COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

pursuant to the second subparagraph of Article 251 (2) of the EC Treaty

concerning the

common position of the Council on the adoption of a Regulation of the European Parliament and of the Council on food additives

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1. BACKGROUND

Date of transmission of the proposal to the EP and the Council (document COM(2006)428 final – 2006/0145 COD):	28 July 2006.
Date of the opinion of the European Economic and Social Committee:	25 April 2007.
Date of the opinion of the European Parliament, first reading:	10 July 2007.
Date of transmission of the amended proposal:	24 October 2007.
Date of political agreement	17 December 2007.
Date of adoption of the common position:	10 March 2008.

2. OBJECTIVE OF THE COMMISSION PROPOSAL

The Commission announced in the White Paper on food Safety (COM (1999)719 final) that it would up-date and simplify existing legislation with regard to food additives (Action 11 in the White Paper). The objectives of this proposal are:

- To simplify food additive legislation by creating a single instrument for principles, procedures and approvals;
- To confer the implementing powers on the Commission to update the Community list of authorised food additives;
- To consult the European Food Safety Authority (EFSA) for the safety evaluation of food additives;
- To set up a re-evaluation programme for existing food additives;
- To require the authorisation of additives that consist of, contain or are produced from genetically modified organism under Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

3. COMMENTS ON THE COMMON POSITION

3.1. General comment

The Commission supports the common position as adopted by the Council on 10 March 2008. It is in line with the aims and the approach taken in the Commission's original proposal and also reflects the principles of several amendments proposed by the European Parliament.

3.2. Amendments made by the European Parliament at first reading accepted by the Commission and which are in line with the common position

The common position reflects the spirit of the majority of the 39 amendments which were accepted by the Commission in full, in part, in principle or subject to drafting changes.

In relation to the criteria for the authorisation of food additives, and in particular what is meant by misleading the consumer, the common position includes changes which address some of the considerations in European Parliament (EP) amendments 3 and 30.

The common position also includes amendments (in recital 7 and Articles 1 and 6) to reflect that, although the environmental impact is not among the general conditions for authorisation of food additives, it is of course a legitimate factor which should be considered. For instance when adverse environmental effects are identified, they can be taken account of during the authorisation or revision of the conditions of use. These changes contain references to the other principles contained within the General Food Law, i.e., that the rules on food additives used in foods will ensure the effective functioning of the internal market and a high level of protection of human health and protection of consumers' interests, including fair practices in food trade, taking into account the environment. These changes reflect the environmental aspects contained in amendments 1, 7 and 25 of the EP. Recital 7 has also been amended in the common position regarding the use of potentially allergenic food additives; this change reflects to some extent the principle in EP amendment 1.

The Council has proposed to amend the proposal so that the definition of *quantum satis* is included in Article 3 and has made consequential changes to Article 11. The EP proposed similar changes in amendments 21 and 36. The Commission can accept these proposals subject to linguistic changes as included in Articles 3 and 12 of the Commission's amended proposal.

The new Article 5 of the common position clarifies that no person shall place on the market a food additive or a food in which a food additive is used if its use does not comply with the Regulation. This clarification was also requested by the EP in amendments 9 and 22.

Regarding the interplay between the proposed Regulation and Regulation (EC) No 1829/2003 on GM food and feed, the EP clarified in amendments 4, 38 and 63 that the evaluation and authorisation procedures under these two Regulations can run simultaneously. This important principle has also been reflected in the common position.

Recitals 20 and 21 and the various articles in the common position have been modified in order to introduce the regulatory procedure with scrutiny and to align in general the proposed Regulation with Council Decision 2006/512/EC amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission. These provisions are coherent with the EP amendments 64rev, 47, 48, 67rev, 79, 68rev, 80, 51 and 69rev on this subject; however the difference is that the common position includes the use of the curtailment of time periods in some cases. This aspect was not reflected in the Commission's amended proposal.

The common position includes a provision in Article 28 to clarify that during the transfer of current authorisations for food additives into the new annexes, those food additives or uses thereof which are no longer necessary should not be transferred. This reflects the principle of amendment 55 of the EP. Similarly the common position reflects a change necessary in Article 28 as a result of the decision to include additives in flavourings in Annex III of the Regulation and not in Annex II. This principle is also proposed by the EP in amendments 58 and 59.

3.3. Amendments made by the European Parliament at first reading which were accepted by the Commission and have not been included in the Common position

Amendment 28 of the EP proposed that the approval of food additives should refer to the consideration given to the criteria for authorisation and the reason for the decision. In its amended proposal the Commission accepted the principle of the amendment in that any decision to authorise a food additive should explain its motivation and therefore included new recital 8 in the amended proposal.

3.4. New provisions introduced by the Council which are accepted by the Commission

As with all food additives, sweeteners used in table top sweeteners are assessed for their safety before they are permitted. The information provided to consumers on food labels should be clear and easy to understand. If there is evidence available that particular groups of consumers are exceeding the acceptable daily intake as a consequence of using table top sweeteners, other non legislative methods could be used locally to provide the necessary information to consumers. It is noted that some manufacturers already provide 'off label' information. The amendment included in the common position (Recital 18 and Article 22), whereby manufactures would be obliged to make the necessary information available by any appropriate means, would provide useful information for the consumer and also to Member States to assist with consumer education campaigns where they are necessary.

The Council has removed the requirement that food additives should **at all times** comply with the specific purity criteria (specifications) which have been set and have simply stated that they should comply with the specifications. This change, whilst ensuring that food additives meet the requirements with regard to levels of contaminants, clarifies that additives when mixed together or made up in solution do not at all times have to meet other quality criteria such as moisture content or acidity. A similar amendment was originally proposed in the EP but was not supported in the first reading vote.

A new recital 16 has been introduced into the common position in order to further describe the principle of carryover set out in Article 17.

As regards the labelling of food additives sold from business to business or directly to the final consumer, the EP adopted in first reading a number of amendments in the proposal on food enzymes with a view to simplifying the labelling provisions. The common position incorporated a similar simplification. Despite the differences in structure and wording, the labelling requirements for food additives are largely in line with those proposed by the EP on enzymes. The common position also contains similar provisions to those proposed by EP amendments 42 and 44 with regard to the date of minimum durability/shelf life and derogations for food additives delivered by bulk transport e.g. tanker. The common position has also gone further in simplifying the labelling provisions for food additives sold directly to the final consumer which are considered food and hence covered by the labelling provisions of Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs. The Commission's amended proposal took over the main ideas of the EP amendments and reflects the labelling provisions endorsed by the Council in the common position.

In its common position the Council has made some adjustments to recital 13 and Article 24 to clarify that a new nanoscale form of a food additive could be considered to be a significantly different production method and therefore would require a new safety assessment. EP amendment 35 also proposed to introduce separate limit values for nanoscale food additives. The Commission considered that the EP amendment was not necessary, as specific restrictions could already be allocated under the conditions if these are necessary following a safety assessment. The Commission agrees however with the spirit of the amendments proposed in the common position. However it is considered that this principle would be better addressed in a separate article as contained in Article 11 of the Commission's amended proposal.

During the period in which the current food additive authorisations are reviewed and transferred into the new Annex, there is a potential that pending requests for new additives or new uses of food additives would be put on hold. Such a move would stifle innovation and have a detrimental effect on the food industry. The Council has therefore proposed an amendment to allow the current Directives to be amended by comitology during this interim period so that those food additives in the pipeline which have already received a positive opinion from the European Food Safety Authority can be authorised. The common position therefore includes a new Article 29 and consequential changes to Article 33.

The common position includes a modification to clarify what is meant by 'extending shelf life through the replacement of sugars' so that this concept is better explained (Article 7 (b). On the contrary the European Parliament proposed to delete this text (amendment 73). The Commission can accept the new wording proposed in the common position. The common position also includes additional clarification on the specific conditions for colours (Article 8 b) in that they are used to help identify flavours which are normally associated with certain foods.

The Commission proposal originally proposed that as a general rule the levels of food additives should apply to the foods as ready to eat, as this could be of relevance for exposure calculations. The Council however considers that for ease of enforcement it would be clearer to establish the levels in food as marketed, although for clarity the common position includes an amendment specifying that, for foods which have to be reconstituted or diluted, the levels should be established for the reconstituted or diluted food. EP amendment 37 also included reference to the diluted state. With the additional clarification proposed by the Council, the Commission can accept the change to 'as marketed'.

The common position has modified Article 18 to include all the interpretation decisions, including the one originally included in Article 2, as to whether a given substance meets the definition of food additive. The application of the provisions in Article 18 is an implementation of the rules contained in the basic act (e.g. the definition of food additive). Therefore it does not fall within the new regulatory procedure with scrutiny and this has been reflected in the common position. EP amendments 12, 40 and 47 propose regulatory procedure with scrutiny for such decisions.

The common position includes a new provision in Article 29 to reflect the need created by the changes to the labelling provisions that a transitional period is provided for products which no longer comply with the new rules. The Commission included a similar provision in Article 32 of its amended proposal which may be better placed.

4. CONCLUSION

The Commission takes the view that the common position fully reflects the key elements of its initial proposal and the spirit of many of the amendments of the European Parliament made in the first reading,

The Commission therefore agrees with the common position as adopted by the Council by unanimity.