

AUDIT
REPORT

Supply and Use of Food
Additives in Meat Products
and Meat Preparations

JUNE 2014



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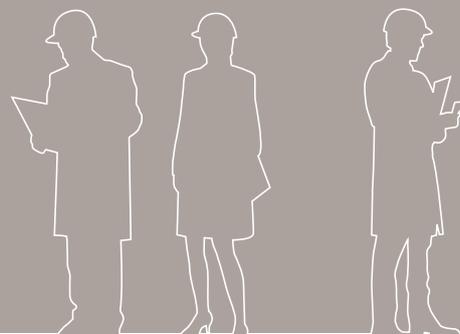


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1. GLOSSARY

BRC	British Retail Consortium
DAFM	Department of Agriculture, Food and the Marine
EHS	Environmental Health Service
FIAP	Food Improvement Agents Package
FSAI	Food Safety Authority of Ireland
HSE	Health Service Executive

2. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) recently completed an audit of food business operators to assess the appropriateness and use of food additives such as nitrites, sulphites, phosphates and colours in meat products and meat preparations. The audit was also used as an opportunity to assess compliance with relevant legislation.

The audit consisted of 16 onsite inspections made up of five local authority supervised premises, four Department of Agriculture, Food and the Marine (DAFM) supervised premises and seven Health Service Executive (HSE)/Environmental Health Service (EHS) supervised premises. The food business operators were selected randomly and were provided with individual reports following the audit of their businesses. These reports were copied to the relevant agency. Verification of the implementation of corrective action to address audit findings is carried out by the official agencies as part of routine official controls.

The FSAI invited personnel from all the relevant supervising official agencies to attend the audit. DAFM and the local authorities attended the audits while the EHS/HSE did not attend.

European food additives legislation (Regulation (EC) No 1333/2008) sets out the additives that may be used in foods, the categories of foods in which they may be used and establishes the maximum levels permitted in those foods. Under this legislation, a limited number of additives are permitted in meat products and meat preparations. The details of the authorised uses are given in Annex II of the Regulation. The authorised additives are used for several different technological purposes in meat products and preparations, e.g. as preservatives.

The audit found that a general improvement in the understanding and knowledge of the legislation on additives and the general labelling requirements is required in some food business operators.

The majority of food business operators audited could identify one step back in the food chain, i.e. where the meat/ingredients delivered to their business came from. However, in terms of complying with their own food safety management or traceability systems, the audit identified a number of gaps and lack of conformance with their own procedures, although this does not necessarily represent a legislative non-compliance.

The majority of food business operators provided customers with information regarding the origin of meat products and preparations.

In relation to approved food business operators audited, all products examined, except one included the appropriate approval numbers as required by Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin. It should be noted that the approval mark on a label does not denote origin; it simply indicates the last place of processing/packaging which may or may not be the country of origin. It does not guarantee that the country of origin of the product was Ireland, i.e. where IE is on the approval mark. Some of the food business operators audited made statements regarding sourcing ingredients and/or meat locally. Whilst sourced from local suppliers, some of the meat product/preparations originated from other Member States, a finding previously made in [a 2013 FSAI audit of labelling and traceability of poultry meat in retail and catering establishments](#).

3. INTRODUCTION

The FSAI has overall responsibility for the enforcement of food law in Ireland, which is carried out predominantly through service contracts with official agencies. Under the provisions of the FSAI Act and as part of this contract arrangement, the FSAI carries out targeted audits of food businesses to determine the level of compliance with a specific piece of food law and the effectiveness of its enforcement.

An audit to assess the appropriateness and use of food additives such as nitrites, sulphites, phosphates and colours in meat products and meat preparations in meat manufacturers, ingredient suppliers and retail outlets, was undertaken by the FSAI as part of the 2013 planned programme of targeted audits.

Food additives have been regulated in the EU for many years under the Framework Directive 89/107/EEC and by Directives 94/35/EC on sweeteners, 94/36/EC on colours and 95/2/EC on food additives other than colours and sweeteners. The EC legislation on food additives was updated in 2008, together with that on flavouring substances. At the same time, new legislative requirements were introduced for use of enzymes in food. This created a comprehensive legislative package, comprising three individual Regulations on food enzymes (Regulation 1332/2008), food additives (Regulation (EC) No 1333/2008), and on flavourings and certain food ingredients with flavouring properties for use in and on foods (Regulation (EC) No 1334/2008). The package also includes an additional piece of legislation (Regulation (EC) No 1331/2008), providing a common authorisation procedure for food additives, flavourings and food enzymes. This legislative package is collectively known as the Food Improvement Agents Package (FIAP).

Food additives are defined in the legislation as *“any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods”* (Regulation (EC) No 1333/2008 Article 3).

Food additives are divided into categories or functional classes according to their technological function, e.g. preservatives, anti-oxidants, sweeteners, colours, etc. Foodstuffs are also divided into categories, and specific conditions are laid down regarding which additives or groups of additives may be used in the different food categories. In the context of this audit, the use of additives in meat products and preparations¹ falling under food categories 8.2 and 8.3 were applicable.

This summary report draws on the findings of the individual site inspections and relates solely to the food business operators visited as part of the audit.

¹ **Meat products** as defined by Regulation (EC) No 853/2004 are *“processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat”*. Processing can mean any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes

Meat preparations as defined by Regulation (EC) No 853/2004 are *“fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat”*.

3.1 Audit Objective

The primary objective of the audit was to determine compliance with relevant legislation, guidance and codes of good practice. A secondary objective was to assess the level of awareness in relation to the supply and use of food additives in meat products and meat preparations in food business operators.

3.2 Audit Scope

To assess food business operators controls in the supply and use of food additives for the manufacture and sale of meat products and meat preparations.

3.3 Audit Criteria and Reference Documents

The principal audit criteria referred to during the audit were:

- **Regulation (EC) No 178/2002** laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety as amended
- **Regulation (EC) No 852/2004** on the hygiene of foodstuffs as amended
- **Regulation (EC) No 853/2004** laying down specific hygiene rules for food of animal origin as amended
- **Regulation (EC) No 854/2004** laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
- **Directive 2000/13/EC** on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs as amended
- **Regulation (EC) No 1333/2008** on food additives as amended
- **Regulation (EU) No 1169/2011** on the provision of food information to consumers as amended
- **Regulation (EU) No 231/2012** laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 as amended

All relevant Statutory Instruments transposing European legislation including:

- European Communities (Labelling, Presentation and Advertising of Food stuffs) Regulations, 2002 (**S.I. No. 483 of 2002**) as amended
- European Communities (Hygiene of Foodstuffs) (**S.I. No. 369 of 2006**) as amended
- European Communities (General Food Law) Regulations, 2007 (**S.I. No. 747 of 2007**) as amended
- European Communities (Food and Feed Hygiene) Regulations, 2009 (**S.I. 432 of 2009**) as amended
- European Communities (Official Control of Foodstuffs) Regulations, 2010 (**S.I. No 117 of 2010**) as amended

All relevant FSAI publications, guidance and guides to good practice including:

- FSAI additives guidance document
- FSAI guidance document for nitrate/nitrite sampling of meat products
- FSAI online training on food additives
- FSAI note to butchers re: additives legislation (July, 2013)
- FSAI note on the use and removal of nitrite in meat products (June, 2012)
- FSAI information note to manufacturers regarding sulphites or sulphur dioxide in sausages and burgers (October, 2010)

3.4 Audit Methodology

This audit was undertaken using documented procedures which are included in the FSAI Quality Management System, namely the FSAI Audit Procedure and Charter. These procedures implement the FSAI audit obligations and are in accordance with the requirements of Regulation (EC) No 882/2004 (including Article 6.1 of Commission Decision 677/2006) and Section 48 (9) of the FSAI Act. Sixteen food business operators were selected randomly for site visits, comprising:

- Nine manufacturers of meat products and meat preparations (under DAFM and local authority supervision)
- Four ingredient/additive suppliers (under HSE/EHS supervision)
- Three butcher/retail establishments (under HSE/EHS supervision)

3.5 Current Legal Requirements

Food business operators are required to place safe food on the market and to ensure that consumer information is accurate and not misleading. Food additives must be approved by the EU and may only be used if they fulfil the criteria laid down in Regulation (EC) No 1333/2008. They must be safe when used and there must be a technological need for their use. The use of food additives must not mislead the consumer and must be of benefit to the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product, including its fruit and vegetable content.

4. AUDIT FINDINGS

4.1 Additive Suppliers and Manufacturers Supervised by the HSE

All products in this part of the audit were either blended, i.e. manufactured or pre-packaged, i.e. supplied or distributed on a business to business basis only with no direct consumer sales. The audit team identified over 25 different additives in use or supplied for use to food business operators producing meat products and/or preparations. No genetically modified ingredients were used or supplied by any of the four additives suppliers/manufacturers audited. The main additives supplied for use as single ingredients or as part of a blended product for meat products and meat preparations included:

- Sodium Nitrate/Nitrite (E250, E251) – supplied as part of cures and brines
- Potassium Nitrate (E252) – supplied as part of cures and brines
- Sodium Metabisulphite (E223) – supplied as part of seasoning blend or as single ingredient
- Sodium Sulphite (E221) – supplied as part of seasoning blend or as single ingredient
- Phosphates (E 450, E451) – supplied as part of seasoning blend
- Monosodium Glutamate (E 621) – supplied as part of seasoning blend or as single ingredient
- Ascorbic Acid (E300)
- Sodium Erythorbate (E316)
- Carmine (E120) - supplied as part of seasoning blend

Two of the four additive suppliers were manufacturing/blending their own products and were British Retail Consortium (BRC) approved, whilst the two other food business operators only supplied pre-blended and packaged additive products, i.e. no blending, repacking or breakdown of ingredients and additives were performed by these food business operators. In the case of the additive suppliers manufacturing their own products, the majority of the products were developed in conjunction with and to meet the specifications of their main customers, i.e. medium/large meat product and meat preparation manufacturers.

An allergen policy and controls was in place in three of the four additive suppliers audited. The audit team noted that the other additive supplier didn't consider it necessary to have an allergen policy or controls because they only sold pre-packaged products through their warehouse and/or retail premises.

Two ingredient suppliers had obsolete product specifications listing the banned colour Red 2G (E128) on file, although these products were no longer purchased, in stock or supplied. The presence of sulphites was not indicated in the specifications of several products assessed by the audit team. [Sulphur dioxide and sulphites are permitted to be used in sausages and burgers with a minimum cereal content of 4%, up to a maximum level of 450mg/kg. However, they are considered to be allergens under Directive 2000/13/EC as amended. Whilst labelled as Preservative E223 on the specification for some seasonings, there was no specific indication of the presence of sulphites as is required by legislation, e.g. Preservative: Sulphur dioxide].

The presence of phosphates in burger mixes was identified in several products. [Under the requirements of Regulation (EC) No 1333/2008, phosphates are not permitted to be used in products falling under Food Category 8.1.2 "Meat preparations as defined by Regulation (EC) No 853/2004", other than in "Breakfast sausages", for which there is a specific authorisation]

The two additive suppliers manufacturing/blending their own products had robust, well documented traceability systems in place. The two other food business operators supplying solely pre-packaged additive products did not have documented traceability systems and used accounts management packages for traceability purposes. The audit team was unable to verify if these systems could effectively recall products if required.

All food business operators audited provided instructions for use of products to their customers. In the case of the two additive suppliers manufacturing/blending their own products, informal onsite training was sometimes provided on request, to their customers.

4.2 Manufacturers of Meat Products and Preparations

The main processes performed by all manufacturers included:

- Injection curing
- Immersion curing
- Dry curing
- Bowl chopping
- Meat tumbling/massaging
- Traditional cold smoking (in two food business operators)
- Cooking
- Slicing
- Vacuum packing

The majority of manufacturers audited produce porcine products predominantly bacon, rashers, sausages, bacon ribs, blood puddings and cooked hams.

Department of Agriculture, Food and the Marine Supervised Premises

All food business operators audited under DAFM supervision were large in terms of product throughput and customer base, i.e. national/international. The audit team noted that in all DAFM supervised plants audited, the preparation and use of brine solutions are carefully controlled using automated systems, e.g. load cells, pre-programmed recipes etc. to control ingredients and processes to ensure levels of additives meet legislative requirements, e.g. nitrates/nitrites in final products. All DAFM supervised food business operators audited had a designated brine preparation area which facilitates direct pumping of prepared brine solutions to sites of use, i.e. injection, immersion etc. within the plant.

The audit team noted that all DAFM premises audited were producing cured, non-derogated pork products and levels of nitrates/nitrites in these products were controlled based on periodic analysis of brine solutions and routine monitoring of product weights pre and post injection. These procedures allowed for the calculation of ingoing amounts of nitrate/nitrite in the product as set out in the FSAI guidance document² published in 2010, i.e. non-derogated products³. None of the DAFM plants audited were producing derogated products.

Local Authority Supervised Premises

All food business operators audited under local authority supervision were small/medium in terms of throughput and customer base, i.e. local/regional customer base. The audit team confirmed that controls for nitrates/nitrites in cured pork products in food business operators under local authority supervision, had been classified as non-derogated and therefore all controls were based on ingoing amounts, i.e. routine monitoring of product weights pre- and post- injection.

Products assessed by the audit team were in compliance with legislative requirements for nitrate/nitrites with one exception. One food business operator had carried out an injection level review to ensure that calculated levels were in compliance with legal requirements for nitrate/nitrites and comparable to official control samples.

Whilst all products had been classified as non-derogated, the audit team noted that in the case of one food business operator, a derogated product, i.e. immersion cured for greater than three days, was being manufactured. However, the food business operator had not identified the product as derogated. The audit team was of the view that this product should be derogated and as such, end-product testing should be undertaken to ensure legislative limits for nitrate/nitrite levels are not exceeded in the product, i.e. analysis of residual levels of nitrate/nitrite in the product rather than ingoing amounts in brine. The audit team noted that no local authority supervised food business operators audited, formally classified their products as derogated or non-derogated².

The audit team observed that a bulk sausage seasoning used by one food business operator was listed as E223, i.e. sodium metabisulphite, as an ingredient. Sulphur dioxide and sulphites are permitted to be used in sausages, up to a maximum level of 450mg/kg. However, sulphur dioxide and sulphites are also considered to be allergens under Directive 2000/13/EC as amended and whilst the food business operator labelled the additive as Preservative E223 on the consumer label, there was no specific indication of the presence of sulphites on the product label as is required by legislation for pre-packaged foods, e.g. Preservative: Sulphur dioxide.

The audit team noted that another food business operator supplied pork sausages which contained E621 monosodium glutamate which was declared in the list of ingredients as a flavour. Monosodium glutamate is considered to be a food additive, with the functional class of "flavour enhancer", and is not considered to be a flavour. Monosodium glutamate cannot be added directly to sausages as an ingredient, and its presence is only

² www.fsai.ie/guidancedocumentfornitratenitritesamplingofmeatproducts.html

³ Non-derogated products are predominately those meat products which are cured by an injection process, possibly followed by a short period of immersion curing for less than three days (Directive 2006/52/EC)

permitted as a result of carry-over from a permitted use of the additive, e.g. its use as a flavour enhancer in a seasoning or spice which in turn, is used as an ingredient in the sausage⁴.

In another food business operator, the audit team observed that a supplied marinated pork rib product contained the colours Sunset Yellow (E110) and Ponceau 4R (E124). However, a warning message on the product label indicating adverse effect on activity and attention in children was not present, i.e. name or E number of the colour(s): may have an adverse effect on activity and attention in children as required by Article 24 and Annex V of Regulation (EC) No 1333/2008. One food business operator also had an obsolete product specification on file listing the banned colour Red 2G (E128) as an ingredient.

In relation to traceability and labelling, the audit team noted that one food business operator had produced product on the day of the audit which had incorrect traceability information applied to product labels. The audit team also observed unlabelled product in the food business operator's chilled/freezer storage. Subsequent examination of the food business operator's traceability system identified significant weaknesses in the ability of the food business operator to track and trace its products and this was communicated to the management of the food business operator and to the local authority authorised officer responsible for the supervision of the plant in question.

In relation to basic hygiene requirements, the audit team observed in one food business operator, a number of significant general hygiene issues including the handling of raw products following the handling of refuse from a bin and the use of a rusted injector unit for hand injection of pork products with brine solutions. In the case of another food business operator, there were no training records for staff in relation to handling and control of allergens.

4.3 Retail Outlets Supervised by the HSE

All food business operators audited (excluding additives manufacturers/suppliers) under HSE supervision were small, e.g. butchers, in terms of throughput and customer base, i.e. local/regional customer base. The audit team confirmed that in many cases, the actual manufacture of meat products/preparations in-store by butchers (excluding sausage and burger type products) has been largely replaced by the direct purchase of pre-packed products from external suppliers, e.g. poultry products which have been bought pre-packed, marinated or glazed containing a variety of additives such as gums, stabilisers and colours. Butchers then apply their own labels/brand to the products for sale to consumers⁵. In some cases, the approval number of the supplier of the product was included on the label the butcher applied to the product⁶.

The audit team noted that some butchers still cure and/or produce their own products in-store for retail sale such as bacon, ribs, sausages and burgers. One butcher audited was also cooking, slicing and selling a cooked ham product produced on the premises. The audit team noted that there were significant hygiene issues associated with this process on the day of the audit. As the audit team was not accompanied by a member of staff from the HSE/EHS, this finding was communicated directly to the Principal Environmental Health Officer in whose area the premises was located.

⁴ Where an additive is used directly in a product, its presence must be indicated on the label, however, where its presence is as a result of carry-over from its use in an ingredient, and where it has no technological function in the final product there is no requirement to indicate its presence in the list of ingredients of the final product

⁵ Sausages, steak burgers, southern fried chicken fillets and other chicken products packed at food business operator's retail premises from which they are sold are exempt from making a full labelling declaration, i.e. all that is required to be displayed on the label is the name of the food See: [Directive 2000/13/EC and S.I. No. 483 of 2002](#)

⁶ It should be noted that the approval mark on a pack does not denote origin, it simply indicates the last place of processing/packaging

In one of the three retailers audited, the presence of monosodium glutamate (E621) as an ingredient for direct use in sausage preparation was identified, and this is not permitted. There was no evidence that direct use of sulphur dioxide (E220) was being used as an additive in any of the three food business operators audited. However, its use was part of pre-blended seasoning mixes used by butchers, which is in line with additive legislation.

In the case of one food business operator, i.e. wholesale/distributor, the audit team observed that bacon ribs were being produced by the food business operator for supply to butchers for direct sale to consumers. The food business operator concerned did not have the required approval to carry on this activity. As the audit team was not accompanied by a member of staff from the HSE/EHS, this finding was communicated directly to the Principal Environmental Health Officer in whose area the premises was located.

The food business operator also informed the audit team that in many cases, the bacon ribs it supplies to butchers would be re-cured by the butchers prior to sale to the final consumer. The audit team informed the food business operator that information should be provided to his customers that the product should not be re-cured as this may result in the product becoming non-compliant with additives legislation. The food business operator also considered its bacon rib product to be derogated. However, no results on residual nitrate/nitrites levels were available to the audit team.

5. CONCLUSIONS

- Awareness of the legislative requirements on food additives and associated labelling requirements was in general, sufficient in DAFM supervised food business operators visited during the audit. However, in some local authority and HSE supervised food business operators, the level of understanding, particularly in relation to labelling and additives legislation, requires improvement.
- The classification of products as either derogated or non-derogated and the level of understanding of food additives legislation, particularly in local authority supervised food business operators, requires improvement.
- Some food business operators audited should review their current food safety management systems to ensure HACCP (Hazard Analysis Critical Control Point) and recall and traceability are commensurate with their current operations.
- Food business operators, through improved documentation management and review, should ensure that obsolete product specifications are not issued to customers and that supplied products include all legislatively required information on component additives.

6. RECOMMENDATIONS

- The FSAI should review the effectiveness of dissemination of its existing training materials and publications in relation to food additives.
- Labelling of food additives and new changes in relation to labelling such as allergens which come into force during 2014 should be communicated to food business operators and authorised officers by the official agencies.
- Advice in relation to potential issues which can arise when specific additives are used in meat products and preparations and when pre-cured products are re-cured should be communicated by the FSAI to authorised officers and food business operators.
- Additives such as sulphur dioxide, phosphates and monosodium glutamate should only (wherever possible) be sold to retail outlets such as butchers as part of a supplied pre-blended product. This would help minimise inappropriate use of additives and resulting non-compliant product.
- Pre-packaged meat products and preparations purchased by a food business operator for re-packaging on the premises for direct sale to the final consumer should be fully labelled including information on any allergens present. Current labelling legislation will change from the 13th December 2014. When the revised legislation (Regulation (EU) No 1169/2011), comes into force, it will require that allergen information is displayed for food sold loose and for food packed on the premises from which it is sold.

7. CORRECTIVE ACTION

A detailed audit report was issued to each food business operator visited. These reports were copied to the relevant official agency. Verification of the implementation of corrective action to audit findings is carried out by the official agencies as part of routine official controls.



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