

Developments in European Union legislation on food preservatives

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Early 1995 saw the publication of the European Parliament and Council Directive No. 95/2/EC on food additives other than colours and sweeteners. The Directive came into force on 25 March. This paper summarises the philosophy and history behind the Directive, and the provisions that it makes regarding food preservatives. The UK responses to the European Union (EU) requirement to establish systems to monitor the consumption and use of food additives are also outlined with particular reference to preservatives. Finally, the proposed Commission Directive that will set harmonised specific purity criteria for food preservatives, replacing in many cases existing legislation, is discussed. © 1997 Published by Elsevier Science Ltd

INTRODUCTION

Over the past 30 years there have been many Directives concerning food additives. Some of the current controls on food additives are contained in so-called 'vertical' Directives on certain types of foodstuffs, such as jams, chocolate, wines and fruit juices. However, 'horizontal' legislation, covering the foodstuffs other than those dealt with in vertical Directives or Regulations, has been in force for some groups of additives from 1962 onwards. Horizontal Directives have covered not just preservatives, but antioxidants; colours; emulsifiers, stabilisers and thickeners; and extraction solvents.

The old horizontal Directives provided positive lists of the additives that all Member States of the European Community had to permit, but (apart from extraction solvents) no conditions of use. Member states were therefore able to impose their own restrictions on the levels of additives that were allowed to be added to the majority of foodstuffs. However, vertical Directives (dealing with specific food commodities) often do have levels of additives specified. For example, the vertical Regulations on wine specify how much of the preservative sulphur dioxide is allowed in particular types of wine. Directives laying down specific criteria of purity for additives also have a long history. The bulk of the current specific purity criteria for preservatives, for example, dates from 1965 (The Council of the European Economic Community, 9.2.65).

These Directives were implemented in the UK by means of Statutory Instruments under, originally, the Food and Drugs Act 1955, then the Food Act 1984 and, more recently, the Food Safety Act 1990 (HMSO,

1990). It has, however, been a long-term aim that food law in the European Community should be harmonised, the trigger for this being the EC White Paper on the Single Market published in 1985 (Commission of the European Communities, 1985). The first part of the drive towards full harmonisation of food additive law was the adoption of the so-called Framework Directive (The Council of the European Communities, 11.2.89) at the end of 1988.

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE No. 95/2/EC ON FOOD ADDITIVES OTHER THAN COLOURS AND SWEETENERS

Under the Framework Directive the definition of an additive is as follows:

"... 'food additive' means 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 nutritional 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."

More specifically, food preservatives are defined in European Parliament and Council Directive No. 95/2/EC on food additives other than colours and sweeteners (The European Parliament and the Council of the

European Union, 18.3.95), or the miscellaneous additives Directive for short, as:

“...substances which prolong the shelf-life of food-stuffs by protecting them against deterioration caused by micro-organisms;...”

Conditionally permitted preservatives are listed (Table 1) in parts A, B and C of Annex III of the miscellaneous additives Directive. This Annex also specifies the foods and drinks in which these preservatives are permitted, and the maximum levels of use allowed (in mg/kg or mg/l as appropriate). To reproduce the relevant parts of the Annex in their entirety here would be pointless. It is, however, useful to summarise the principles upon which the entries in the Annexes of the Directive were decided.

During the negotiations, the first, but not the most important, consideration was whether an additive was needed. In a few cases, additives, some of whose need was last assessed perhaps more than 20 years ago, were no longer in use, technological change or other factors having made them redundant. These were deleted from the draft proposals and do not appear in the Directive as published. In the case of the preservatives, formic acid (E236) was deleted when it was established that the only product in which there was a strong case of need for it was a traditional Danish soft drink, where it was acting primarily as a flavouring substance (thus coming under the scope of flavourings legislation). It was also found that for certain categories of product, modern High Temperature Short Time techniques of sterilising foodstuffs, coupled with aseptic processing and packaging technology, made it possible to reduce (or eliminate) the levels of preservatives previously permitted under the national legislation of some member states for certain categories of product. This was particularly so for low-viscosity liquid products. Great care was taken that only those levels of preservative necessary to achieve the desired technological effect were permitted.

Legislators were conscious of the need to avoid describing product categories in which additives were to

be permitted so narrowly that it would produce lists of inordinate length in the Annexes, or stifle future innovation. However, it was necessary in some cases to specify particular traditional national products. Often there was no easy way of describing these products, particularly as with nine (now 11) different official languages in the EU, translational misunderstandings had to be avoided. In such cases it was decided to refer to traditional national products in the language of their country of origin in all 11 official language versions of the Directive. Table 2 gives examples of this principle as applied to preservatives.

As the UK has had a relatively long history of additive usage, it is not surprising that six of the 16 products listed are British. ‘Made wine’ is manufactured in the UK from imported grape must, and residual levels of preservative from the must are high compared with the majority of wines. Burger meat has a cereal content defined so as to stop sulphur dioxide being added to minced meat to improve the colour, and possibly mislead the consumer about its freshness. The traditional British sausage proved impossible to define, and as the low moisture, lactic acid fermented sausages enjoyed on mainland Europe need no added preservatives, the term breakfast sausage was coined. Breakfast sausages can, however, be eaten at any time. It is strange at first sight to see jams and jellies made with sulphited fruit defined, in effect, as a national product. However, the UK and the Irish Republic both have a history of buying fruit for jam making from eastern Europe, and sulphites are necessary to preserve such fruit over the long transport distances involved. A specific entry was granted too for barley water after it was explained that Wimbledon would not be the same without it. Specific cases were also made for nisin in clotted cream and propionic acid in Christmas puddings—which proved impossible to define.

Some traditional British products could be defined, however, such as cask-conditioned or so-called ‘real’ ale. Described as ‘beer with a second fermentation in the cask’, a practice unique in the Community, it needs a relatively high level (50 mg/l) of sulphur dioxide to prevent spoilage by *lactobacilli*. Several linguistic problems were encountered when drafting the sections of the Directive dealing with preservatives, amongst which were the Dutch concern that ‘burgers’ translates as ‘citizens’ in their language, and the contention of the main wine-producing Member States that ‘alcohol-free wine’ is a contradiction in terms. Fortunately, a spirit of compromise prevailed.

It should be noted that, although the general philosophy for control of additives by horizontal Directives remains, it did not prove feasible to incorporate the existing vertical Regulations* on wine word for word

*A Directive has to be implemented into the national law of the member states of the EU, whereas a Regulation is EU law as it stands and does not need national implementation.

Table 1. Preservatives permitted under Directive 95/2/EC

Preservative	E number
Sorbic acid and its salts	E200, E202 and E203
Benzoic acid and its salts	E210-E213
Hydroxybenzoates	E214-E219
Sulphur dioxide and sulphites	E220-E224 and E226-E228
Biphenyl	E230
Orthophenylphenol and its Na salt	E231 and E232
Thiabendazole	E233
Nisin and natamycin	E234 and E235
Hexamethylene tetramine	E239
Dimethyl dicarbonate	E242
Boric acid and sodium tetraborate	E284 and E285
Na and K nitrate and nitrite	E249-E252
Propionic acid and its salts	E280-E283
Lysozyme	E1105

Table 2. Traditional national products in which preservatives are permitted

Product	Preservative	Level (mg/kg or mg/l)
Made wine	Sorbic acid	200
	Sulphur dioxide	260
Sod... Saft or Sødets... Saft	Sorbic acid	500
	Benzoic acid	200
Mermeladas	Benzoic acid	500
	or with sorbic acid	1000
Fruitgrød and Rote Grütze	Sorbic acid	1000
	Benzoic acid	500
Gnocchi	Sorbic acid	1000
Polenta	Sorbic acid	200
Burger meat with a minimum vegetable and/or cereal content of 4%	Sulphur dioxide	450
Breakfast sausages	Sulphur dioxide	450
Longanzia fresca and Butifarra fresca	Sulphur dioxide	450
Jams, jellies and marmalades made with sulphited fruit	Sulphur dioxide	100
Barley water	Sulphur dioxide	350
Capilé groselha	Sulphur dioxide	250
Clotted cream	Nisin	10
Provolone cheese	Hexamethylene tetramine	25 residual amount expressed as formaldehyde
Foie gras, foie gras entier, blocs de foie gras	Sodium nitrite	100
	Potassium nitrite	Expressed as NaNO ₂
Christmas pudding	Propionic acid	1000

into the miscellaneous additives Directive. To do so would have meant repealing selected parts of these extremely complex vertical Regulations, and the legal delays this would have caused, along with other factors, were judged to be unacceptable. The miscellaneous additives Directive does cross-reference other vertical Directives or Regulations as necessary in order to make use of the definitions of food categories contained therein. However, the actual conditions of use of the non-wine vertical Directives are repeated in the horizontal miscellaneous additives Directive for ease of reference.

After considering the case of need for a preservative, the second, but most important, consideration for legislators was the matter of its safety in use. This applied not only to the levels of a preservative permitted for a particular product, but to the overall dietary intake of the preservative. It is important to set conditions of use for additives that ensure that their acceptable daily intake (ADI) is unlikely to be exceeded, even by unusually high consumers. The ADI of an additive is defined as:

An estimate of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without an appreciable risk to health.

In order to make sure that the ADI of the preservatives is unlikely to be exceeded by consumers, it was necessary to estimate their dietary intake. Methods for doing this are described in Dr Massey's paper on 'Estimation of daily intake of food preservatives' reported in

these proceedings. It is therefore unnecessary to go into detail here, except to say that the methods favoured by each member state vary, and that attempts to adopt a unified approach are taking place under the Scientific Co-operation Procedure (SCOOP) initiative.

THE LEGAL REQUIREMENT TO MONITOR THE CONSUMPTION AND USE OF ADDITIVES

Under Article 7 of the miscellaneous additives Directive, member states must, within three years of the entry into force of the Directive (25 March 1998), establish systems to monitor the consumption and use of food additives and report their findings to the Commission.

This is no problem for the UK, which already has a long established additive monitoring system operating via the Working Party on Food Additives (WPFA). This working party is just one of 11 UK Working Parties set up to carry out food surveillance. From the beginning of 1996, the Working Party will report to the UK's Food Advisory Committee.

It is the policy of MAFF to publish surveillance results. The last major report of the working party was published in 1993 as a food surveillance paper (HMSO, 1993). Of more recent interest is the analytical survey of sulphur dioxide and benzoates in certain foods and drinks recently carried out under the WPFA programme of work. The results of this survey were reported briefly in MAFF's Food Safety Information Bulletin (MAFF, June 1995a), and in more detail as a Food Surveillance Information Sheet (MAFF, June 1995b).

The findings will be reported to the Commission in due course under Article 7.

Also under Article 7, the Commission has to report (by 25 March 2000) to the European Parliament and the Council on the changes which have taken place in the food additives market, the levels of use and consumption. Within the same time-scale, the Commission is obliged to review the conditions of use referred to in it, and propose amendments where necessary. Although the Commission is not yet undertaking a full review, some amendments to the Directive are already necessary in order to tie up loose ends, allow for technological innovations, and to accommodate the needs of the three new member states (Finland, Sweden and Austria) that have joined the EU since the Directive was agreed. This is not expected to be a major task. [N.B. The Commission's proposals were submitted as a draft proposal to a Commission Working Group on 6 March 1996].

IMPLEMENTATION OF THE MISCELLANEOUS ADDITIVES DIRECTIVE INTO UK LAW

The miscellaneous additives Directive required implementation into national law by 25 September 1996. In the UK this was done via the Miscellaneous Additives in Food Regulations 1995 (HMSO 1996) which came into force on 1 January 1996. Guidance Notes, designed to help familiarise users with the new rules and to answer some common questions, have also been issued (MAFF 1996). The Regulations cover England, Scotland and Wales, and were implemented at the same time as parallel Directives on Colours and Sweeteners, and also coincided with changes in UK food law on vertical compositional rules. Separate regulations, with identical provisions, have been made for Northern Ireland. There is a transitional period during which manufacturers may continue to use additives in accordance with the old rules, but prohibition on non-conforming products must be effective by 25 March 1997.

SPECIFIC PURITY CRITERIA FOR PRESERVATIVES

Harmonised specific purity criteria on many, but not all, controlled additives already exist, principally for preservatives, antioxidants, emulsifiers and stabilisers. However, most of these are very old and need updating. The bulk of the specific purity criteria for preservatives date back 30 years, and EC purity criteria for a few preservatives, such as nisin and dimethyl dicarbonate, only exist in draft. The Commission has decided to review or adopt specific purity criteria for all controlled additives, and has already done so for colours and sweeteners. The review is being carried out under procedures laid down in Articles 3.3(a) and 11 of the additives framework Directive. This allows the existing

Council Directives on specific purity criteria to be repealed and replaced rapidly by Commission Directives.

The specific purity criteria for miscellaneous additives are being reviewed by category rather than as a whole. The first category under review just happened to be preservatives. The latest proposals at the time of writing are in the 'draft Commission Directive laying down specific purity criteria for food additives other than colours and sweeteners' (5112/III/EN-Rev1). These proposals have now been discussed at two meetings of a Commission Working Group, and it is hoped that the result will shortly go to the Standing Committee for Foodstuffs. If the proposals are adopted, the next step is to publish them in the Official Journal of the European Communities, followed by implementation into national legislation. Until new specific purity criteria are agreed, the UK's miscellaneous additives Regulations are using old Community specifications where available, and national specific purity criteria in other cases. Only for a few additives do EC or national purity criteria not exist.

In reviewing the preservative specifications, the Working Group took account of those drawn up by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). However, JECFA specifications have not necessarily been adopted in their entirety as some are as old as the existing Community specifications and in need of review themselves. A notable addition to the specific purity criteria are specifications for total and certain individual heavy metals (principally lead and mercury) and also arsenic. In each case, limits have been set to the lowest level believed to be technologically feasible.

An additional point of interest is the incorporation of a 'whereas' clause in the preamble to the proposed Directive which states:

"Whereas, food additives, prepared by production methods or starting materials significantly different from those included in the evaluation of the Scientific Committee for Food, or different from those mentioned in this Directive, shall be submitted for evaluation by the Scientific Committee for Food for the purposes of a full evaluation with emphasis on the purity criteria;"

A "whereas" clause is not legally binding. However if, for example, additives such as the antibiotic preservatives nisin or natamycin were to start being manufactured using genetically modified micro-organisms as a source, then the Commission would undoubtedly call for a review.

FUTURE LEGISLATION

The miscellaneous additives Directive does not, in general, cover the use of additives in additives, e.g. the use of a preservative in a colour or in a flavouring

preparation. The single exception to this concerns carriers and carrier solvents. It is not known yet when legislation on additives in additives will definitely be proposed by the Commission, but it is not believed to be high up their list of priorities.

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