The New EU-Regulation of Food Additives - Now Complete

Introduction

After several years of preparation the EU published a new food additive regulation (Regulation (EC) 1333/2008) replacing former four food additive directives. This regulation covers general aspects and specific authorizations but not purity criteria of food additives.

The new regulation changes the former regulatory framework for food additives significantly, as it applies for all groups of food additives and not, as the former directives only general aspects, sweeteners, colors or miscellaneous additives.

The new regulation brings some important advantages:

- As a regulation it is directly applicable legislation in all Member States.
- Details will be subject to the “Regulatory Procedure with Scrutiny and no longer to the co-decision procedure.
- It uses a new food categorization system equally applied to all types of food additives.
- It brings, for the first time, harmonized rules for the use of carriers and additives for all groups of substances being part of the “Food Improvement Agents” package.

Rules adopted from former legislation

The requirements for listing of an additive in the regulation are, as before,

- Safety
- A technological case of need
- No consumer deception

A definition of processing aids is given in the regulation. They are, however, as well as nutrients, not in the scope of this regulation.

The list of substances exempt from the food additive status, the definitions of sweeteners and colors as well as carry-over rules remain mostly unchanged.

New rules

The regulation contains five Annexes:

I. Functional classes of additives
II. Community list of permitted additives with conditions for use
III. Community list of carriers
IV. List of traditional foods in which a ban of additives can be maintained
V. List of colors with special labelling requirements

The new procedure for authorization of food additives and new uses of existing additives brings substantial advantages. The “Regulatory Procedure With Scrutiny” applied now allows commission regulations be prepared against which the European Parliament may object within three months. Without objection the regulation can be published and, except for major changes with longer periods, normally comes into force thirty days after publication.

This will result in much faster authorizations than under the earlier procedure. The time-consuming involvement of the European Parliament for all details of intended directives and the normally applied 18 months for adoption by national legislation caused long delays for all intended authorizations.

Food additives falling in the scope of the regulation for genetically modified organisms (Regulation (EC) 1829/2003) require authorization by this regulation before they can be listed as food additives.

Obligations of producers and users of food additives have been extended over former requirements. They have to inform the Commission immediately about new scientific or technical information which may have an influence on the safety assessment of an additive.

The Member States have to monitor the intake of additives systematically and to inform the Commission about the results in due course.

Food additives authorized before January 20, 2009, will have to undergo a new risk assessment by EFSA. A respective program has been established and is presently implemented. First reassessments, e. g. for colors, have been published, and calls for data submission for other additive classes were published by EFSA.

Most parts of the regulation including Annex I, IV and V have already been in
force for some time. The remaining and most important parts, i.e. the Annexes II (Regulation (EU) 1129/2011) and III (Regulation (EU) 1130/2011), were published only recently.

The new Annexes

The outline of Annex II

Annex II contains the recently published specific authorizations of food additives. It consists of five parts:

A General provisions
B A list of approved food additives
C A list of additives which may be regulated in groups
D A food categorization system as the basis for authorizations
E The specific authorization of food additives within the categorization system

Part A contains a table lists 12 food groups in which no carry-over is permitted, equivalent to the respective list in the directive on miscellaneous additives (Directive 95/2/EC). Examples are unprocessed foods, butter and honey. One more table contains a list of 32 food groups into which carry-over of food colors is not permitted. It is equivalent to the respective list in the directive on food colors (Directive 94/36/EC). Examples are unprocessed foods, butter and honey, but also milk, eggs and egg products, flour and foods for infants and small children.

Part B lists all authorized food additives, including their E numbers, grouped into colors, sweeteners and miscellaneous additives.

Part C groups additives into five functional groups which may be authorized as the group. Group I contains mostly substances which are approved under the “quantum satis” principle. Exempt are only substances for which certain limitations exist like konjac and also polyols which are authorized under this principle only for purposes other than sweetening. Two more groups contain lists of food colors with and without numerical maximum levels. Part 4 lists polyols which are authorized under the “quantum satis” principle for purposes other than sweetening but limited to certain food groups when used as sweetening agents. In part 5 several groups of additives are defined which may be regulated in combination. These are several groups of preservatives, antioxidants, phosphates, adipates, polysorbates, sugar esters of fatty acids and sugar glycerides, salt of stearoyllactic acids, sorbitan esters, silicon dioxide and silica, glutamic acids and glutamates and ribonucleotides.

Part D is a newly introduced food categorization system with 19 main food categories which contain different levels and numbers of sub-categories. It is similar to the system of the Codex Alimentarius but adapted to the specific needs of the EU. The Codex system contains, in contrast to the EU system, only 16 main categories but a larger number of sub-categories.

The main categories of the EU Food Categorization System

0 All categories of foods
1 Dairy products and analogues
2 Fats and oils and fat and oil emulsions
3 Edible ices
4 Fruit and vegetables
5 Confectionery
6 Cereals and cereal products
7 Bakery wares
8 Meat
9 Fish and fisheries products
10 Egg and egg products
11 Sugars, syrups, honey and table-top sweeteners
12 Salts, spices, soups, sauces, salads and protein products
13 Foods for particular nutritional uses as defined by Directive 2009/39/EG Beverages
14 Ready-to-eat savories and snacks
15 Desserts, excluding products covered in categories 1, 3 und 4
16 Foods supplements as defined in Directive 2002/46/EG, excluding food supplements for infants and young children
17 Processed foods not covered by categories 1 - 17, excluding foods for infants and young children

These main categories are divided into sub-categories some of which are again divided to address specific food groups. This system is similar to the food categorization system of the Codex Alimentarius, the international program for food standardization, but contains more main and less sub-categories. In some parts the EU categorization system is different from the respective categories of the Codex Alimentarius, which makes comparison of authorizations in the EU with internationally accepted uses sometimes difficult.

Part E is the core part of the regulation on additive uses as it lists, by food category, the specific authorizations of all authorized food additives. The list contains five columns with number, name of the additive, permitted maximum level, footnotes limiting the applicability and limitations to certain types of foods within the category. The footnotes refer, for example, to the basis of calculation for additives permitted as a group or permitted as the acid and its salts or refer to naturally occurring which has to be included in the calculation of applicable levels. The advantage of part E is a uniform description of food categories in which additives are permitted while in the former directives different descriptions of food categories were used.

Transitional measures for Annex II

The authorizations as listed in part E will come into force on June 1, 2013. Until then the authorizations of the three directives on sweeteners (94/35/EC), colors (94/36/EC and miscellaneous food additives (95/2/EC) will still be valid. This transition will not be critical, as almost all provisions of these directives have been transferred to the new system. Foods produced under the present authorization can be sold until their expiry date.

Conclusion and outlook for Annex II

With the new food categorization system the EU establishes uniform definitions of groups of food for all types of food additives. The will solve some difficulties in assessing whether a given food additive can be used in a certain food or not. It still lacks guidance for interpretation, as it is available for the categories of the General Standard for Food Additives of the Codex Alimentarius. Such guidance has, however, been announced.
by the Commission. It will facilitate interpretation of the categories and allocation of products to a category.

The new regulatory procedure will result in faster authorizations, and a first amendment to the regulation to authorize steviol glycosides was published at the same date as the regulation itself. More amendments are under discussion and may be published in the near future.

With all types of food additives covered in one regulation and the chance for faster authorizations it is progress in the field of food additives, although not perfect in some details.

The outline of Annex III

Annex III contains harmonized and mostly new conditions for the use of additives and carriers in food additives, enzymes and flavoring. It is of special importance for suppliers of these substances.

Additives like preservatives may be necessary to stabilize these products, and carriers are often required to facilitate addition to foods as these substances are often used in very small quantities only. Although carriers are often necessary and additives are also required for some additives, only carriers for food additives were generally regulated in the EU. Some other authorizations were made specifically in the directive on miscellaneous additives, and sometimes only substances permitted for the final food could be used. Sometimes these uses were covered by national legislation, as no EU legislation was made.

The Annexes of this regulation consist of definitions and five parts:

- Part 1 Carriers in food additives
- Part 2 Food additives other than carriers in food additives
- Part 3 Food additives including carriers in food enzymes
- Part 4 Food additives including carriers in food flavorings
- Part 5 Food additives in nutrients
- Part 6 Definitions of groups of food additives

The Regulation for Annex III defines “nutrients” as substances added for nutritional purposes covered by several respective EU regulations and directives. Carriers have a technological function in or on the additive, enzyme, flavor or nutrient but no technological function in the final food. “Preparations” are formulations consisting of one or more food additives, food enzymes and/or nutrients in which substances such as food additives and/or other food ingredients. Although food ingredients are not specifically referred to as carriers, this definition implies that they can also be used for this purpose.

Part 1 on carriers for food additives lists E numbers and names of the carriers, conditions for use and additives for which the carrier may be used in four columns. It is more or less identical with the former rules for their use (directive 95/2/EC, Annex 5). With only few exceptions with numerical maximum levels the carriers can be used under the “quantum satis” principle, i.e. at the lowest level technologically necessary.

Part 2 harmonizes the rules for the use of additives in additives. Although mixing of additives was possible, the legal status of additives having a function in other additives but not in the final food was not fully clear, and some Member States had their own rules for at least some such additives. Now, with the new provisions the status of additives in additives is clear and they will normally not fall in the definition of ingredients and therefore not require labelling in the list of ingredients, unless they are obtained from allergenic sources.

The outline is equivalent to part 1. For the majority of these additives, however, numerical maximum levels apply. Sometimes even maximum levels are allocated to the final food, obviously with the intention that no functions like preservation should be brought into the final food through these additives.

Part 3 is a new long list of additives including carriers for food enzymes. Rules for use of additives in enzymes existed on a national basis only. This part consists of six columns with the E number and the name of the additive, a maximum level in the enzyme preparation, numerical maximum levels in final foods except beverages, numerical levels in beverages and reference to possible use as a carrier. The reasons for introduction of numerical maximum levels in final foods and beverages are the same as for additives in additives. Many substances can, however, be used under the “quantum satis” principle.

Part 4 regulates additives including carriers in flavorings. It contains the E number and name of the additive, the fields of use and permitted maximum levels in four columns. No specific reference to use as an additive or carrier is made. Maximum levels mostly apply for the flavorings themselves but sometimes for the final food. Some of these authorizations were contained in the directive on miscellaneous additives but not in a separate section.

Part 5 consists of two sections, a longer list for additives and carriers in nutrients except for those intended to be used in foods for infants and young children and a shorter list with nutrients for these foods.

Section A contains five columns with E number and name of the additive, maximum level, nutrients to which the additive may be added and reference to use as a carrier. With few exceptions the authorizations are for use under the “quantum satis” principle and in all nutrients. Only in few cases numerical maximum levels are listed, and use of these substances is often permitted for preparations of vitamins and similar substances.

Section B contains five columns with E number and name of the additive, maximum level, nutrients to which the additive may be added and reference to use as a carrier. With few exceptions the authorizations are for use under the “quantum satis” principle and in all nutrients. Only in few cases numerical maximum levels are listed, and use of these substances is often permitted for preparations of vitamins and similar substances.

Part 6, the final part of the Annex is a list of additives authorized in the preceding five parts, sometimes listed together as functional groups.

Transitional measures for Annex III

The regulation has come into force on December 2, 2011, however, preparations
not complying with parts 2, 3 and/or section A of part 5 of the Annex but conforming to national provisions can be marketed for 24 months after that date. A similar provision applies for preparations not complying with parts 1 and section B of part 5 but with the provisions of the directive on miscellaneous additives. They can be marketed until May 31, 2013. Foods containing such preparations can, in both cases, be sold until the stocks are exhausted.

Conclusion and outlook for Annex III

Annex III facilitates the use of additives and carriers in the classes of substances covered. While the use of carriers in additives was regulated in some detail by the EU, the other provisions were, when existing on EU level, listed in several Annexes of the directive on miscellaneous additives. In many cases no harmonized legislation existed at all, as for additives in additives for which some countries had national provisions. The situation for nutrients was especially difficult, as rules existed for dietary supplements only, and preparations had therefore to rely on substances with authorization for use in foods in general or could use other substances under reverse carry-over only. Therefore publication of this Annex paves the way for easier use of additives and carriers, especially in enzymes and nutrients.

Listing in the Annex makes clear that all these substances are additives and therefore exempt from the definition as an ingredient in the scope of the food labelling directive (directive 2000/13/EC) and therefore exempt from labelling whenever they have no technological function in the final food. The food information regulation (Regulation (EU) 1169/2011) which will replace the directive, contains an equivalent provision. It should be noted that the maximum levels for the final food as allocated to some additives do not necessarily represent levels above which a function in the final food can be expected. For additives brought into a composite food from one of the ingredients the level above which a function can be observed may be substantially higher and therefore also exempt from labelling requirements.

The outline of the different parts is, unfortunately, different. Therefore the question arises whether these differences are really necessary. It seems questionable whether a decision between uses as an additive or a carrier is always possible. It seems possible that a more uniform outline of the different parts would be possible. This may be a task for future modifications.

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