

COMMISSION REGULATION (EC) No 1565/2000**of 18 July 2000****laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

European Commission (SCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs⁽¹⁾ and in particular Article 4 thereof,

Whereas:

- (1) Commission Decision 1999/217/EC⁽²⁾ adopted a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96.
- (2) Regulation (EC) No 2232/96 lays down in its Annex the general criteria for the use of flavouring substances. It covers, in particular, that they present no risk to the health of the consumer and that their use does not mislead the consumer.
- (3) In order to check that the flavouring substances contained in the register comply with the general use criteria, Article 4(1) of Regulation (EC) No 2232/96 provides that a programme for the evaluation of these flavouring substances is to be carried out. According to Article 4(3) substances have to be deleted from the register, where, following evaluation, it is clear that they do not comply with the general use criteria.
- (4) As the first step of the evaluation programme the substances of the register should receive FL-numbers according to their chemical characteristics and should be distributed in groups of structurally related compounds which are expected to show some metabolic and biological behaviour in common.
- (5) In the light of the large number of flavouring substances in the register and the deadline set by the Regulation by which a list of authorised flavouring substances shall be adopted, the evaluation programme should not waste scientific resources and, therefore, make use of safety assessments already performed by the Committee of Experts on Flavouring Substances of the Council of Europe (CEFS), the Scientific Committee on Food of the

- (6) The Scientific Committee on Food has been consulted, addressing especially the question whether results of evaluations of other scientific committees can be accepted. In its conclusion expressed on 2 December 1999, the SCF was of the opinion that, subject to certain exceptions, flavourings considered acceptable at the current estimated intake by JECFA comply with the general use criteria and could be included in the list of authorised substances without undergoing a separate SCF evaluation for the time being. Likewise, the SCF concluded that flavourings previously evaluated by the SCF and CEFS as being safe, need not be re-evaluated as the criteria previously used are stringent enough to consider the substances to be safe in current use.
- (7) The Scientific Committee on Food further considered that for the remaining flavouring substances, unnecessary duplication of work could be avoided by dividing different groups of substances between JECFA and the SCF for evaluation.
- (8) Article 4(2) of Regulation (EC) No 2232/96 provides that the person responsible for placing the substances on the market shall forward the data necessary for the evaluation to the Commission. Information about the substances on purity, chemical specification, natural occurrence in food, total amount added to foods and results of toxicological and metabolic studies are considered to be essential for the evaluation. In order to enable a constant evaluation over the whole period the information should be presented as soon as possible and be available well in advance of the evaluation of a particular substance. The information should be updated as soon as new data are available.
- (9) If the data provided on chemical identity of a substance and the amount added to foods or the toxicological and metabolic studies on a substance or on closely related substances appear to be insufficient, further data may be requested. Following the initial exposure assessment which should be based on the total amounts added to foods more refined usage data might become necessary for the evaluation of certain substances.

⁽¹⁾ OJ L 299, 23.11.1996, p. 1.⁽²⁾ OJ L 84, 27.3.1999, p. 1.

- (10) In order to enable the completion of the evaluation programme within five years, deadlines for the submission of information have to be set as well as minimal numbers of substances to be evaluated within a given time period.
- (11) Where the necessary information is not provided, so that the evaluation of a flavouring substance cannot be undertaken, that substance may not be included in the definitive list of flavouring substances referred to in Article 5 of Regulation (EC) No 2232/96.
- (12) The register contains about 2 800 substances. Following the opinion of the SCF, it can be concluded that about 800 substances need not be re-evaluated for the time being. Based on the assumption that JECFA would evaluate a considerable number of substances during the next five years, about 1 000 to 1 250 remain for evaluation by the SCF. In order to make the evaluation process as efficient as possible a group-based approach should be followed, i.e. substances which are expected to show some metabolic and biological behaviour in common should be evaluated together.
- (13) By Commission Decision 94/652/EC ⁽¹⁾, as last amended by Decision 1999/634/EC ⁽²⁾, the task 1.1 on 'chemically defined flavouring substances' has been defined to be undertaken within the framework of scientific cooperation by Member States in the examination of questions relating to food (SCOOP). This task has built up the Flavis database which compiles information for the scientific evaluation of flavouring substances. The information provided by the person responsible for placing the substance on the market should be added to the database and be critically reviewed in order to establish if it is sufficiently complete for evaluation.
- (14) In accordance with the opinion of the SCF, the evaluation of the substances by the SCF should follow the procedure applied by JECFA, which is the most updated and systematic procedure presently applied. After approval by the SCF, results of future evaluations of flavouring substances of the register performed by JECFA should also be accepted.
- (15) The JECFA procedure is a stepwise approach that integrates information on intake from current uses, structure-activity relationships, metabolism and toxicity. In addition, information on purity and chemical specification is assessed. One of the key elements in the procedure is the subdivision of flavourings into three structural classes for which human exposure thresholds that

are not considered to present a safety concern have been specified. Toxicological and metabolic studies performed within a group of chemically related substances can be used to draw conclusions about possible toxicological effects of substances not studied or studied but not intensively.

- (16) A substance should be re-evaluated if, in the light of new data on toxicological effects or on human intake, doubt arises on the validity of the already performed and accepted evaluation.
- (17) By Commission Decision 1999/217/EC certain flavouring substances received first priority in the evaluation programme since concerns about the safety of the health of consumers were expressed by some Member States. The programme should then proceed group-wise giving priority to those groups of substances for which most information is available. However, higher priorities for certain substances may be requested in the future.
- (18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

The first step in the establishment of the evaluation programme shall be the attribution of FL-numbers, as defined in the Flavis database system, to each flavouring substance of the register and subdivision of all substances into groups of related substances according to the list of groups as laid down in Annex I to this Regulation. This stage shall be completed within three months of the adoption of this Regulation by the Member States participating in SCOOP task 1.1, established by Decision 94/652/EC.

Article 2

1. Substances that are contained in the register and have already been classified
- by the SCF in Category 1 (substances considered safe in use) ⁽³⁾, or
 - by the CEFS in Category A (substances which may be used in foodstuffs) ⁽⁴⁾, or
 - by JECFA so as to present no safety concern at current levels of intake with the exception of substances which have been accepted on the sole basis that their estimated intake is lower than the threshold of concern of 1,5 µg per person per day, as laid down in the reports of the 46th, 49th, 51st and 53rd JECFA meetings ⁽⁵⁾,

⁽³⁾ Annex 6 to the minutes of the 98th meeting of the Scientific Committee on Food, 21 and 22 September 1995.

⁽⁴⁾ *Flavouring substances and natural sources of flavourings*, Volume I, *Chemically-defined flavouring substances*, Fourth Edition. Council of Europe, *Partial agreement in the social and public health field*, Strasbourg, 1992, including its subsequent loose-leaf modifications until year 1999.

⁽⁵⁾ Evaluation of certain food additives and contaminants. 46th Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical report, series 868, Geneva 1997.

Evaluation of certain food additives and contaminants. 49th Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report, series 884, Geneva 1999.

51st Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report, series to be published.

53rd Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report series to be published.

⁽¹⁾ OJ L 253, 29.9.1994, p. 29.

⁽²⁾ OJ L 249, 22.9.1999, p. 32.

need not be re-evaluated within the present evaluation programme,

- if information on purity and chemical specification of the substance as outlined in Annex II is provided, and
- unless the SCF receives new information which might change the results of the evaluations.

2. Substances that are contained in the register and will be classified in the future

- by JECFA so as to present no safety concern at current levels of intake

will be considered by the SCF, who may then decide that no further evaluation is necessary.

3. In the event that the SCF decides that further evaluation of a substance referred to in paragraph 1 or 2 is necessary, the person responsible for placing a substance of the register on the market shall provide the information laid down in Article 3(1).

Article 3

1. The person responsible for placing on the market a substance contained in the register which is not covered by Article 2(1) has to provide the following information within 12 months of the adoption of this Regulation in order to enable the evaluation of a substance:

- purity and chemical specification of the substance as outlined in Annex II,
- natural occurrence in foodstuffs,
- total amount of the substance which is added to foods in the Community,
- normal and maximum use levels of the substance in food categories as outlined in Annex III, if available,
- all relevant toxicological and metabolic studies on the substance or on closely related substances.

This information has to be transmitted in a standardised format, as outlined in Annex IV.

2. If the information referred to in paragraph 1 does not become available for a particular substance within 12 months of the adoption of this Regulation, the person responsible for placing it on the market shall inform the Commission, within this period, of the date on which he can fulfil his obligation under paragraph 1 either for individual substances or for groups of substances as laid down in Annex I.

3. In the light of the information received according to paragraphs 1 and 2, the Commission may establish different deadlines from that proposed under paragraph 2, for individual substances or groups of substances as laid down in Annex I, in order to allow the smooth running of the evaluation process.

4. The Commission may request additional information considered to be relevant for the evaluation of a particular substance from the person responsible for placing it on the

market within deadlines which are consistent with the overall deadline of the programme. In particular, for certain substances it might become necessary to submit information on the normal and maximum use levels in food categories as outlined in Annex III.

5. Where the information specified in paragraph 1, or additional information specified in paragraph 4, is not provided, the substance may not be evaluated.

6. The information specified in paragraph 1 shall be updated, including for those substances already evaluated, by the person responsible for placing the respective substance(s) on the market as soon as new data become available.

7. Information which has already been provided shall be made available to Member States.

Article 4

1. At least 200 substances per year shall be evaluated provided that the information specified in Article 3(1), or additional information specified in Article 3(4), is supplied within the specified deadlines.

2. Within the SCOOP task 1.1, established by Decision 94/652/EC, participating Member States shall:

- incorporate the information of each substance given according to Article 3(1) and (4) into the Flavis database,
- check if the information is sufficiently complete for evaluation and inform the Commission if this is not the case,
- prepare data sheets which collate and summarise the information and which contain a pre-evaluation, and
- present these data sheets to the SCF.

The SCOOP task shall be organised so as to meet the requirement of paragraph 1.

3. On basis of the data sheets referred to in paragraph 2 the SCF will evaluate the substances for their compliance with the general use criteria. The SCF shall check the information for its completeness and shall inform the Commission if this is not the case. If necessary, measures to restrict the levels of use can be proposed. The evaluation procedure applied shall follow the procedure applied by JECFA, as far as considered appropriate by the SCF.

4. The Commission or a Member State may request the re-evaluation of a substance already accepted as complying with the general use criteria, if new data that may lead to a different result become available.

Article 5

1. Substances in the register that bear the remark '2' or '3' in the 'Comments' column of Decision 1999/217/EC, shall be evaluated first.

2. Without prejudice to paragraph 1, those groups of substances as laid down in Annex I, for which the information as referred to in Article 3(1) is most complete, shall receive priority for evaluation.
3. By way of derogation from paragraph 2, the Commission or a Member State may request priority for the evaluation of (a) particular substance(s) or (a) group(s) of substances.

Article 6

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 July 2000.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

CHEMICAL GROUPS FOR FLAVOURING SUBSTANCES ⁽¹⁾

1. Straight-chain primary aliphatic alcohols/aldehydes/acids, acetals and esters with esters containing saturated alcohols and acetals containing saturated aldehydes. No aromatic or heteroaromatic moiety as a component of an ester or acetal.
2. Branched-chain primary aliphatic alcohols/aldehydes/acids, acetal and esters with esters containing branched-chain alcohols and acetals containing branched-chain aldehydes. No aromatic or heteroaromatic moiety as a component of an ester or acetal.
3. α , β -unsaturated (alkene or alkyne) straight-chain and branched-chain aliphatic primary alcohols/aldehydes/acids, acetals and esters with esters containing α , β -unsaturated alcohol and acetal containing α , β -unsaturated alcohols or aldehydes. No aromatic or heteroaromatic moiety as a component of an ester or acetal.
4. Non-conjugated and accumulated unsaturated straight-chain and branched-chain aliphatic primary alcohols/aldehydes/acids, acetals and esters with esters containing unsaturated alcohols and acetals containing unsaturated alcohols or aldehydes. No aromatic or heteroaromatic moiety as a component of an ester or acetal.
5. Saturated and unsaturated aliphatic secondary alcohols/ketones/ketals/esters with esters containing secondary alcohols. No aromatic or heteroaromatic moiety as a component of an ester or ketal.
6. Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols. Esters may contain any acid component.
7. Primary alicyclic saturated and unsaturated alcohols/aldehydes/acids/acetals/esters with esters containing alicyclic alcohols. Esters/acetals may contain aliphatic acyclic or alicyclic acids or alcohol component.
8. Secondary alicyclic saturated and unsaturated alcohols/ketones/ketals/esters with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols. Esters may contain aliphatic acyclic or alicyclic acid component.
9. Primary aliphatic saturated or unsaturated alcohols/aldehydes/acids/acetals/esters with a second primary, secondary or tertiary oxygenated functional group including aliphatic lactones.
10. Secondary aliphatic saturated or unsaturated alcohols/ketones/ketals/esters with a second secondary or tertiary oxygenated functional group.
11. Alicyclic and aromatic lactones.
12. Maltol derivatives and ketodioxane derivatives.
13. Furanones and tetrahydrofurfuryl derivatives.
14. Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms.
15. Phenyl ethyl alcohols, phenylacetic acids, related esters, phenoxyacetic acids and related esters.
16. Aliphatic and alicyclic ethers.
17. Propenylhydroxybenzenes.
18. Allylhydroxybenzenes.
19. Capsaicin related substances and related amides.
20. Aliphatic and aromatic mono- and di- thiols and mono-, di-, tri-, and polysulfides with or without additional oxygenated functional groups.
21. Aromatic ketones, secondary alcohols and related esters.
22. Aryl-substituted primary alcohol/aldehyde/acid/ester/acetal derivatives, including unsaturated ones.

⁽¹⁾ These chemically based groups are expected to show some metabolic and biological behaviours in common.

23. Benzyl alcohols/aldehydes/acids/esters/acetals. Benzyl and benzoate esters included. May also contain aliphatic acyclic or alicyclic ester or acetal component.
 24. Pyrazine derivatives.
 25. Phenol derivatives containing ring-alkyl, ring-alkoxy, and side-chains with an oxygenated functional group.
 26. Aromatic ethers including anisole derivatives.
 27. Anthranilate derivatives.
 28. Pyridine, pyrrole, and quinoline derivatives.
 29. Thiazoles, thiophene, thiazoline and thienyl derivatives.
 30. Miscellaneous substances.
 31. Aliphatic and aromatic hydrocarbons.
 32. Epoxides.
 33. Aliphatic and aromatic amines.
 34. Amino acids.
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ANNEX II

CHEMICAL SPECIFICATIONS TO BE PROVIDED FOR FLAVOURING SUBSTANCES

- chemical name as used in the register of Decision 1999/217/EC,
 - IUPAC name, if different from chemical name as used in the register,
 - synonyms,
 - CAS-, E-, EINECS-, FL-, CoE- and FEMA numbers, if available,
 - chemical and structural formula, molecular weight,
 - physical form/odour,
 - solubility,
 - solubility in ethanol,
 - identity test (infra red-, nuclear magnetic resonance- and/or mass spectrum),
 - minimum assay value,
 - impurities,
 - physical parameters related to purity (justification is required if information is not provided):
 - boiling point (for liquids),
 - melting point (for solids),
 - refractive index (for liquids),
 - specific gravity (for liquids),
 - stability and decomposition products, if relevant,
 - interaction with food components, if relevant,
 - any other relevant information.
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ANNEX III

FOOD CATEGORIES

1. Dairy products, excluding products of category 2.
 2. Fats and oils, and fat emulsions (type water-in-oil).
 3. Edible ices, including sherbet and sorbet.
 4. Processed fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes), and nuts and seeds.
 - 4.1. Fruit.
 - 4.2. Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes), and nuts and seeds.
 5. Confectionery.
 6. Cereals and cereal products, including flours and starches from roots and tubers, pulses and legumes, excluding bakery.
 7. Bakery wares.
 8. Meat and meat products, including poultry and game.
 9. Fish and fish products, including molluscs, crustaceans and echinoderms (MCE).
 10. Eggs and egg products.
 11. Sweeteners, including honey.
 12. Salts, spices, soups, sauces, salads, protein products, etc.
 13. Foodstuffs intended for particular nutritional uses.
 14. Beverages, excluding dairy products.
 - 14.1. Non-alcoholic ('soft') beverages.
 - 14.2. Alcoholic beverages, including alcohol-free and low-alcoholic counterparts.
 15. Ready-to-eat savouries.
 16. Composite foods (e.g. casseroles, meat pies, mincemeat), foods that could not be placed in categories 1 to 15.
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ANNEX IV

FORMAT FOR THE TRANSMISSION OF INFORMATION ON FLAVOURING SUBSTANCES

1. The information as specified in Article 3(1) first to fourth indents as well as summaries of information requested by the fifth indent have to be provided in a standard electronic format, the 'Input form for the Flavis database' (IF-FL). The summaries of information requested by the fifth indent should contain the main findings of the referred study to allow conclusions on the metabolic and toxicological effects of the substances. The IF-FL can be downloaded from the following internet site or ordered from the coordinating institute of the SCOOP task 1.1 which address is given below.
<http://www.flavis.net>
2. The information has to be provided in English. To identify a substance the name in the column headed 'Name' of the English version of the register of Decision 1999/217/EC has to be used. If already available, the FL-number has to be given in addition.
3. (a) The completed IF-FL has to be sent to the coordinating institute of the SCOOP task 1.1
by e-mail to the address (input@flavis.net) given on the abovementioned internet site or
by post to the address below (recommended for substances in part 4 of the register);
(b) three separately bound copies of the information as specified in Article 3(1), fifth indent have to be provided in paper format. Each copy needs to be clearly identified with the English 'Name' of the substance and the chemical grouping (as listed in Annex I) to which it relates. If already available, the FL-number has to be given in addition. The copies have to be sent to the coordinating institute of SCOOP task 1.1:

Danish Veterinary and Food Administration
Institute of Food Safety and Toxicology
Flavis
Mørkhøj Bygade 19
DK-2860 Søborg
