The Food Additives Revival*

Four imminent proposals for new regulations on additives, flavourings, enzymes and a common authorisation procedure

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Revivals, renewals and reforms seem to be popular amongst politicians and legislators. However, they often do not really modernise, vitalise or rejuvenate anything and it all just amounts to pouring old wine into new bottles. This does not necessarily imply anything about the quality of the win, but the more one examines the changes to food additives legislation the blander they seem. Was it really necessary to re-enact current law relating to food additives and flavourings? Probably not. Was there a need to regulate enzymes in the same way? Not really. And do uniform new authorisation procedures help? Perhaps. On the whole there is little novelty in the legislation, but lots of people were involved in the process and everyone concerned will have to adapt to new legislative instruments. The author presents four draft regulations which are meant to replace current food additives law and highlights their significant features. Please do not blame him if you find the subject matter boring!

I. Current food additives law

1. The "mother directive"

Since 1989 the law on food additives has been regulated by Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption.[1] Surprisingly this "mother directive" has only been changed twice since entering into force and can thus rightly be called a fundamental cornerstone of current food law. When it was enacted it was mainly directed at approximating the law of the member states, because the differences between national laws relating to food additives and the conditions for their use were impeding the free movement of foodstuffs within the Community. Directive 89/107/EEC essentially laid down a legal definition of the technical term "food additive" and at the same time excluded from its scope of application among other things flavourings, substances added to foodstuffs as nutrients, particularly minerals, trace elements and vitamins, and processing aids. Still, a footnote to the directive also contained a hidden definition of the technical term "processing aids".

2. Food additives

The essential criterion of a food additive was that it had to be added to food "for a technological purpose", thus becoming a component of the food. The use of food additives was confined to certain categories, had to conform with general criteria for the use of food additives and could be restricted to authorised substances. The necessary authorisation was to be granted on the basis of agreed scientific

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1 OJ 1989, L 40, p. 27, last amended by Regulation (EC) No. 1882/2003, OJ 2003, L 284, p. 1.

and technological criteria, the existence of a reasonable technical need and the prevention of any hazard to consumer health. Authorisation was also only granted on condition that the use of additives did not mislead consumers. Moreover food additives had to be needed in the sense that it was essential they were of benefit to consumers. In particular they had to be necessary to preserve a foodstuff`s nutritional quality, provide for special dietary needs, enhance the quality and stability of a foodstuff or aid in the manufacture itself. All authorised food additives were to be assessed as to their possible harmful effects which had to comprise toxicological testing and evaluation, and they were to be continuously observed and re-evaluated. No food additives would be authorised unless they complied with approved purity criteria. It was of course possible to limit the approval of food additives to specific foodstuffs or conditions, as well as to limit their use to the lowest necessary level and to take into account acceptable daily intakes.

3. "Daughters" and "nieces"

Subsequently three "daughter directives" were enacted, namely Directives 94/35/EC on sweeteners,[2] Directive 94/36/EC on colours[3] and Directive 95/2/EC on miscellaneous other additives[4]. These legislative instruments defined and authorised numerous specified additives with particular restrictions and maximum levels, if any, they generally allowed the carry-over principle and they demanded the monitoring of consumption. The parallel enactment of additional "niece directives" on purity criteria[5] was an important contribution to guaranteeing food safety and standardising products all over Europe with respect to the use of food additives.

4. Implementation and application

In the meantime mother and daughter directives have long been implemented into the respective national laws of all EU Member States. Particularly the daughter directives have been continuously amended in order to keep up with new developments and scientific research results adding newly developed or acknowledged substances and restricting or deleting others for safety reasons at the same time. On the whole, albeit complicated in detail, the system appears to be working: it is usually possible to find out which substances may be added to particular foodstuffs for certain technological purposes and up to what amounts they may be employed in each individual case. In fact, although the different authorisations and their interrelations can be perceived as a maze, food law practitioners with legal as well as scientific backgrounds seem to be coping with the application of this law.

II. The new draft legislation

1. "Revival"

Nonetheless the European legislator felt the need to simplify food additives legislation. This was meant to be done by creating a single legal instrument, conferring updating powers to the Commission and introducing consultation with EFSA for safety evaluations. At the same time a reworking of the European law on flavourings and the parallel creation of rules on food enzymes were intended essentially to mirror the reformed food additives legislation. First drafts of new EC regulations on food additives, flavourings and enzymes were put forward as early as August/November 2003. They were continuously revised until three final working documents appeared on 2 February 2005[6], each of them still containing its own chapter on authorisation. These proposals by the Commission met with considerable criticism from the food industry particularly because of the envisaged ten year authorisation periods. Such a concept would naturally have caused immense problems for the whole industry, because it would inevitably have led to continuous, as well as tedious, cumbersome and costly, application procedures. It would also have meant the potential loss of some authorisations (in cases where no-one applied for an exten-

2 OJ 1994 L 237, p. 3, last amended by Directive 2003/115/EC, OJ 2004 L 24, p. 65.

3 OJ 1994 L 237, p. 13.

4 OJ 1995 L 61, p. 1, last amended by Directive 2003/114/EC, OJ 2004 L 24, p. 58.

5 Directives 95/31/EC, 95/45/EC and 96/77/EC.

6 WGA/004/03 rev10 on food additives, WGF/002/02 rev3 on flavourings and WGA/003/03 rev8 on enzymes.

sion). Furthermore the definition of "processing aid" contained the clause that the relevant substance must be intentionally removed after treatment or processing. This requirement would have limited the use of many enzymes commonly employed in food manufacturing as processing aids because they cannot be removed for technical reasons; they are rather inactivated or destroyed in the course of the treatment.

2. The four drafts

On 28 July 2006 the Commission published the four final proposals on the following legislative instruments:

- a regulation on food additives[7]
- a regulation on flavouring and certain food ingredients with flavouring properties for use in and on foods[8]
- a regulation on food enzymes[9] and additionally
- a regulation establishing a common authorisation procedure for food additives, food enzymes and food flavourings.[10]

It is planned that these proposals are passed by the European Parliament and are then approved by the Council of Ministers. Twenty days after their subsequent publication in the Official Journal – which may happen next year – they are meant to enter into force and replace mother Directive 89/107/EEC together with its three daughter Directives 94/35/EC, 94/36/EC and 95/2/EC. As the legislator has opted for regulations rather than directives, there will be no need for renewed national implementation measures. On the contrary, the direct applicability of the regulations all over the European Union will necessitate the repeal of current implementing legislation in all Member States. However, it is still unclear whether the proposals will survive the legislation process unchanged, particularly since they considerably limit the influence of the European Parliament on future additives authorisation.

7 COM (2006) 428 final – 2006/145 (COD).

8 COM (2006) 427 final – 2006/147 (COD).

9 COM (2006) 425 final – 2006/144 (COD).

10 COM (2006) 423 final – 2006/143 (COD).

3. New features and structures

Neither the original ten-year authorisation period nor the active removal criterion for processing aids has made it into the final drafts of the four regulations. The food additives regulation in particular appears to contain little changes compared to current law. The main feature of the revival is the introduction of uniform Community lists of substances which may be used for the production of food. For this purpose the regulations define food additives, flavourings as well as enzymes and establish criteria for the inclusion of those substances on the relevant Community lists. Furthermore an obligation to inform the Commission of safety aspects regarding the relevant substances has been included. Apart from the regulation on a common authorisation procedure, the drafts essentially share the same structure (see table on page 298).

III. Essential details of the drafts

1. Proposal for a regulation on food additives

Art. 1 sets out the subject matter of the regulation. Art. 2 expressly excludes from the scope of application among other things processing aids, substances added to foods as nutrients and food enzymes. The new definition of the technical term "food additive" is contained in Art. 3; it is identical with its predecessor from Directive 89/107/EEC. A number of substances are by definition not considered to be food additives, namely foods used for their sweetening properties, foods incorporated because of their aromatic, sapid or nutritive properties etc.; these definitions continue the relevant rules from Art. 1 para. 4 of Directive 94/35/EC, Art. 1 para. 3 of Directive 94/36/EC and Art. 1 para. 5 of Directive 95/2/EC. Furthermore Art. 3 contains a refined definition of the technical term "processing aid" which looks more sophisticated but in fact is all but identical with its predecessor.

Art. 4 provides that only food additives included in the Community list in Annex II may be placed on the market as such and used in foods. Whilst Annex II still appears as a blank page in the draft, it is meant to be filled with all food additives currently authorised. Food additives to be used in food additives, particularly carriers, and in food enzymes

	Regulation on		
	food additives	**flavourings**	**food enzymes**
	Chapter I: Subject matter, scope and definitions		
Subject matter	Art. 1	Art. 1	Art. 1
Scope	Art. 2	Art. 2	Art. 2
Definitions	Art. 3	Art. 3	Art. 3
	-	Chapter II: Conditions for use of flavourings	-
	Chapter II: Community lists of approved food additives Chapter III:	Community lists of flavourings	Chapter II: Community lists of approved food enzymes
Community lists of approved substances	Art. 4	Art. 9	Art. 4
General conditions for inclusion and use of substances in Community lists	Art. 5	cf. Art. 4	Art. 5
The content of the Community lists	Art. 9	cf. Art. 10	Art. 6
Specifications of food additives	Art. 12	-	-
	Chapter III: Use of food additives in foods	-	-
	Chapter IV: Labelling	Chapter IV: Labelling	Chapter III: Labelling
	Section 1: Labelling of substances not intended for sale to the final consumer		
Labelling of substances not intended for sale to the final consumer	Art. 19	Art. 12	Art. 8
Information requirements	Art. 20-23	Art. 13-14	Art. 9-12
	Section 2: Labelling of Substances intended for sale to the final consumer		
Labelling of substances intended for sale to the final consumer	Art. 24	Art. 15	Art. 13
	Section 3: Other labelling requirements	-	Section 3: Other labelling requirements
Other labelling requirements	Art. 25	-	Art. 14
	Chapter V: Procedural provisions and implementation		
Information, Monitoring and Reporting obligation	Art. 26-27	Art. 16-17	Art. 15
	Chapter VI: Transitional and final provisions		
Establishment of Community list of substances	Art. 30	Art. 22	Art. 18
Re-evaluation of approved food additives	Art. 31	-	-
Repeals	Art: 32	Art. 21	-
Amendment to Directive 2000/13/EC	-	Art. 26	Art. 22
Entry into force	Art. 34	Art. 27	Art. 24

are to be listed on a Community list in Annex III; this concept has no immediate predecessor in current law apart from previous stipulations concerning carriers. The general conditions for inclusion and use of food additives in those Community lists can be found in Art. 5. They essentially resemble the criteria formerly enacted in Annex II of Directive 89/107/EEC. Specific conditions for sweeteners and for colours are provided for in Art. 6 and 7.

The content of the Community list of food additives is specified in Art. 9, whilst specifications of food additives relating in particular to origin and purity criteria are to be included in the lists pursuant to Art. 12. Art. 8 perpetuates the well known functional classes to be listed in Annex I whilst Art. 10 continues rules on maximum levels. The carry-over principle is now codified in Art. 16. Labelling provisions are provided for in Art. 19-23 regarding food additives not intended for sale to the final consumer and in Art. 24 regarding food additives intended for sale to the final consumer; as before they hardly differ.

The unprecedented information obligation can be found in Art. 26. Accordingly a producer or user of a food additive shall inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food additive. Furthermore a producer or user of a food additive shall, at the request of the Commission, inform it of the actual use of the food additive. This provision has now replaced the ten-year authorisation period previously envisaged by the legislator. Additionally a re-evaluation of approved food additives shall be carried out in the course of an evaluation programme pursuant to Art. 31. The exact design of this programme itself has been postponed; it shall be adopted after consultation with EFSA within one year after the entry into force of the regulation. Whilst Art. 32 repeals Directives 89/107/EEC, 94/35/EC, 95/36/EC, 95/2/EC and several others, some essential provisions of the three daughter directives shall remain in force for a transitional period pursuant to Art. 33.

2. Regulation on flavourings

The parallel draft regulation on flavourings and certain food ingredients with flavouring properties is intended to repeal and replace the current Flavourings Directive 88/388/EEC. It was felt necessary to recodify this area of law in order to take into account technological and scientific developments in the area of flavourings. At the same time maximum levels of undesirable substances were meant to be adapted, i.e. lowered. Furthermore the term "natural-identical" was to be abolished, because it allegedly confuses the consumer. Since consumers purportedly request to be informed about the source of natural flavourings a respective labelling obligation was to be introduced, too.

As its predecessor the new draft regulation is rather brief. Its scope is limited pursuant to Art. 2 to flavourings, food ingredients with flavourings properties, food containing such substances and the relevant source materials; it excludes substances which have exclusively a sweet, sour or salty taste and raw or non-compound foods. Art. 3 continues the well-known definitions of the technical terms "flavourings", "flavouring substances", "natural flavouring substances" and "smoke flavouring" whilst at the same time introducing definitions of the technical terms "flavouring preparations", "thermal process flavourings", "flavour precursor", "other flavouring", "food ingredients with flavouring properties", "source materials" and "appropriate physical processes". Only flavourings or food ingredients with flavouring properties which do not pose a safety concern to the health of consumers and do not mislead the consumer through their use may be used pursuant to Art. 4. Certain substances and source materials are excluded under Art. 5 and 6 and shall be listed in Annexes III and IV; these limitations which include the well known issue of "active principles" may be slightly less restrictive than under the present legal rules. Flavouring substances and source materials may only be used if they are included in a Community list to be drawn up pursuant to Art. 8-10.

Comprehensive labelling rules on flavourings not intended for sale to the final consumer are prescribed by Art. 12-14 and by Art. 15 on labelling of flavourings intended for sale to the final consumer. Furthermore a reporting obligation identical to the one on food additives is entrenched in Art. 16. Art. 21 repeals the current Flavourings Directive 88/388/EEC whilst Art. 22 envisages the establishment of the Community list of flavouring substances. Some consequential changes of current food law are contained in Art. 23-26, the

most important of which being a replacement of Annex III of Food Labelling Directive 2000/13/EC. As a result of this change "smoke flavourings" will have to be labelled as such in future and cannot longer be presented in an ingredients list as "flavourings" only.

3. Regulation on food enzymes

With this draft regulation the European legislator enters uncharted waters. Currently a small number of enzymes used as food additives are regulated by Directive 89/107/EEC. These will of course be governed by the new food additives regulation mentioned above. The remaining enzymes however, are currently either not regulated at all or come under the processing aid regime, which differs from member state to member state. The European legislator's concern was primarily for the safety of food enzymes at a European level and the avoidance of potential hazards arising from the chemical nature of enzymes, particularly with a view to allergenicity, activity related toxicity, residual microbiological activity and chemical toxicity. Furthermore it was felt necessary to introduce labelling provisions. Art. 3 sets out a definition of the technical term "food enzyme"; accordingly this is meant to be "a product obtained by extraction from plants or animals or by a fermentation process using micro-organisms." It has to contain one or more enzymes capable of catalysing a specific biochemical reaction and it must be added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of foods. Pursuant to Art. 2 the regulation shall apply to such enzymes, but not to enzymes used exclusively in the production of food additives, flavourings or novel foods.

Art. 4 provides that only food enzymes included in a Community list, to be drawn up pursuant to Art. 6, 7 and 18, may be placed on the market as such and used in foods. Art. 5 establishes that food enzymes may only be included in that Community list if they do not pose a safety concern to the health of the consumer, if there is a reasonable technological need and if their use does not mislead the consumer. The Community list shall specify such food enzymes, list specifications and appropriate conditions of use or restrictions similar to the current criteria for using food additives. Comprehensive labelling rules are contained in Art. 8-12 regarding food enzymes not intended for sale to the final consumer and in Art. 13 regarding food enzymes intended for sale to the final consumer.

Art. 18 provides that the Community list of food enzymes shall be drawn up on the basis of applications which may be submitted by interested parties. The Commission shall then establish a register of all food enzymes to be considered for inclusion in the Community list and submit the application to EFSA for its opinion. The relevant procedure will be explained further below. In any event all enzymes currently authorised shall be put on the Community list when it is drawn up pursuant to Art. 19; this applies specifically to invertase, lysozyme, urease and beta-glucanase. Some consequential changes of current law are contained in Art. 20-23. The most important is again a change of the Food Labelling Directive 2000/13/EC. This provides that enzymes will be deemed to be "ingredients" in future and have to be labelled as additives in the ingredients list, unless they are employed as processing aids only. They have to be indicated there with their specific name preceded by a class name in accordance with Annex II of the Food-Labelling Directive. In view of the fact that most enzymes are in fact employed as processing aids and therefore exempt from additives labelling the practical significance of this rule remains unclear.

4. Regulation on a common authorisation procedure

Whilst each of the three last working documents still contained its own set of authorisation procedures, the final drafts have been relieved of the relevant rules which now find themselves condensed in a fourth draft regulation on a common authorisation procedure. This document is perceived by the legislator as a piece of "from farm to fork" legislation which increases food safety by subjecting potentially dangerous substances to scientific examination and official approval. The regulation thus aims to establish a uniform authorisation procedure for food additives, flavourings and their source materials as well as food enzymes. The envisaged procedure is meant to be centralised, effective, expedient and transparent. At the same time the new legislation takes up principles of

Regulation (EC) No. 178/2002 by basing the procedure on risk assessment carried out by EFSA and a risk management system involving the Commission and the member states. With the repeal of Directive 89/107/EEC the new authorisation procedures for food additives will replace those currently in force.

The task of creating, maintaining and updating all the above mentioned Community lists of authorised substances is assigned to the Commission. Pursuant to Art. 2 the technical term "updating" comprises adding substances to the lists and removing them as well as changing conditions, specifications or restrictions mentioned there. According to Art. 3 the common procedure may be initiated either by the Commission itself or upon application by either a Member State or any interested party. An essential part of the procedure – at least for adding substances to the lists – is the opinion of EFSA which shall generally be delivered within six months pursuant to Art. 5 and forwarded not only to the Commission but also the Member States and the applicant. Where substances are merely removed from the lists or their conditions of use are being changed the opinion of EFSA is only compulsory if such updates may have an effect on public health. In any event EFSA as well as the Commission may request additional information from applicants concerning risk assessment under Art. 6 and 8; relevant requests may lead to an extension of the statutorily prescribed periods of time. Art. 11 establishes as a principle of transparency that EFSA opinions have to be made public without delay.

The procedure is generally concluded with the adoption of an implementing regulation in accordance with Art. 7. Such regulation shall be submitted by the Commission within nine months of delivery of the EFSA opinion and may take into account not only the opinion itself and – as a matter of course – relevant Community law, but also the notorious other legitimate factors. The Commission is not bound by the EFSA opinion but has to explain potential deviations. If the Commission judges that an update is not justified it may at any stage decide to terminate the common procedure pursuant to Art. 3; applicants have to be informed directly about the reasons of such a termination. Details of content, drafting and presentation of an application as well as the necessary contents of an EFSA application have been postponed by the legislator. Pursuant to Art. 9 such implementing measures will have to be laid down within two years after the entry into force of the regulation. However, some provisions on confidentiality of information submitted by applicants are already safeguarded in Art. 12.

IV. Conclusion

As with all man-made law its success does not only depend on the quality of the individual provisions and their coherence but to a large extent also on the prudence of those applying them. The food additives revival may streamline the authorisation of food additives and will certainly lead to fewer obstacles for the free movement of foodstuffs within the Community for the simple reason that national implementation measures will lapse. The extension of authorisation procedures to flavourings and food enzymes may even increase food safety, although one should not expect substantially new dimensions to be reached here – after all, lawfully marketed food in the European Union is already safer than ever before. On the whole the question whether such revival was worth a year long legislation process remains debatable. If one dares to ask "cui bono?" the suspicion arises that this reform project is more legislation for legislation's sake than that it amounts to a truly measurable progress. But presumably the four new regulations will not cause any harm either – and they keep us occupied!