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**Guidance on the Revised Provisions on Nitrites/Nitrates in Meat Products set out in The Miscellaneous Food Additives and Sweeteners in Food (Amendment) (England) Regulations 2007 and parallel regulations in Scotland, Wales and Northern Ireland.**

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## Summary

<b>Intended audience:</b>	Manufacturers and retailers of meat products, enforcement authorities.
<b>Regional coverage:</b>	UK
<b>Legal status:</b>	This guidance is to accompany The Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007 and parallel regulations in Scotland, Wales and Northern Ireland.
<b>Purpose:</b>	Guidance on the revised provisions on nitrates/nitrates in meat products set out in The Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007 and parallel regulations in Scotland, Wales and Northern Ireland.

## REVISION HISTORY

Revision No.	Revision date	Purpose of revision	Revised by
1	October 2008	Draft Guidance	Glynis Griffiths (FSA)

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## REGULATIONS REFERRED TO IN THIS GUIDANCE

These Guidance Notes cover separate but parallel regulations in all four countries of the UK.

Details are below of how the regulations are referred to in the text, plus the full name and number of the respective regulation in each country. A summary of these regulations by country is in Annex A.

### **The Miscellaneous Food Additives and the Sweeteners in Food (Amendment) Regulations 2007**

The Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007 No. 1778

The Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (Wales) Regulations 2008 No. 138 (W. 20)

The Miscellaneous Food Additives and the Sweeteners in Food Amendment (Scotland) Regulations 2007 No. 412

The Miscellaneous Food Additives and the Sweeteners in Food (Amendment) Regulations (Northern Ireland) 2007 No. 325

## INTENDED AUDIENCE

1. These guidance notes are intended for manufacturers and retailers of meat products, and for enforcement authorities.

## PURPOSE AND LEGAL STATUS

2. These guidance notes have been produced to provide informal, non-binding advice on the legal requirements of The Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007 and parallel regulations in Scotland, Wales and Northern Ireland and should be read in conjunction with the legislation itself. The text should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power. Every effort has been made to ensure that these guidance notes are as helpful as possible. However, it is ultimately the responsibility of individual businesses to ensure their compliance with the law. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards/environmental health department of the local authority.

## INTRODUCTION

3. The notes in this section cover only those aspects of the above legislation that are specific to the use of nitrites and nitrates in meat products. (E249 potassium nitrite, E250 sodium nitrite, E251 sodium nitrate and E252 potassium nitrate).
4. The Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007 (“the Regulations”), which implement European Council and Parliament Directive 2006/52/EC amending Directive 95/2/EC for the sixth time, came into force on 25 July 2007. (Similar legislation exists in Scotland, Wales and NI). Food additives legislation can be accessed on the European Commission's website at the following address:  
[http://www.europa.eu.int/comm/food/food/chemicalsafety/additives/index\\_en.htm](http://www.europa.eu.int/comm/food/food/chemicalsafety/additives/index_en.htm)
5. The legislation amends the existing provisions in Schedule 2 Part C of the Miscellaneous Food Additives Regulations 1995 (as amended) to introduce a reduction in the authorised levels for nitrites and nitrates in meat and other food products, which takes account of the opinion of the European Food Safety Authority (EFSA), published on 26 November 2003 and aims to keep

levels of nitrosamines as low as possible whilst maintaining the microbiological safety of food products.

6. In addition, in line with EFSA's recommendations, controls on the level of nitrites and nitrates in meat products, are in future to usually be based on added rather than residual amounts. However, during Brussels discussions on the legislation, Member States recognised that a degree of compromise was required in order to achieve the objective of further controls on the use of nitrates and nitrites in most meat products, whilst allowing the continued production of certain traditional products. These compromises, which include provisions which permit traditional UK meat products such as Wiltshire cured ham, bacon and similar products to be produced based on residual amounts, are contained within the new legislation.
7. The legislation includes transitional provisions permitting food containing nitrites and nitrates that do not comply with the legislation to continue to be marketed until 15 August 2008, provided these products comply with the provisions in previous miscellaneous food additives legislation. In addition, existing stocks which do not comply with the Regulations and which have been placed on the market or labelled before 15 August 2008, can be marketed until they are exhausted. After this date, no new foods containing nitrites/nitrates can be placed on the market unless they conform to the requirements of the Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007.

## GENERAL STRUCTURE OF THE LEGISLATION

8. Other than certain traditional products, the legislation limits the use of potassium and sodium nitrite in meat products to a maximum amount added of 150 mg/kg, and in sterilised meat products ( $F_0 > 3$ ), to 100 mg/kg. The use of potassium and sodium nitrate is permitted only in non-heat-treated meat products, to a maximum amount added of 150 mg/kg, although nitrates may be present in some heat treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment. The limits for both nitrites and nitrates relate to the maximum amount that may be added during the manufacture of the product i.e. ingoing limits.
9. The traditional meat products for which derogations have been requested by EU Member States, which include categories for six traditional UK meat products, are listed in italics, which indicates they are Member States' national products. They are grouped under three headings:

- **traditional immersion cured meat products**, including *Wiltshire bacon* and *Wiltshire ham* and similar products and *cured tongue*;
  - **traditional dry cured meat products**, including *dry cured bacon* and *dry cured ham* and similar products; and
  - **other traditionally cured meat products**, which includes *jellied veal and brisket*.
10. For traditional products, the limits for both nitrites and nitrates relate to the maximum residual levels permitted in finished products.
11. Footnotes in the legislation specify in detail the manufacturing method for each of these traditional products. When interpreting the legislation, the information in the footnotes for each specific product should be read in conjunction with the general description for the type of product. For example, to meet the specification for *Wiltshire bacon*, the product would need to comply with:
- the description at footnote 1 for traditional immersion cured meat products (i.e. it would need to be immersed in curing solution containing nitrites and/or nitrates, salt and other components, and it may also undergo further treatments e.g. smoking); **AND**
  - the manufacturing process for *Wiltshire bacon* at footnote 1.1 (i.e. it would need to be injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution includes microbiological starter cultures).

## TRADITIONAL PRODUCTS WHICH DO NOT FIT INTO ANY NAMED CATEGORY

12. Only certain types of traditional products are specifically referred to in the legislation. If a product does not meet the requirements for any named product (allowing for “similar products” explained below), it then defaults to a general category e.g. “meat product” or “non-heat-treated meat product” and the maximum ingoing permitted levels should be used.

### “SIMILAR PRODUCTS”

13. The Directive contains the words “and similar products” against many, but not all, of the categories for which derogations have been granted. The Directive does not define similar products and currently there are no decisions by the EU Standing Committee or by a Court. The overall intention of the legislation is to reduce the use of nitrites and nitrates so the Council and European Parliament saw the derogations for certain traditional products as being of a limited nature, and the Parliament in particular wished to see the footnotes include specifications which limit the named derogations. With this background, we consider that a similar product:
  - will closely resemble the product named (but may obviously have a different name);
  - has been traditionally produced;
  - has been produced using the same stages as described in the footnotes, though there may be some variation in the times and temperatures cited in the footnotes.
14. To be 'traditionally produced' we consider a product needs to have been produced for more than 25 years at the time EC Directive 2006/52 came into force (ie since before September 1981). Traditional is not defined within EC Directive 2006/52 and it is ultimately for a Court to decide the interpretation. We have suggested it should be taken to be of the order of 1 generation / 25 years, which would be in line with Regulation (EC) No 509/2006 of 20 March 2006 on Agricultural Products and Foodstuffs as Traditional Specialities Guaranteed, that introduced a legal definition of the term “traditional”, specifically for the purpose of the regulation. This definition requires a period of 25 years for production/recipe for a traditional food that is registered under the Scheme.

## DRY CURED HAM

15. The 'dry cured ham' produced in the UK, which is different to that produced elsewhere in the EU, is defined by way of the manufacturing process at footnote 2.1. The process used must comply with that stipulated in the footnote; otherwise the product will default into the relevant general meat product category.

## WILTSHIRE BACON/HAM

16. Whilst no definition of Wiltshire cure has been included in the legislation, the manufacturing process for Wiltshire cured ham and bacon is defined in footnote 1.1. The use of 'live' immersion brines is the main distinguishing factor between Wiltshire and other cures.
17. Footnote 1.1 states that the immersion brine solution includes microbiological starter cultures. We do not consider it is necessary for a culture to be added prior to each immersion; the culture may well be present, as it traditionally was, from previous use of the immersion solution. The micro-organisms present perform the function of reducing added nitrate to nitrite which then goes on to become the active curing compound.

## CURE-IN-THE-BAG PRODUCTS

18. Cure-in-the-bag products are injected with curing solution, and not immersed, and it is possible to accurately regulate the ingoing amount of curing solution. This type of product therefore falls under the general meat products category and not in the derogations for traditional immersion cured meat products.

## NON-HEAT-TREATED MEAT PRODUCTS

19. Sodium and potassium nitrates are permitted to be added to non-heat treated products. In its proposal the European Commission considered that the use of nitrate would not be necessary in products which have been heat treated to the extent that any bacteria have been destroyed. It follows therefore that the relevance of any heat treatment and the use of nitrates needs to take into account the stage in which the heat treatment is applied and the effectiveness of any heat treatment (temperature and time). For example, a piece of bacon or ham is cooked before consumption (and possibly before

purchase); however this level of heat treatment could not be considered to negate the need for nitrates at the earlier stages of preparation.

20. Cooked bacon and ham should therefore be classified as “non heat-treated products”. In the case of bacon, this would apply to both heat set bacon (briefly cooked at circa 50 °c in order to partially heat-set some of the protein in order to aid slicing) and to cured bacon that is cooked prior to addition to a sandwich.
21. Permitted levels of nitrates will depend on whether the product in question falls into the general (non-heat treated) meat product category (permitted up to 150 mg/kg) or into one of the traditional categories e.g. Wiltshire bacon/ham (permitted up to 250 mg/kg) or cured tongue (permitted up to 10 mg/kg).
22. Products that should be considered as “heat treated” include many products which are cooked after canning.
23. If a non-heat treated meat product is used as an ingredient in a compound food (e.g the cooked bacon in a BLT sandwich), the presence of nitrate would be permitted in the compound product up to the limit permitted for the non-heat treated product under the ‘carry over’ provision for compound foods in the legislation.

## BACON, FILET DE BACON

24. The entry for ‘*Bacon, Filet de bacon*’ refers to a traditional French product and is not the same as standard bacon. Hence, the maximum permitted level (250 mg/kg residual, without added E249 or E250) only applies to this and similar products.

## CONVERSION FACTOR FOR POTASSIUM SALTS

25. All levels given in the legislation are for the sodium salts. Conversion factors for the equivalent potassium salts are:

To convert sodium nitrite to potassium nitrite: multiply by 1.23

To convert sodium nitrate to potassium nitrate: multiply by 1.19

26. For example the maximum amount of sodium nitrite which can be added to sterilised meat products is 100 mg/kg, which is equivalent to 123 mg/kg potassium nitrite. And the maximum amount of sodium nitrate which can be added to non-heat treated meat products is 150 mg/kg, which is equivalent to 178 mg/kg potassium nitrate.

## VEGETABLE EXTRACT NITRITES

27. The indirect addition of nitrates to foods via extracts of vegetables such as spinach or celery should be considered an additive use, and not a food use (i.e. the extract is being added for preservation as it contains a standardised level of nitrate) and consequently such use would not be permitted by Directive 95/2/EC as these extracts have not been approved as preservatives.

## ANNEX A: SUMMARY OF REGULATIONS BY UK COUNTRY

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### **England**

The Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007 No. 1778

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