dry cured whole meat products are cured using a combination of nitrite and nitrate (saltpetre) or sometimes only nitrate, as discussed in section 1.2.

2.4 Other traditionally salted products

This is a mixed group, consisting of: 1) whole meat products (*Rohschinken*) made by a combination of wet and dry salting (3.1); 2) jellied veal and brisket (3.2); 3) different Central European sausages (3.5) see pictures in appendix B.

Product type (3.1), *Rohschinken* do not differ in principle from wet or dry cured *Rohschinken*, except that the two curing methods are used in combination (sequence). The limitations on residual nitrite (50 mg/kg) are the same.

Jellied veal and brisket (3.2) is produced by injection of brine into the meat followed by cooking in boiling water for up to 3 hours (Directive 2006/52/EC). The nearest Danish equivalent is *sylte*.

The variety of sausages is incredible (Pearson & Gillet 1996, pp. 210-290), but basically the production of Northern and Central European sausages is based on minced/ground meat and fat. The required amount of blended salts is added to pieces of meat and fat and mixed thoroughly with different spices, curing salt and other ingredients under vacuum using a bowl chopper, also called a silent cutter. Water may be added in the form of ice (to keep temperature down). The produced mass (emulsion or paste) is then stuffed in casings. The amount of nitrite and salt is controlled by the added amount of blends of salt (Budesheim 2011). Sausages may be left in the raw state to ferment, dry and mature, or they may be cooked in cooking cabinets, often in combination with smoking. In fermented sausages aromas are formed during the maturation process due to the present microorganisms. The sausages are sometimes smoked after the ripening process.

The production of dry Mediterranean small-diameter sausages with surface mould is also produced according to the principles above, but the drying stage is long and no fermentation takes place inside the sausage (Sanz *et al*. 1998). The surface is often inoculated with white mould. The product type is mentioned in connection with the regulation of *nitrate* in Directive 2006/52/EC.

Only sparse literature has been found regarding the manufacturing processes for the Central European sausages, and the literature search only revealed rather outdated literature in Polish or commercial reports and news which cannot be procured without a substantial fee (225 DKK per piece). However, judging from the pictures all the first products in this category are very similar, consisting of fermented raw sausages (Appendix A, 8.4). It is assumed that the manufacturing processes are also similar and the technological need for nitrite are the same (Nille 2012). In Guidance to food categories (2013), the first three products specified, Vysočina,

Selský salám, and Turistický trvanlivý salám, are described as “dried product cooked to 70°C followed by 8-12 day drying and smoking process”. The pictures of the products indicate that the products are uncooked, however. The reason for this apparent discrepancy is not known, but resolving it has no consequence for the present discussion.

The production process for Hungarian salami is closer to the Mediterranean dry sausages because there is a smaller drop in pH, a longer ripening method and the growth of white mould on the surface (Incze 1987).

3. The development in legislation on nitrite

3.1 Overview of permitted dosages of nitrite in Directive 2006/52/EC compared with present and past Danish legislation

It is no simple task to compare the list of permitted dosages of nitrite in the different products from Directive 2006/52/EC (section 2) with the products mentioned in the Danish Positive List of 2008 (now Bekendtgørelse nr. 542 (2013)). A major reason is that many special products are not comparable, another reason is that in Directive 2006/52/EC the limitations are in most cases on residual nitrite, while Danish legislation specifies in-going amounts. It should be adduced that the Danish Positive List from 2008 was superseded from 1 June 2013 by Bekendtgørelse nr. 542 (2013), but with regard to nitrate the specifications are exactly the same.

Before the implementation of Directive 2006/52/EC, EFSA made a similar comparison of the then valid Danish Positive List with the former Directive 95/EC. Directive 95/EC was not very detailed in its specifications; in general, permitted residual amounts were 100 mg/kg, with bacon as the exception, allowing 175 mg/kg nitrite. Directive 95/EC also specified “indicative ingoing amount” of 150 mg/kg nitrite for all meat products except bacon, where no limits were given. This concept, “indicative ingoing amount” is not maintained in Directive 2006/52/EC.

As clearly stressed by EFSA (2003) in their conclusion, only ingoing (added) amount of nitrite is relevant for assessing the antimicrobial effect of nitrite; therefore “control of nitrite in cured meat products should be via the input levels rather than the residual amount” (EFSA 2003). This recommendation is followed for sterilised meat products and for the Central European sausages (3.5), but not for traditionally immersion cured or dry cured products. Possible reasons for not specifying added amounts for these products are further discussed in section 3.5.

For meat products in general, a limitation on *ingoing* amount of KNO_2 (in molecular equivalent $NaNO_2$) is specified in Directive 2006/52/EC as 150 mg/kg.

Table 1 on the next page is an attempt of making a juxtaposition of the present legislation in the EU (except DK) with that of Denmark. This table will briefly be commented on the following pages.

Table 1. Limits of Na-nitrite (E250) in the EU legislation (2006/52/EC) and in Danish legislation (Positivlisten 2008 and Bekendtgørelse nr. 542 (2013))

EU product category	Maximum ingoing (added) amount (EU)	Maximum residual amount (EU)	Danish product category	Maximum ingoing (added) amount (DK)
Sterilised meat products (F_0 >3.00 min.)	100 mg/kg		"Helkonserverede produkter"	100 mg/kg
Traditional pickle cured products (1)				
Wiltshire bacon (1.1)		175 mg/kg	"Wiltshire bacon og udskæringer heraf"	150 mg /kg
Various Iberian bacon types (1.2)		175 mg/kg		
Wiltshire ham (1.1)		100 mg/kg		
Rohschinken, nassgepökelt (1.3)		50 mg/kg	"Spegeskinker"	150 mg /kg
Traditional dry cured products (2)				
Dry cured bacon (2.1)		175 mg/kg		
Dry cured ham (2.1)		100 mg/kg		
Various Iberian dry cured hams (2.2, 2.3)		100 mg/kg		
Rohschinken, trockengepökelt (2.5)		50 mg/kg	"Spegeskinker"	150 mg /kg
Other tradional cured products (3)				
Rohschinken, trocken-/nassgepökelt (3.1)		50 mg/kg	"Ikke-varmebehandlede kødprodukter fremstillet af hele kødstykker samt udskivede stykker heraf"	60 mg/kg
Jellied veal and brisket (3.2)		50 mg/kg	"Varmebehandlede do."	60 mg/kg
			"Rullepølse"	100 mg/kg
			"Leverpostej, kødboller"	0 mg/kg
			"Halvkonserverede produkter – hele kødstykker"	150 mg/kg
Various Central European sausages	180 mg/kg		"Ikke-varmebehandlede kødprodukter fremstillet af findelt kød samt udskivede stykker af produkterne"	60 mg/kg
Various Central European sausages	180 mg/kg		"Fermenterede spegepølser"	100 mg/kg
			"Varmebehandlede kødprodukter fremstillet af findelt kød samt udskivede stykker af produkterne"	60 mg/kg
			"Halvkonserverede produkter – findelt kød"	150 mg/kg

In brief, Table 1 shows that:

- For *heat sterilised products* the EU limit of 100 mg/kg on added nitrite is identical to the level specified in the Danish legislation.
- For *bacon* the EU limit of 175 mg/kg on residual nitrite is obviously higher than the DK limit of 150 mg/kg on added nitrite.
- 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, cf. section 1.3. *However, a strictly quantitative conversion from added to residual amount of nitrite is not possible*.
- For *raw fermented sausages*, the EU limit of 180 mg/kg on added nitrite for Central European sausages is obviously higher than the DK limit of 100 mg/kg on added nitrite for fermented sausages. However, Denmark also specifies a limit of 60 mg/kg for non-heat-treated comminuted meat, and a limit of 150 mg/kg for other (semi-preserved) non-heat-treated comminuted meat; both these catgories might also apply for raw sausages.
- For other heat-treated, but not sterilised meat products, the EU limit of 50 mg/kg on *residual* nitrite in jellied veal and brisket is probably the most relevant to compare with the Danish specifications on a number of different heat-treated products. These are:
    a. Products permitting 150 mg/kg added nitrite (semi-preserved products).
    b. Products permitting 100 mg/kg added nitrite ("rullepølse").
    c. Products permitting 60 mg/kg added nitrite ("varmebehandlede kødprodukter").
    d. Products where nitrite addition is not allowed ("leverpostej, kødboller").

It appears that for this kind of products the picture is quite confusing, and the belonging to group a and c is not entirely clear. Group d, "leverpostej, kødboller" is covered by a special exemption for certain traditional products given in Regulation (EC) 1333/2008, and this category *will therefore not be discussed further*.

A major reason for the discrepancies between the EU and DK legislation is that Directive 2006/52/EC in many cases specify residual amounts, while Denmark specifies added amounts of nitrite. The Danish National Provisions are in accordance with the recommendations by EFSA (2003), as stressed before. However, this is not the only reason, and to better understand the differences in limitations on added amounts, it is useful with a brief historical review of the changes in the legislation.

3.2 Changes in the allowed added level of nitrite in meat products in Denmark (1973-2008)

The Danish positive list concerning nitrite addition to meat products has changed over time since 1973 when the positive list was first introduced. The different meat products were not specified in the positive lists at the beginning, but later they were divided into subgroups. A summary of the changes in the positive list is given in table 2. The full changes over time in the positive list concerning nitrite and nitrate addition are found in appendix C.

Table 2. Summary of the Danish positive lists from 1973-2008 (Danske positivlister 1973-2008, The Danish Veterinary and Food Administration)

Positive lists from 1973-2008	Max. Nitrite addition ($NaNO_2$)	Products	Comments
1973-1974	100 mg/kg	Other meat products	
1975-1979	175 mg/kg	Other meat products	
1980-1981	100-175 mg/kg	Dependent on the type of meat products	
1983-1988	60-175 mg/kg	Dependent on the type of meat product. The addition of nitrite is more restricted; however it is for example still allowed to add 175 mg/kg in Wiltshire bacon (non-heat treated)	In 1983 it is no longer allowed to add nitrite to liver paste and meatballs
1989-2008	60-150 mg/kg	Dependent on the type of meat products	

In 1975-1979 it was allowed to add 175 mg/kg nitrite in unspecified meat products. From 1980, the limit value of nitrite was changed to 100-175 mg/kg depending on the type of meat product (Table 2). The study by Gry *et al.* (1983) discussed in the following contributed to another change in the 1980s, where the maximum amount of added nitrite in most meat products was set to 60 mg/kg. It was still allowed to add 175 mg/kg nitrite to Wiltshire bacon; however, this changed in 1989 to 150 mg/kg (Table 2, cf. also Table 1).

3.3 The Danish 1983 study on nitrite in commercially prepared products

In 1981, a working group was formed to carry out a project about the application of nitrite in Danish meat products. Employees from the Danish Food Institute (Statens Levnedsmiddelinstitut) and several meat processing plants in Denmark were represented in the group. Senior researcher Jørn Gry from the Institute of Toxicology (now part of DTU National Food Institute) was chairman of the group. The main objective was to collect sufficient background information of the use of nitrite in Danish meat products from a perspective of future negotiations of nitrite regulations.

The report was finished in 1983 and covered planning, implementation and results of the study of nitrite in Danish meat products (Gry *et. al.* 1983). The investigation covered 10 product types, and a total of 74 products were prepared with differing levels of nitrite and ascorbate. The effects of nitrite were studied, with the emphasis on shelf life and taste. The tested products were produced in full production scale using normal manufacturing procedures but varying nitrite and ascorbate levels. Zero, 50 or 100 mg/kg nitrite, and 0 or 250 mg/kg ascorbate were added to all meat products; only in sliced bacon a level of 150mg/kg nitrite was also tested.

Overall, it was found that many of the products with only 50mg/kg nitrite (added amount) were acceptable from the manufacturers point of view, both with regard to shelf life and taste. Only one product was found to be acceptable without the addition of nitrite (whole luncheon

sausage, cooked = *kødpølse*). It was also found that addition of 100 mg/kg added nitrite in some products (e.g. pork loaf = *rullepølse*) was recommendable (Gry *et al*. 1983, p. 150).

Sliced bacon was tested at levels of 50, 100 and 150 mg/kg. The results for sliced bacon were uneven, and all products except one did *not* live up to declared shelf-life (Gry *et al*. 1983, p. 142-143). The shorter shelf-lives observed were not clearly related to the levels of added nitrite, and the cause of the shorter shelf-lives was never clarified.

Based on the findings by Gry *et al.* (1983) the allowed levels of added nitrite were reconsidered in the Danish positive lists, and for many meat products only 60 mg/kg added nitrite was allowed from 1983 (Table 1). Furthermore, from 1983 it was no longer allowed to add nitrite to Danish liver paste (*leverpostej*) and meatballs. The study represents a milestone in the efforts of reducing the amount of nitrite in Danish meat products.

Wiltshire bacon was not included in the study with the argument that these products were almost exclusively for export (Gry *et al*. 1983, p. 15). This may explain why the limits for this product was maintained at 175 mg/kg until 1989 and then only lowered to 150 mg/kg.

The Danish positive list has not only changed considering the allowed level of added nitrite, but also with regard to the differentiation of meat products. Until 1980 the level of added nitrite was only described for "other meat products" and was not further explained. Over time, the different types of meat products has been divided into sub groups, and it is specified how much added nitrite is allowed in each group of meat products, as appears from Table 1.

3.4 The parallel development in EU legislation

In the first European Parliament and Council Directive 95/2/EC from 1995 on food additives other than colours and sweeteners, it was allowed to add an *indicated* amount of 150mg/kg nitrite to almost all meat products (non-heat-treated cured dried meat products, other cured meat products, and canned meat products). The residual amount of nitrite was also specified for some products; in general, it was allowed to have 50 mg/kg nitrite in non-heat-treated cured and dried meat products and 100 mg/kg in other cured meat products. The allowed residual amount of nitrite in cured bacon was 175 mg/kg (Honikel, 2008; Directive 95/2/EC).

In 2003 it was decided to reconsider these limits, and in the present Directive 2006/52/EC, the meat products became divided into large groups, as discussed in section 2: Sterilised meat products; traditional immersion cured meat products; traditional dry cured meat products; and other traditionally cured meat products. The indicated levels of added (ingoing) amounts were abandoned as a specifying principle. The specifications were now either given as added amounts or in most cases as residual amounts.

Thus, the levels specified in Denmark before 1983 (100-175 mg/kg) were roughly comparable with the overall indicated ingoing amounts of 150 mg/kg in Directive 95/2/EC. The later changes has meant a considerable decrease in allowed amounts in Denmark, while the only major change in the EU legislation seems to be a decrease in the added amounts for sterilised meat from 150 mg/kg to 100 mg/kg, which is identical to the level specified in the Danish National Provisions. *Heat sterilised products* are therefore not an issue.

For non-sterilised meat products Directive 2006/52/EC specifies, for example, that the allowed amount of added nitrite is 180 mg/kg for a designated number of Central European sausages. This level is slightly higher than the previous, general level of indicated amount (150 mg/kg). In practice, however, meat producers in the EU (outside Denmark) do not utilise the allowed levels for addtion of nitrite to their maximum. A desk study from 2012 dealing with the implementation of Directive 2006/52/EC concluded that "with some exceptions, the typical amount of nitrites added to non-sterilised meat products is lower than the EU maximum but higher than the Danish levels." (Final Report on a Desk Study 2012).

3.5 Specification of ingoing or residual amount of nitrite?

As mentioned in section 3.1, 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, as mentioned in section 1.2, 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.

For traditional immersion curing, such as it is employed for old-fashioned Wiltshire bacon, it is also difficult to assess the amount of nitrite which diffuses into the product, because the mass balance is not so simple as in e.g. sausages or canned products, and large concentration gradients in the beginning of the curing process are analytically challengning. This was amply demonstrated for several productions in the Danish 1983 study (Gry *et al.* 1983).

However, for the majority of cured products, including canned meat and sausages it is technically not difficult to assess the ingoing amount of nitrite:

- For *canned meat* there is no volume change during the production, and the containment of the product means that there is no possible transfer of salt after the can has been closed.
- For all products produced by *stich salting* (injection curing) there is usually a volume and weight increase, because the salt increases the water binding capacity of the meat and thereby allows the meat to absorb the added water with the brine. In general, the process aims at securing that all injected brine stays in the final product. However, many stich-salted whole meat products are further processed using immersion curing, as specified in the product footnotes in Directive 2006/52/EC, page 17 and in Guidance to food categories. This is commented further below.
- For *fermented sausages* there is usually a volume and weight decrease because of drying, but there is no transfer of salt across the casing after stuffing the initially dry salted meat into the casing. So, dosage of nitrite can be calculated, either on ingoing product weight or on final product weight basis.
- The above considerations also applies for *heat-treated sausages*.
- For other products that are heat treated after curing, these are usually also contained in a casing, and no transfer of salt is intended. Thus, the same considerations apply as for sausages.

One of the problems with the product list in Directive 2006/52/EC is that it does not distinguish between stich-salted (injection-cured) and immersion-cured products with respect to specifications on the limitations on nitrite level. For products that are injection-cured followed by immersion curing it should in principle be possible to specify that nitrite is added in the injection step and that the subsequent immersion curing is performed with pure salt brine. The disadvantage is, of course, that some nitrite may diffuse back into the immersion brine.

4. Discussion

The review of the technological function of nitrite (section 1) led to the tentative first conclusion that the technological objectives (colour stabilisation, flavour enhancement, antioxidative effect) for using nitrite can be accomplished within the range of 50-100 mg/kg, which is recommended by EFSA as sufficient in general to protect against possible toxin formation from *C. botulinum* (EFSA 2003).

The presentation of the production technologies (section 2) together with the information in table 1 allows a number of additional partial conclusions with respect to the possible technological need for the levels of nitrite specified in Directive 2006/52/EC. The different product categories will be discussed in the following.

4.1 Sterilised meat products

As mentioned above the EU limit of 100 mg/kg on ingoing nitrite is identical to the DK legislation. It complies with the recommended level on ingoing nitrite of 50-100 mg/kg (EFSA 2003). It also complies with the general recommendation that levels should be specified on ingoing amounts, rather than on residual amounts (EFSA 2003).

4.2 Traditionally cured products (both pickle cured and dry cured)

Regardless of the production methods the levels specified in Directive 2006/52/EC are the same for the same type of product, but differ with the product. There are three product categories mentioned, bacon, cured ham and *Rohschinken*.

For *bacon* the EU limit of 175 mg/kg on residual nitrite is obviously higher than the DK limit of 150 mg/kg on ingoing nitrite. We have not come across studies documenting that bacon may need higher than 100 mg/kg ingoing amount of nitrite for flavour reasons, but as discussed in section 3.3. the results of the Danish 1983 study were inconclusive for the particular bacon type tested (sliced bacon). To get a better assessment of the possible need for higher than 100 mg/kg ingoing amount of nitrite in bacon would require more extensive studies and in particular discussions with industry.

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. It is outside the assignment to investigate documentations on the contribution to the dietary exposure of nitrosamines from bacon relative to the total exposure; however, an estimation of the exposures appear from a Danish PhD study (Hermann 2014).

The two last products, cured ham and *Rohschinken* are essentially the same, using the same parts of the pig and using more or less the same production methods. There are, of course, differences in residual water and salt concentration in the products, and there are examples of traditionally produced dry cured hams with a very high residual salt content (Vestergaard *et al*. 2005; Troeger *et al*. 2007). There is no immediate technological explanation for the fact that the EU limit for *Rohschinken* is 50 mg/kg residual nitrite, while it is 100 mg/kg for other cured hams. Resolving this question would require more extensive studies and in particular discussions with industry and researchers who are experts in the traditional cured hams. No strictly quantitative conversion from ingoing to residual amount of nitrate is possible, and as discussed in section 3.5, the production methods for several of these products may make it meaningless to specify limits on ingoing amounts of nitrite.

4.3 Other traditionally cured products

For *Rohschinken, trocken-/nassgepökelt* the EU limit is the same as for other *Rohschinken*, namely 50 mg/kg on residual nitrite, cf. above.

For *jellied veal and brisket* there are no obvious technological reasons for the EU limit of 50 mg/kg on *residual* nitrite instead of specifying an ingoing amount of probably 100 mg/kg. The product is a British speciality, and a further clarification of the matter cannot be made without discussions with the British meat industry.

For *raw fermented sausages of Central European origin*, the EU limit of 180 mg/kg on ingoing nitrite is obviously higher than the DK limit of 100 mg/kg on ingoing nitrite for fermented sausages. It is also higher than the original indicated level of 150 mg/kg ingoing nitrite specified in the previous Directive 95/2/EC . Arguments for maintaining this high level of 180 mg/kg are lacking in the available literature. On the basis of what can be deduced with respect to the manufacturing processes for these products, it is hard to conceive of substantial arguments for the level of 180 mg/kg, except perhaps for reasons of obtaining a particular flavour. However, as documented in the Danish 1983 study, it is possible without negative effects on quality for similar products to lower the levels of nitrite from those conventionally applied, down to levels of 50 to 100 mg/kg (Gry *et al*. 1983).

As discussed in section 3.1 the EU limit of 50 mg/kg on *residual* nitrite in heat treated comminuted and/or whole meat products, such as jellied veal and brisket, should be juxtaposed with the first three groups of different heat-treated products mentioned in the Danish Positive List:

a. Products permitting 150 mg/kg added nitrite (“halv- og helkonserverede produkter”).
b. Products permitting 100 mg/kg added nitrite (“rullepølse”).
c. Products permitting 60 mg/kg added nitrite (“varmebehandlede kødprodukter”).

For the rather unspecified category “halv- og helkonserverede produkter” the Danish Positive List allows a level of ingoing nitrite *above* the recommended level of 50-100 mg/kg (EFSA 2003). The background for this and a further clarification of the matter cannot be made without discussions with the Danish meat industry.

5. Conclusions

In many ways the Danish National Provisions position regarding nitrite have a strong scientific foundation. Most of the Danish product categories comply with EFSA's recommended ingoing nitrite level of 50-100 mg/kg (EFSA 2003). However, there is an issue regarding bacon and the above-mentioned unspecified products where Danish legislation allows 150 mg/kg.

The general position of EFSA is that specifications should be on ingoing amount of nitrite and not on residual amount. This is a principle also shared by Danish legislation. However, as discussed in section 3.5, this principle is difficult to uphold for in particular dry cured whole meat, because the particularities of the production methods make such a quantification rather uncertain.

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7. Appendix A: Directive 2006/52/EC, pp. 15-17

'E No	Name	Foodstuff	Maximum amount that may be added during manufacture (expressed as $NaNO_2$)	Maximum residual level (expressed as $NaNO_2$)
E 249	Potassium nitrite (x)	Meat products	150 mg/kg	
E 250	Sodium nitrite (x)	Sterilised meat products (Fo > 3,00) (y)	100 mg/kg	
		Traditional immersion cured meat products (1): *Wiltshire bacon* (1.1); *Entremeada, entrecosto, chispe, orelheira e cabeça (salgados)* *Toucinho fumado* (1.2); and similar products		175 mg/kg
		Wiltshire ham (1.1); and similar products		100 mg/kg
		Rohschinken, nassgepökelt (1.6); and similar products		50 mg/kg
		Cured tongue (1.3)		
		Traditional dry cured meat products (2): *Dry cured bacon* (2.1); and similar products		175 mg/kg
		Dry cured ham (2.1); *Jamón curado, paleta curada, lomo embuchado y cecina* (2.2); *Presunto, presunto da pá* and *paio do lombo* (2.3); and similar products		100 mg/kg
		Rohschinken, trockengepökelt (2.5); and similar products		50 mg/kg
		Other traditionally cured meat products (3): *Vysočina* *Selský salám* *Turistický trvanlivý salám* *Poličan* *Herkules* *Lovecký salám* *Dunajská klobása* *Paprikáš* (3.5); and similar products	180 mg/kg	
		Rohschinken, trocken-/nassgepökelt (3.1); and similar products *Jellied veal and brisket* (3.2)		50 mg/kg

E No	Name	Foodstuff	Maximum amount that may be added during manufacture (expressed as $NaNO_2$)	Maximum residual level (expressed as $NaNO_2$)
E 251 E 252	Potassium nitrate (z) Sodium nitrate (z)	Non-heat-treated meat products	150 mg/kg	
		Traditional immersion cured meat products (1):		
		Kylmäsavustettu poronliha/*Kallrökt renkött* (1.4);	300 mg/kg	
		Wiltshire bacon and *Wiltshire ham* (1.1); *Entremeada, entrecosto, chispe, orelheira e cabeça (salgados)*, *Toucinho fumado* (1.2); *Rohschinken, nassgepökelt* (1.6); and similar products		250 mg/kg
		Bacon, Filet de bacon (1.5); and similar products		250 mg/kg without added E 249 or E 250
		Cured tongue (1.3)		10 mg/kg
		Traditional dry cured meat products (2): *Dry cured bacon* and *Dry cured ham* (2.1); *Jamón curado, paleta curada, lomo embuchado y cecina* (2.2);		250 mg/kg
		Presunto, presunto da pá and *paio do lombo* (2.3); *Rohschinken, trockengepökelt* (2.5); and similar products		
		Jambon sec, jambon sel sec et autres pièces maturées séchées similaires (2.4)		250 mg/kg without added E 249 or E 250
		Other traditionally cured meat products (3): *Rohwürste (Salami* and *Kantwurst)* (3.3);	300 mg/kg (without added E 249 or E 250)	
		Rohschinken, trocken-/nassgepökelt (3.1); and similar products		250 mg/kg
		Salchichón y chorizo tradicionales de larga curación (3.4); *Saucissons secs* (3.6); and similar products	250 mg/kg (without added E 249 or E 250)	
		Jellied veal and brisket (3.2);		10 mg/kg

E No	Name	Foodstuff	Maximum amount that may be added during manufacture (expressed as $NaNO_2$)	Maximum residual level (expressed as $NaNO_2$)
		Hard, semi-hard and semi-soft cheese	150 mg/kg in the cheese milk or equivalent level if added after removal of whey and addition of water	
		Dairy-based cheese analogue		
		Pickled herring and sprat	500 mg/kg	

(x) When labelled "for food use", nitrite may be sold only in a mixture with salt or a salt substitute.

(y) 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).

(z) Nitrates may be present in some heat-treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment.

1 Meat products are immersed in curing solution containing nitrites and/or nitrates, salt and other components. The meat products may undergo further treatments e.g. smoking.

1.1 Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures.

1.2 Immersion cured for 3 to 5 days. Product is not heat-treated and has a high water activity.

1.3 Immersion cured for at least 4 days and pre-cooked.

1.4 Meat is injected with curing solution followed by immersion curing. Curing time is 14 to 21 days followed by maturation in cold-smoke for 4 to 5 weeks.

1.5 Immersion cured for 4 to 5 days at 5 to 7 °C, matured for typically 24 to 40 hours at 22 °C, possibly smoked for 24 hrs at 20 to 25 °C and stored for 3 to 6 weeks at 12 to 14 °C.

1.6 Curing time depending on the shape and weight of meat pieces for approximately 2 days/kg followed by stabilisation/maturation.

2 Dry curing process involves dry application of curing mixture containing nitrites and/or nitrates, salt and other components to the surface of the meat followed by a period of stabilisation/maturation. The meat products may undergo further treatments e.g. smoking.

2.1 Dry curing followed by maturation for at least 4 days.

2.2 Dry curing with a stabilisation period of at least 10 days and a maturation period of more than 45 days.

2.3 Dry cured for 10 to 15 days followed by a 30 to 45 day stabilisation period and a maturation period of at least 2 months.

2.4 Dry cured for 3 days + 1 day/kg followed by a 1 week post-salting period and an ageing/ripening period of 45 days to 18 months.

2.5 Curing time depending on the shape and weight of meat pieces for approximately 10 to 14 days followed by stabilisation/maturation.

3 Immersion and dry cured processes used in combination or where nitrite and/or nitrate is included in a compound product or where the curing solution is injected into the product prior to cooking. The products may undergo further treatments e.g. smoking.

3.1 Dry curing and immersion curing used in combination (without injection of curing solution). Curing time depending on the shape and weight of meat pieces for approximately 14 to 35 days followed by stabilisation/maturation.

3.2 Injection of curing solution followed, after a minimum of 2 days, by cooking in boiling water for up to 3 hours.

3.3 Product has a minimum 4-week maturation period and a water/protein ratio of less than 1,7.

3.4 Maturation period of at least 30 days.

3.5 Dried product cooked to 70 °C followed by 8 to 12 day drying and smoking process. Fermented product subject to 14 to 30 day three-stage fermentation process followed by smoking.

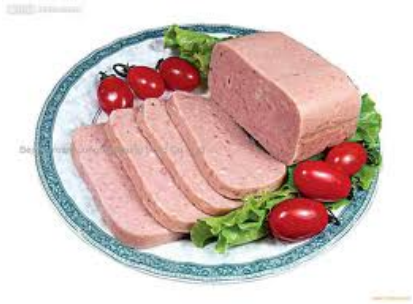
3.6 Raw fermented dried sausage without added nitrites. Product is fermented at temperatures in the range of 18 to 22 °C or lower (10 to 12 °C) and then has a minimum ageing/ripening period of 3 weeks. Product has a water/protein ratio of less than 1,7.';

8. Appendix B: Products listed in 2006/52/EC, pp. 15-17

The different pictures were found by searching on the internet.

8.1 Sterilised to F_0 = 3 min.

Luncheon meat:



SPAM:

Canned whole pork (foreleg):

8.2 Traditional immersion cured meat products (1):

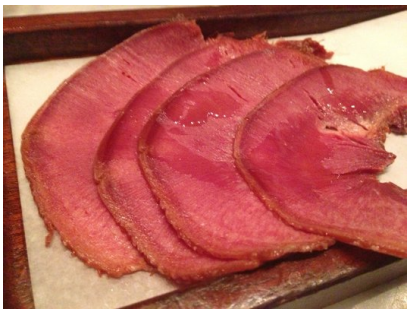
Wiltshire bacon (1.1):

Toucinho fumado (1.2):

Wiltshire ham (1.1):

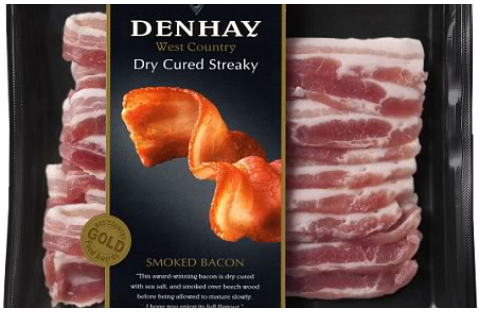
Rohschinken (1.6):

Cured tongue (1.3):



8.3 Traditional dry cured meat products (2):

Dry cured bacon (2.1):



Dry cured ham (2.1):

Jamon curado, Paleta curada, lomo embuchado y cecina (2.2):

Presunto, presunto da pá, paio do lombo(2.3):

Trochengepökelt (2.5):

8.4 Other traditionally cured meat products (3):

8.4.1 Jellied veal and brisket (3.2):

8.4.2 Central European sausages (3.5)

(see next page)

Vysočina, Selský salám, Turistický trvanlivý salám, Poličan, Lovecký salám, Dunajská klobása:

Paprikáš:

9. Appendix C: Danish positive list 1973-2008

For Nitrite and Nitrate

Year	Product	Nitrite max ingoing amount	Nitrite max residual amount	Notes	Nitrate max ingoing amount
1973	hest, stort kvæg, kalv, får, lam, geder, svin, kaniner og fjerkræ	100mg/kg			
1973	Andre kødvarer	100mg/kg i form af nitritsalt			500mg/kg
1974	Andre kødvarer	100mg/kg i form af nitritsalt			50mg/kg
1975	Andre kødvarer	175mg/kg i form af nitritsalt (NaNO2)	100mg/kg for helkonserves, dog 75mg/kg som NaNO2)		500mg/kg
1976	Andre kødvarer	175mg/kg i form af nitritsalt (NaNO2)	75mg/kg for helkonserves, dog 25mg/kg som NaNO2		500mg/kg

1977	Andre kødvarer	175mg/kg i form af nitritsalt (NaNO2)	75mg/kg for helkonserves, dog 25mg/kg som NaNO2		500mg/kg
1979	Andre kødvarer	175mg/kg i form af nitritsalt (NaNO2)	75mg/kg for helkonserves, dog 25mg/kg som NaNO2		500mg/kg
1980	Wiltshire bacon og udskæringer heraf	175mg/kg i form af nitritsalt (NaNO2)			500mg/kg
	farsvarer og spegepølse	100mg/kg i form af nitritsalt			
	andre saltede kødvarer	150mg/kg i form af nitritsalt			
	konserves, dog ikke konserves, der er botulinumkogt	150mg/kg i form af nitritsalt			
1981	Wiltshire bacon og udskæringer heraf	175mg/kg i form af nitritsalt (NaNO2)			
	farsvarer og spegepølse	100mg/kg i form af nitritsalt			

	andre saltede kødvarer	150mg/kg i form af nitritsalt			500mg/kg
	konserves, dog ikke konserves, der er botulinumkogt	150mg/kg i form af nitritsalt			
1983	Saltede/røgede hele kødstykker og udskivede produkter heraf	60mg/kg			ingen information
	spegepølse, salami o.l.	60mg/kg,			
	fermenterede spegepølser	100mg/kg			
	kølekonserves, kødstykker	150mg/kg			
	kølekonserves, farsvarer	150mg/kg		ikke til leverpostej og kødboller	
	pålægspølser	60mg/kg			
1985	Saltede/røgede hele kødstykker og udskivede produkter heraf	60mg/kg			
	spegepølse, salami o.l.	60mg/kg,			
	fermenterede spegepølser	100mg/kg			
	kølekonserves, kødstykker	150mg/kg			
	kølekonserves, farsvarer	150mg/kg		ikke til leverpostej og	

				kødboller	
	pålægspølser	60mg/kg			
	Andre kødprodukter end konserves fremstillet af kødstykker (og udskivede produkter af disse)	60mg/kg			
	rullepølse	100mg/kg			
	Andre kødprodukter end konserves fremstillet af kødfars	60mg/kg		ikke til leverpostej og kødboller	
	helkonserves fremstillet af kødstykker	150mg/kg		dog ikke til botulinumkogte produkter	
	helkonserves fremstillet af kødfars	150mg/kg		dog ikke til botulinumkogte produkter	
	Wiltshire bacon og udskæringer heraf	175mg/kg			500 mg/kg
	spegeskinker (varmebehandlet og ikke-varmebehandlet)	175mg/kg			
1988	Saltede/røgede hele kødstykker og udskivede produkter heraf	60mg/kg			
	spegepølse, salami o.l.	60mg/kg,			

	fermenterede spegepølser	100mg/kg			
	kølekonserves, kødstykker	150mg/kg			
	kølekonserves, farsvarer	150mg/kg		ikke til leverpostej og kødboller	
	pålægspølser	60mg/kg			
	Andre kødprodukter end konserves fremstillet af kødstykker (og udskivede produkter af disse)	60mg/kg			
	rullepølse	100mg/kg			
	Andre kødprodukter end konserves fremstillet af kødfars	60mg/kg		ikke til leverpostej og kødboller	
	helkonserves fremstillet af kødstykker	150mg/kg		dog ikke til botulinumk ogte produkter	
	helkonserves fremstillet af kødfars	150mg/kg		dog ikke til botulinumk ogte produkter	
	Wiltshire bacon og udskæringer heraf	175mg/kg			500mg/kg
	spegeskinker (varmebehandlet og ikke-varmebehandlet)	175mg/kg			
1995	?				?
1997	?				?
2000					?
2002					?

2005	varmebehandlede kødprodukter fremstillet af hele kødstykker samt udskivede stykker heraf	60mg/kg			
	rullepølse	100mg/kg			
	halv og helkonserverede produkter	150mg/kg			
	Wiltshire bacon og udskæringer heraf	150mg/kg			300mg/kg
	spegeskinker	150mg/kg			300mg/kg
	ikke-varmebehandlede kødprodukter fremstillet af findelt kød samt udskivede stykker af produkterne	60mg/kg			
	fermenterede spegepølser	100mg/kg			
	halv og helkonserverede produkter	150mg/kg			
	varmebehandlende kødprodukter fremstillet af findelt kød sam udskivede stykker af produkterne	60mg/kg		ikke til leverpostej og kødboller	
	til halv-og helkonserverede produkter	150mg/kg			

2008	ikke-varmebehandlede kødprodukter fremstillet af hele kødstykker samt udskivede stykker af produkterne	60mg/kg			150mg/kg
	Wiltshire bacon og udskæringer heraf	150mg/kg			
	spegeskinker	150mg/kg			
	varmebehandlede kødprodukter fremstillet af hele kødstykker samt udskivede stykker heraf	60mg/kg			
	rullepølse	100mg/kg			
	halv og helkonserverede produkter	100mg/kg			
	spegeskinker	150mg/kg			
	Wiltshire bacon og udskæringer heraf	150mg/kg			
	ikke-varmebehandlede kødprodukter fremstillet af findelt kød samt udskivede stykker af produkterne	60mg/kg			
	fermenterede spegepølser	100mg/kg			

	halv og helkonserverede produkter	150mg/kg			
	varmebehandlende kødprodukter fremstillet af findelt kød sam udskivede stykker af produkterne	60mg/kg		ikke til kødboller og leverpostej	
	halv og helkonserverede produkter	150mg/kg			

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