Food Improvement Agents
=
Food additives, enzymes and flavourings; (+ extractions solvents)

Unit E2: Food Processing Technologies and Novel Foods
DG SANTE, European Commission

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union'

Explanatory Meeting on Acquis, 22 February 2019, Brussels

SUMMARY

Food Improvement Agents (FA, FF, FE)

- **EU Regulatory status**
- **Common Authorisation Procedure**
  - Risk Assessment (EFSA)
  - Risk Management (COM + MS)

Food Additives

Food Flavourings

Food Enzymes

Extraction Solvents

European Commission

Food Improvement Agents

EU Regulatory status

Food Improvement Agents

. Food additives, food enzymes and food flavourings are also known as "food improvement agents"

Harmonised EU legislation - essential aspect of the internal market contributing to the health and well-being of the EU citizens and to the free movement of safe and wholesome food

The EU positive lists envisaged for all FIAs – "positive" - what is not authorised cannot be added to food.

Why add food additives, enzymes and flavourings to food?

- **Among others, food additives preserve, colour and stabilise food during its production, packaging or storage.**
- **Enzymes have specific biochemical actions which serve technological purposes at any stage of the food chain**
- **Flavourings give or change the odour or taste to food**

Food Improvement Agents

- **Regulation (EC) No 1332/2008 on <u>Food Enzymes</u>**
  - Definitions, conditions of use, labelling requirements
  - Procedure for establishing a Union list (possibly by 2020)

- **Regulation (EC) No 1333/2008 on <u>Food Additives</u>**
  - Definitions, conditions of use, labelling requirements
  - Union list of authorised food additives (320) and conditions of use
  - Programme for the re-evaluation of food additives

- **Regulation (EC) No 1334/2008 on <u>Flavourings</u>**
  - Definitions, conditions of use, labelling requirements
  - Union list of authorised flavouring substances (2500)
  - Specific rules for smoke flavourings

European Commission

Food Improvement Agents

Common Authorisation Procedure

Food Improvement Agents

- **Regulation (EC) No 1331/2008 establishing a common authorisation procedure**
  - Risk assessment by EFSA (9 months)
  - Risk management by the Commission (9 months)

- **Regulation (EU) No 234/2011 implementing Regulation (EC) No 1331/2008 including:**
  - Measures on the content, drafting and presentation of applications
  - arrangements to check the validity of applications
  - Information that should be included in the opinion of EFSA

Food Improvement Agents

- **European Commission Practical guidance for applicants**
  - For addresses, contact points and the relevant documents (check-lists for the dossier completeness)
  - Available at DG SANTE's website https://ec.europa.eu/food/safety/food_improvement_agents/common_auth_proc_guid_en

- **EFSA's Guidance documents – several guidance docs for FA, FF and FE available at EFSA's website, including intake models - Food additives intake model (FAIM), Food Enzyme Intake Model (FEIM)**

https://www.efsa.europa.eu/en/applications/foodingredients/regulationsandguidance
https://www.efsa.europa.eu/en/applications/foodingredients/tools

Common Authorisation Procedure Regulation (EC) No 1331/2008

- Applies to substances for which placing on the market in the EU is authorised by an Union list (food additives, flavourings and food enzymes)
- Procedure for updating the Union list
  - Adding the substance on the list
  - Removing the substance from the list
  - Addition, removing or changing of the conditions, specifications or restrictions which are associated with the presence of the substance on the list

Main stages of the common procedure

- Starts on the initiative of the Commission or following an application.
- Applications shall be sent to the Commission.
- Consultation of the European Food Safety Authority (risk assessment) except if the updates in question are not liable to have an effect on human health.
- Consultation of MS on risk management aspects.
- If the conditions for the authorisation are met a draft measure is prepared and presented for an opinion of the Standing Committee

Timing for an authorisation

- Opinion of the European Food Safety Authority (EFSA): nine months
- Proposal by the Commission after consulting Member States, industry and stake holders: nine months
- Scrutiny by the European Parliament and the European Council: 2 months
- Time needed for translation (24 languages), adoption by the Commission and publication in the Official Journal

Full Risk Assessment by EFSA

- Identity of the substance
- Specifications
- Manufacturing process
- Methods of analysis in food
- Reaction and fate in food
- Case of need and proposed uses
- Use levels (proposed ML; ML given by legislation; reported ML; analytical results)

Full RA – Exposure Assessment

- Food consumption data (Individual consumption data related to individual body weights based on the dietary surveys of the EU's MS – 26 surveys of 17 EU countries)

- Estimation - exposure to the substance (Average + 95th percentile for toddlers, children, adolescents, adults and the elderly; different scenarios (1) MPL; (2) reported data + MPL; (3) reported data;

Conservative assumptions - all processed foods contain FA at MPL or at MReportedL)

- Main food categories contributing to the exposure

- Exposure via other sources (e.g. FF, cosmetics, FCM, natural occurrence)

- Total estimated exposure

- Uncertainty analysis (qualitative evaluation)

Full Risk Assessment – Biol. + TOX data

- ADME (absorption, distribution, metabolism, excretion)
- Tox data (acute oral toxicity, short-term and subchronic toxicity, genotoxicity, chronic toxicity and carcinogenicity, reproductive and developmental toxicity, hypersensitivity, allergenicity, intolerance and other studies)

Risk Management

Data required:

- Identity of the substance
- Proposed normal and max. use levels for every food category
- Exposure assessment
- Other specific data given by the sectoral legislation (different requirements for additives, enzymes and flavourings)…details are provided further in this presentation

Risk management measures

- Based on the outcomes of the risk assessment
- Conditions for authorisation and use given in the sectoral legislation on FA, FF and FE
- Other relevant factors taken into account including societal, economic, traditional, ethical and environmental factors, the precautionary principle and the feasibility of controls.

Risk management measures

- COM is assisted by MS at the "Standing Committee on Plants, Animals, Food and Feed" section "Novel Food and Toxicological Safety"
- The "preparatory work" is done at the Working Parties

"Working Party of Governmental experts on:

Additives/Enzymes/Flavourings"

where the risk management measures, understanding of the provisions of the legislation and other relevant matters are discussed with the technical experts of MS

Risk management measures

- Once the legislation is in place the EU Member States are responsible for the enforcement of the legislation!

Food additives

Food Additives – EU regulatory framework

- **Regulation (EC) No 1333/2008** on food additives
- **Regulation (EU) No 231/2012** laying down specifications for food additives
- **Regulation (EU) No 257/2010** setting up a programme for the re-evaluation of approved food additives

Regulation (EC) No 1333/2008

It provides for:

- *Definitions*
- *Conditions of use*
- *Union list of authorised food additives*
- *Labelling requirements*

Regulation (EC) No 1333/2008 Definitions

*'**Food Additive**' means any substance:*

- **Not** normally consumed as a **food** in itself,
- **Not** normally used as a **characteristic ingredient** of food,
- Intentionally added for a **technological purpose** in the manufacture, processing, preparation, treatment, packaging, transport or storage of food,
- That **becomes** directly or indirectly a **component of the food**, including its by-products.

Regulation (EC) No 1333/2008 Definitions

*'**Processing aid**' means any substance:*

- **Not** consumed as a **food** by itself,
- **intentionally used** in the processing of raw materials, foods or their ingredients, **to fulfil a certain technological purpose during treatment or processing**; and
- May result in the **unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives** provided they do not present any health risk and do not have any technological effect on the final product.

What are food additives?

E100–E199 (colours)

E200–E299 (preservatives, acidity regulators…)

E300–E399 (antioxidants, acidity regulators…)

E400–E499 (thickeners, stabilisers, emulsifiers…)

E500–E599 (acidity regulators, anti-caking agents…)

E600–E699 (flavour enhancers…)

E900–E999 (glazing agents, gases and sweeteners)
E1000–E1599 (additional additives)

Functional classes (based on the technological function a food additive exerts in the foodstuff)

sweeteners, colours, preservatives, antioxidants, acidity regulators, carriers, acids, anti-caking agents, emulsifiers, anti-foaming agents, bulking agents, emulsifying salts, firming agents, flavour enhancers, foaming agents, gelling agents, glazing agents, humectants, modified starches, packaging gases, propellants, raising agents, sequestrants, stabilisers, thickeners, flour treatment agents and contrast enhancers

Conditions of use

- Do not pose **a safety concern** to the health of the consumer at the level of use proposed;
- Reasonable **technological need** for their use which cannot be achieved by other economically and technologically practicable means;
- Do not **mislead the consumer**
- **Advantages and benefits** for the consumer
- Specific conditions for **colours** and **sweeteners**

Specific conditions for colours

- **Restore the original appearance** of food of which the colour has been affected by processing, storage, packaging and distribution, whereby visual acceptability may have been impaired
- Make food more **visually appealing**
- Give **colour to** food otherwise **colourless**

Specific conditions for sweeteners

- Replace sugars for the **production of energy-reduced food** (*), non-cariogenic food or **food with no added sugars**
- Replace sugars where this permits an **increase in the shelf-life** of the food
- Produce food intended for **particular nutritional use**

Union list of food additives authorised in food (Annex II to R. 1333/2008)

- Listed on the basis of the **categories of food** to which they may be added (Codex GSFA food category system was used as a starting point)
- Food additives which were permitted for use in foods under Directives 94/35/EC, 94/36/EC and 95/2/EC and their conditions of use have been transferred into Annex II to Regulation (EC) No 1333/2008.
- Established by Regulation (EU) No 1129/2012 in application since 1 June 2013
- Since adoption of Union list **more than 80 new regulations amending Annexes II and III**

Food categorisation system – 1st level

0 *All foodstuffs*
1 *Dairy*
2 *Fats and Oils*
3 *Edible Ice*
4 *Fruit and Vegetables*
5 *Confectionery*
6 *Cereals and Cereal Products*
7 *Bakery Wares*
8 *Meat*
9 *Fish and Fish Products*
10 *Eggs and Egg Products*
11 *Sugars and Table Top Sweeteners*
12 *Salt, Spices, Seasonings, Sauces etc.*
13 *PARNUTS*
14 *Beverages*
15 *Snacks*
16 *Desserts*
17 *Food Supplements*
18 *Processed foodstuffs not belonging to 1 - 17*

Guidance on food categories

https://ec.europa.eu/food/safety/food_improvement_agents/additives/eu_rules_en

10.	**Eggs and egg products**
	This category covers all fresh in-shell eggs and other egg products.
10.1.	Unprocessed eggs
	This category covers unprocessed eggs in their shell.
10.2.	Processed eggs and egg products
	This category covers eggs and egg products which may have been frozen, dehydrated, dried or concentrated, as well as boiled eggs.
11.	**Sugars, syrups, honey and table-top sweeteners**
	Includes all standardised sugars (11.1), non-standardised products (11.2), honey (11.3) and table top sweeteners (11.4).

Food additives database

- See: Food Additives Database

https://webgate.ec.europa.eu/foods_system/main/?sector=FAD&auth=SANCAS

Food Additives

Homepage

Introduction

Welcome

Welcome to the database on Food Additives.
This database can serve as a tool to inform about the food additives approved for use in food in the EU and their conditions of use. It is based on the Union list of food. This list is in Annex II of Regulation (EC) No 1333/2008.
The Union list was established after the transfer of the food additives permitted for use in foods under Directives 94/35/EC, 94/36/EC and 95/2/EC, in a new food categorisation system. Some additives and uses which are not longer needed are not entered in Annex II.

Important remark:

The provisions that have been transferred from the old directives in the Union list will apply from 1 June 2013. In the mean time the authorisation of food additives according following provisions of the Directives 94/35/EC, 94/36/EC and 95/2/EC continue to apply:
(a) Article 2(1), (2) and (4) of Directive **94/35/EC** and the Annex thereto;
(b) Article 2(1) to (6), (8), (9) and (10) of Directive **94/36/EC** and Annexes I to V thereto;
(c) Articles 2 and 4 of Directive **95/2/EC** and Annexes I to VI thereto.

New additives or new conditions that have been introduced in the Union list can already apply now (e.g. authorisations of Steviol glycosides).

Getting started

- Food additives database user guide (09/11/2011)
- Flash Demo (11/11/2011)
- Flash Demo (pdf version) (11/11/2011)

Disclaimer

This database is made available solely for the purpose of information. It has no legal value. The Commission declines all responsability or liability whatsoever for errors or deficiencies in this database. Neither the Commission nor any person acting on behalf of the Commisssion is responsible with regard to the improper use of the document and its contents. The official authorisations of food additives are published in the Official Journal of the European Union. Legislation on the food additives is also available on the Europa Food Safety website: http://ec.europa.eu/food/food/fAEF/additives/index_en.htm

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Union list of food additives authorised in Food Additives, Food Enzymes, Flavourings and Nutrients

- **Annex III** to Regulation (EC) No 1333/2008
  1. Carriers in food additives
  2. Food additives other than carriers in food additives
  3. Food additives including carriers in food enzymes
  4. Food additives including carriers in food flavourings
  5. Carriers in nutrients and other substances added for nutritional and/or for other physiological purposes

Labelling requirements for food additives sold as such (intended for sale to the final consumer)

- The name and E-number (of each food additive);
- The statement '*for food*' or the statement '*restricted use in food*';

- Rules of **Regulation (EU) No 1169/2011** on the provision of food information to consumers

https://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation_en

Labelling requirements for food additives not intended for sale to the final consumer

- The name and/or E-number;
- The statement '*for food*' or the statement '*restricted use in food*';
- if necessary, the special conditions of storage and/or use; the name or business name and address of the manufacturer, packager or seller; instructions for use; net quantity; date of minimum durability or use-by-date; a mark identifying the batch or lot;
- Indication of the maximum quantity of each component or group of components subject to quantitative limitation in food enabling the purchaser to comply with Union law
- Presence of allergens

Food Additives – EU regulatory framework

- **Regulation (EC) No 1333/2008** on food additives
- **Regulation (EU) No 231/2012** laying down specifications for food additives
- **Regulation (EU) No 257/2010** setting up a programme for the re-evaluation of approved food additives

Specifications of Food Additives

- **Commission Regulation (EU) No 231/2012**

"Food additives must comply with the approved specifications, which should include information to adequately identify the food additive, including origin, and to describe the acceptable criteria of purity." Recital (8) of R. 1333/2008

"A food additive already approved which is prepared by production methods or using starting materials significantly different from those included in the risk assessment of the Authority, or different from those covered by the specifications laid down, should be submitted for evaluation by the Authority. 'Significantly different' could mean, inter alia, a change of the production method from extraction from a plant to production by fermentation using a micro-organism or a genetic modification of the original micro-organism, a change in starting materials, or a change in particle size, including the use of nanotechnology." Recital (13) of R. 1333/2008

+ Articles 4, 12 and 14 of R. 1333/2008

E 300 ASCORBIC ACID, L-ASCORBIC ACID

Synonyms	L-xylo-Ascorbic acid; L(+)- Ascorbic acid
Definition	
Einecs	200-066-2
Chemical name	L-ascorbic acid; Ascorbic acid; 2,3-Didehydro-L-threo-hexono-1,4-lactone; 3-Keto-L-gulofuranolactone
Chemical formula	$C_6H_8O_6$
Molecular weight	176,13
Assay	contains not less than 99 % of $C_6H_8O_6$ after drying in a vacuum desiccator over sulphuric acid for 24 hours,
Description	White to pale yellow, odourless crystalline powder
Melting range	Between 189 °C and 193 °C with decomposition
Identification	
Test for ascorbic acid	Passes test
pH	Between 2,4 and 2,8 (2 % aqueous solution)
Specific rotation	$[\alpha]_D^{20}$ between + 20,5° and + 21,5° (10 % w/v aqueous solution)
Purity	
Loss on drying	Not more than 0,4 % (in vacuum over sulphuric acid, 24 hours)
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

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Re-evaluation

"Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. Where necessary, the Commission together with the Member States should consider appropriate action."

Recital (14) of R. 1333/2008

Re-evaluation programme

- Established by Commission Regulation (EU) No 257/2010
- All additives authorised before 20 January 2009
  - **Colours completed by 31.12.2015**
    Some revisions of use finalised in September 2011
    Further revisions of use started during 2013
  - **Sweeteners completed by 31.12.2020**
    Exception aspartame (new scientific data)
  - **All other additives completed by 31.12.2018**

Re-evaluation programme

State of play of the re-evaluation of safety of permitted food additives by EFSA as of 20 July 2018:

- **316 food additives** approved before 20 January 2009 to be re-evaluated by EFSA
- **104 scientific opinions** published by EFSA on the re-evaluation of the safety of food additives, covering **175 individual food additives**
- **141 food additives** still to be re-evaluated by EFSA before 31 December 2020

Approach for the follow-up of EFSA's scientific opinions by the COM:

https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

Calls for data: for e.g. sorbates, sulphites, iron oxides and hydroxides etc.

FOOD IMPROVEMENT AGENTS

- Additives
  - EU Rules
  - Database
  - Re-evaluation Programme
- Enzymes
- Flavourings
- Extraction Solvents
- Common Authorisation Procedure

ALL TOPICS

Re-evaluation

Food additives permitted **before 20 January 2009 must go through a new risk assessment** by the European Food Safety Authority (EFSA).

Commission Regulation (EU) No 257/2010 set up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008.

Deadlines for re-evaluation:

Most food colours	by the end of 2011 (closed)
Aspartame	by November 2013 (closed) - *NB: this re-evaluation was advanced due to the publication of new scientific data*
Remaining colours	by the end of 2015 (closed)
Preservatives, antioxidants, glutamates, silicon dioxide	by the end of 2015-2016
Other sweeteners	by the end of 2020
All other additives	by the end of 2018

State of play of the re-evaluation of safety of permitted food additives by EFSA as of 10 October 2017:

- **316 food additives** approved before 20 January 2009 to be re-evaluated by EFSA
- **93 scientific opinions** published by EFSA on the re-evaluation of the safety of food additives, covering **150 individual food additives**
- **166 food additives** still to be re-evaluated by EFSA before 31 December 2020

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QUICK LINKS

- Rapid Alert for Food and Feed (RASFF)
- Health and food audits and analysis
- European Food Safety Authority (EFSA)
- Better Training for Safer Food (BTSF)
- E-News
- Press Releases
- Events
- Videos
- Infographics and factsheets

State of play of the re-evaluation of safety of permitted food additives by EFSA as of 10 October 2017:

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Summary table of permitted food additives and status of their re-evaluation by EFSA (status as of 10 October 2017).

Approach for the follow-up of EFSA's scientific opinions on the re-evaluation of the safety of permitted food additives for which some concerns have been identified.

[Expand All]

Follow-up of EFSA's scientific opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives CALL CLOSED

Follow-up of EFSA's scientific opinion on the re-evaluation of sulphur dioxide (E 220), sodium sulphite (E 221), sodium bisulphite (E 222), sodium metabisulphite (E 223), potassium metabisulphite (E 224), calcium sulphite (E 226), calcium bisulphite (E 227) and potassium bisulphite (E 228) as food additive - CALL CLOSED

Follow-up of EFSA's scientific opinion on the re-evaluation on the re-evaluation of iron oxides and hydroxides (E 172) as food additives - CALL CLOSED

Follow-up of EFSA's scientific opinion on the re-evaluation of titanium dioxide (E 171) as a food additive - CALL CLOSED

Follow-up of EFSA's scientific opinions on the re-evaluation of E 140(i) chlorophylls, E 140(ii) chlorophyllins, E 141(i) copper complexes of chlorophylls and E 141(ii) copper complexes of chlorophyllins as food additives - CALL CLOSED

Follow-up of EFSA's scientific opinions on the re-evaluation of propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312) as food additives CALL OPEN

European Commission

Calls for scientific and technical data from individual food additives

- Background
- Main conclusions of EFSA's scientific opinion
- Overall purpose of this call for data
- Scientific and technical data required
- Procedure of the call for data
  - ✓ Step 1: Registration of the contact details of business operators interested in submitting data
  - ✓ Step 2: Confirmation of data submission, deadlines and milestones
- Procedure for submission of the required data
- Confidential data
- Possibility for EFSA to use the data for the safety assessment of the same substance under other legal or regulatory frameworks

Calls for scientific and technical data from individual food additives

- List of data that will be submitted, deadlines and milestones will be published in the web site after completion of step 2
- Once the new data are received, they are submitted to EFSA for evaluation and preparation of a scientific opinion, if appropriate.
- A risk management decision (whether an additive remains permitted or not, and its uses/use levels, specifications) will be taken on the basis of the outcome of analysis of the new data submitted.

No additional calls for data will be organised

Calls for scientific and technical data

- Sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) (call closed)
- Sulphur dioxide (E 220), sodium sulphite (E 221), sodium bisulphite (E 222), sodium metabisulphite (E 223), potassium metabisulphite (E 224), calcium sulphite (E 226), calcium bisulphite (E 227) and potassium bisulphite (E 228) (call closed)
- Iron oxides and hydroxides (E 172) (call closed)
- Titanium dioxide (E 171) (call closed)
- Chlorophylls E 140(i), chlorophyllins E 140(ii), copper complexes of chlorophylls E 141(i) and copper complexes of chlorophyllins E 141(ii) (call closed)
- Propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312) (call closes on 31/11/17)

Codex Alimentarius

Participation in the work on the General Standard for Food Additives (GSFA)

Other Committees on issues related to FA

EU is currently chairing 3 eWG on food additives:

CCFA: eWG on nitrites and nitrates

CCNFSDU: eWG on mechanism for technological justification of substances before including them on the JECFA priority list

CCFO: eWG on the alignment of FA provisions and technological justificaiton for use of emuslifiers in FC 02.1.2 of the GSFA

Food flavourings

Food Flavourings – EU regulatory framework

- **Regulation (EC) No 1334/2008** on food flavourings
- **Regulation (EC) No 2065/2003** on smoke flavourings

European Commission

Flavourings

Flavourings are products added to food in order to impart or modify odour and/or taste. EU legislation defines several types of flavourings:

- flavouring substances
- flavouring preparations
- thermal process flavourings
- smoke flavourings
- flavour precursors
- other flavourings

The EU Rules on flavourings and certain food ingredients with flavouring properties ensure the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection.

1. Framework legislation on flavourings

*Regulation (EC) No **1334/2008***
of the European Parliament and of the Council of 16-12-2008

on flavourings and certain food ingredients with flavouring properties for use in and on foods

Lays down:

- **General and specific requirements for the use of flavourings**
- **Union list of flavourings and source materials**
- **Labelling rules for flavourings**

What does Regulation 1334/2008 cover?

Applies to:

1) **Flavourings**
2) **Food ingredients with flavouring properties**
3) **Food containing the ones above (flavourings and/or food ingredients with flavourings properties)**
4) **Source materials of flavourings and/or source materials for food ingredients with flavouring properties**

Does not apply to:

1) **Substances which have exclusively a sweet, sour or salty taste**
   (like sugar, common salt or citric acid)
2) **Raw foods**
3) **Non-compound foods and mixtures such as, fresh, dried of frozen <u>spices and/or herbs</u>, mixtures of tea and mixtures for infusion as such as long as they have not been used as food ingredients.**

Objectives of Reg 1334/2008

*To ensure **effective functioning of internal market***

whilst assuring
*- a **high level of protection of human health***
*- including the **protection of consumer interests** and*

***fair practices in food trade**,*

*taking into account where appropriate, the **protection of the environment**.*

Definitions (I)

Flavourings *= products:*

not intended to be consumed as such,

added to food ***to impart or modify: odour and/or taste****;*

made or consisting of the following categories:

- **flavouring substances**
  (Chemically defined)
- **flavouring preparations**
  (ex. vanille extract, black pepper oleoresin)
- **thermal process flavourings**
- **smoke flavourings**
- **flavour precursors, or**
- **'other' flavourings**
- **or mixtures thereof;**

Definitions (II)

- **thermal process flavourings =**

Product obtained after heat treatment from a mixture of ingredients (food or source material), of which at least one contains nitrogen (amino) and another is a reducing sugar

- **smoke flavourings =**

Obtained by fractionation and purification of a condensed smoke . Smoke flavourings are regulated in a separate specific legislation Regulation (EC) No. 2065/2003.

Definitions (III)

- **flavour precursors =**

intentionally added to food for the sole purpose

of producing flavour by breaking down or reacting with other components during food processing

(ex. carbohydrates, oligopeptides, aminoacids)

"food processing" not specifically defined

- **other flavourings =**

Intended to impart odour and/or taste and not following under the other definitions

Definitions (IV): "Food ingredient with flavouring properties"

Food ingredient with flavouring properties *=*

food ingredient other than flavourings which may be added to food for the main purpose of adding flavour to it or modifying its flavour *and*

which ***contributes*** *significantly to the presence in food of certain* ***naturally occurring undesirable substances*** *(mentioned in* ***Annex III****);*

Example: cinnamon is a food ingredient with flavouring properties (contains coumarin which is the naturally occurring undesirable substance). Cinnamon is added to a biscuit

Definitions (V): "source material"

Source material *= material of vegetable, animal, microbiological or mineral origin from which flavourings or food ingredients with flavouring properties are produced; it may be:*

- **(i) food;**

or

- **(ii) source material other than food;**

"food" can be unprocessed or processed

Part A of Annex IV contains a list of source materials not to be used for the production of flavourings and food ingredients with flavouring properties

Flavourings and food ingredients with flavourings properties for which evaluation and approval <u>are not required</u>

(Article 8)

1. **flavouring preparations** obtained from food
2. **thermal process flavourings** obtained from food which comply with the conditions for the production of thermal process set out in Annex V
3. **flavour precursors** obtained from food
4. **food ingredients with flavouring properties**

Flavourings and source materials for which evaluation and approval <u>are required</u>

(Article 9)

- **flavouring substances**
- **flavouring preparations, thermal process flavourings, flavour precursors** obtained from non-food
- **thermal process flavourings** obtained from food but which do not comply with the criteria in Annex V
- **smoke flavourings**
- **'Other' flavourings**
- **source materials other than food**

General requirements of flavourings

Only flavourings or food ingredients with flavouring properties which meet the following conditions may be used in or on foods:

(a) they do not, on the basis of the scientific evidence available,

pose a safety risk to the health of the consumer; and

(b) their use does not mislead the consumer.

Annex I - Union list of flavourings and source materials

- Commission Implementing Regulation (EU) No **872/2012** – laid down the initial list of flavouring substances in the EU

Part A: Flavouring substances

- **Around 2500 authorised flavouring substances**
- **Including among them around 300 flavouring substances currently under completion of their evaluation, and which may continue to be placed on the market**
- **Only the substances in the list can be used as flavouring substances (positive list principle)**
- **Applications on new substances follow the Common Authorization Procedure for food additives, food enzymes and food flavourings**

Union List of flavourings

COMMISSION IMPLEMENTING REGULATION (EU) No 872/2012

of 1 October 2012

adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 2232/96 of the European

substances notified by the Member States and on the basis of a specific evaluation programme.

(3) The notified substances were entered in a register laid down by Commission Decision 1999/217/EC of

Union List Part A Flavouring substances Table 1: elements

Table 1

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
FL No.	Chemical Name	CAS No.	JECFA No.	CoE No.	Purity of the named substance at least 95% unless otherwise specified	Restrictions of Use	Footnote	Reference
01.001	Limonene	138-86-3		491				EFSA
01.002	1-Isopropyl-4-methylbenzene	99-87-6	1325	620				EFSA
01.003	Pin-2(10)-ene	127-91-3	1330	2114			2	EFSA
01.004	Pin-2(3)-ene	80-56-8	1329	2113			2	EFSA
01.005	Terpinolene	586-62-9	1331	2115				EFSA
01.006	alpha-Phellandrene	99-83-2	1328	2117	At least 85%; secondary components 10-12% cymene and other terpene hydrocarbons			EFSA
01.007	beta-Caryophyllene	87-44-5	1324	2118	80-92% beta-caryophyllene and 15-19% C15H24 terpene hydrocarbons (eg. valencene)		2	EFSA

Annex I: Parts B to F

Part B to F - Other categories of flavourings and non-food source materials subject to premarketing authorisation

Part E: other flavourings: 1 entry (pyroligneous distillate, FL no: 21.001)

These parts are currently empty:

- Part B: Flavouring preparations
- Part C: Thermal process flavourings
- Part D: Flavour precursors
- Part F: Source materials

Food flavourings database

- See: Food flavourings Database

https://webgate.ec.europa.eu/foods_system/main/?sector=FAD&auth=SANCAS

European Commission

Database of food flavourings

The database reflects the Union list

https://webgate.ec.europa.eu/foods_system/main/?sector=FFL&auth=SANCAS

Most Visited

FOOD FLAVOURINGS

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Homepage

Introduction

Welcome

Welcome to the database on Food Flavourings.

This database can serve as a tool to inform about the flavouring substances approved for use in food in the EU and their conditions of use. It also contains those flavouring substances which may currently remain on the market until the risk assessment and authorisation procedures have been concluded. The information in the database is based on the Union list of flavourings and source materials as laid down in Part I of Annex I of Regulation (EC) No 1334/2008.

Important remark:

The Union list of flavourings and source materials is to apply without prejudice to other provisions laid down in sector specific legislation.

Getting started

- Food Flavourings Database Users Guide (10/09/2012)

Disclaimer

This database is made available solely for the purpose of information. It has no legal value. The Commission declines all responsibility or liability whatsoever for errors or deficiencies in this database. Neither the Commission nor any person acting on behalf of the Commission is responsible with regard to the improper use of the document and its contents. The official authorisations of food flavourings are published in the Official Journal of the European Union. Legislation on the food flavourings is also available on the Europa Food Safety website: http://ec.europa.eu/food/safety/food_improvement_agents/flavourings/eu_rules_en

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Annex III: presence of certain (naturally occurring substances of toxicological concern)

Part A: Substances not to be added as such to food

- Agaric acid
- Aloin
- Capsaicin
- Coumarin
- Hypericine
- Beta asarone
- Estragole
- Hydrocianic acid
- Menthofuran
- Methyleugenol
- Pulegone
- Quassin
- Safrole
- Teucrin A
- Thujone

Part B: Lays down maximum levels of these substances in certain compound food as consumed to be respected

Annex IV

List of source materials to which restrictions apply for their use in the production of flavourings and food ingredients with flavouring properties

Part A: Source materials not to be used

- **Calamus**

Part B: limitations for certain source materials

- **Quassia**
- **White agaric mushroom**
- **St John's wort**
- **Wall germander**

Annex V

Conditions for the production of thermal process flavourings and maximum levels for certain substances in thermal process flavourings

- Part A: conditions for the proccess:

- **Max temperature <180°C**
- **Max duration of thermal processing**
- **Max pH < 8.0**

- Part B: levels for certain substances

- **2 substances with limits**

Some specific labelling aspects (Chapter IV of Reg. 1334/2008)

- Labelling of flavourings **intended** for sale to the final consumer (Art 15)

- Designation of flavourings in the **list of ingredients** (amendment to Directive 2000/13)
  - **'flavourings'** or a more specific name or description of the flavouring, if the flavouring component contains flavourings defined in flavourings Regulation
  - **smoke flavouring(s)** or **smoke flavouring(s) produced from 'food(s) or food category or source(s)'** (e.g. smoke flavouring produced from beech), if the flavouring component contains smoke flavourings and imparts a smoky flavour to the food.
- Specific requirements for use of the term **"natural"**

- Also covers labelling of flavourings **not intended** for sale to the final consumer (Art 14)

Managing the EU legislation

- **Update of the Union lists**
  - Adding a substance;
  - Removing a substance;
  - Adding, removing or changing conditions, specifications or restrictions related to the presence of a substance

- **There has been 20 modifications to the Union list of flavourings since the initial union list of 2012 They concern some 98 flavourings: additions, removals, or modifications of the conditions of use)**

Annex I – Evolution for substances under completion of their evaluation

Currently EFSA (following the programme of evaluation of flavourings) is evaluating

- some 260 substances in the Union List are still under completion of their evaluation, and also
- new substances object of applications and there are also applications to change the conditions of use

2. Smoke Flavourings Regulation

*Regulation (EC) No **2065/2003** of the European Parliament and the Council of 10 November 2003 on smoke flavourings used or intended for use in or on food.*

Applies to :

- **Smoke flavourings used or intended for use in or foods**
- **Food in or on which smoke flavourings are used**

Smoke Flavourings Regulation

General use and safety requirements

- **Sufficiently demonstrated that the smoke flavouring does not present risks to human health**
- **The use does not mislead the consumer**

Union list of authorised primary products: Exclusion of all others for use as such in or on foods and/or for the production of derived smoke flavourings

Smoke Flavourings Regulation Definitions

'smoke flavouring' = *Obtained by fractionation and purification of a condensed smoke*

1.'primary smoke condensate' = purified water-based part of condensed smoke

2. 'primary tar fraction' = purified fraction of the water-insoluble high-density tar phase of condensed smoke;

3. 'primary products' = primary smoke condensates and primary tar fractions;

4. 'derived smoke flavourings' = flavourings produced as a result of the further processing of primary products

Conditions of production

- *wood certified untreated*
- *additional requirements in Annex I, including max levels of benzo[a]pyrenes, benz[a]atrazenes*

Union list of authorised smoke flavourings primary products

Union list of authorised primary products (2013)

Regulation 1321/2013

- Use as such in or on foods and/or for the production of derived smoke flavourings
- 10 products
- Authorisations limited in time, granted for a 10 year period and to specific authorisation holders

Contents of Union List of smoke flavourings

- *Unique code*
- *Name of the product*
- *Name and address of authorization holder*
- *Description and characterisation of the product*
- *Conditions of its use*
- *Date from which it is authorised*

Other aspects

- traceability provisions to ensure respect of max levels and labelling

- application for new primary smoke flavourings (amendment of the Union list). These are done under this Regulation (not under the CAP Regulation for additives enzymes and the other flavourings): one application on going currently

-EFSA has guidance on the requirements for smoke flavourings

International aspects of flavourings

- Flavourings are discussed in Codex Alimentarius at the Codex Comittee on Food additives.

- The WHO/ FAO JECFA evaluates flavourings in its sessions every second year.

EFSA takes into account the JECFA assessments. This happened particularly during the program of evaluation of the existing flavouring substances which started in 2000. EFSA applies a system of evaluation of flaovuring substances (The EFSA procedure) which is adapted from the JECFA one.

Food enzymes

Food Enzymes Legislation

Regulation No 1332/2008 lays down rules on food enzymes used in foods, including such enzymes used as processing aids.

Definition of food enzyme

FE means a product….containing one or more enzymes capable of catalyzing a specific biochemical reaction; and that are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of food, including enzymes used as processing aids.

Food Enzymes Legislation

Reg 1332/2008 does not apply to

- *Enzymes used exclusively in the production of FAs and PAs.*
- *Enzymes intended for human consumption, such as enzymes for nutritional purposes.*
- *Microbial cultures that are traditionally used in the production of food, such as cheese and wine, which may contain enzymes but are not specifically used to produced them.*

Food Enzymes Legislation

*This Regulation **provides for***:

a) *A Union list of approved food enzymes;*

b) *Conditions of use of food enzymes in foods;*

c) *Rules on the labelling of food enzymes sold as such*

Food Enzymes Legislation

Establishment of the Union list of Food Enzymes

- *Union list in one single step. After EFSA has delivered its opinion on all the FE listed in the Register.*

- *Until the date of application of the Union list, national provisions in force on food enzymes shall continue to apply in the MS.*

Food Enzymes Legislation

Establishment of the Union list of Food Enzymes.
Article 7-Content

Name	Specifications	Foods	Conditions of use	Restrictions on the sale of the food enzyme to the final consumer	Specific requirement in respect of labelling of food

Food Enzymes Legislation

Conditions of use

RA

*Do not pose **a safety concern** to the health of the consumer at the level of use proposed;*

RM

*Reasonable **technological need** for their use;*

*Its use does not **mislead the consumer***

Food Enzymes Legislation

Rules of the labelling of food enzymes sold as such

- *If food enzymes are sold as such to food manufacturers*
- *If food enzymes are sold as such to final consumers*
- *If food enzymes are present in foods intended for final consumers.*

For options 1 and 2 the legal provisions are laid down in Art 10-12 of the enzyme Regulation

The views expressed are purely those of the speaker and may not in any circumstances be regarded as stating an official position of the European Commission

Labelling of food enzymes: food intended for final consumer

FE as an ingredient

- *Food enzymes are covered by the definition of food in Regulation (EC) No 178/2002 and are therefore, when used in food,* ***required to be indicated as ingredients in the labelling of the food*** *in compliance with labelling Regulation.*
- *Food enzymes should be designated by* ***their technological function*** *in food,* ***followed by the specific name of the food enzyme.***

Labelling of food enzymes: food intended for final consumer

FE not to be included in the list of ingredients

Art. 20 of Reg No 1169/2011

*The enzyme performs **no technological function in the final product** but is present in the foodstuff:*

- ✓ *If the enzyme is only present in the foodstuff **as a result of carry-over** (Art 18(1) of Reg 1333/2008) from one or more of the ingredient of the foodstuff*
- ✓ *If used as a **processing aid.** Residues are not considered as "ingredients"*

Guidance on food enzymes

1-Article 3 of Reg 234/2011-The applicant shall take into account the practical guidance on the submission of applications made available by DG SANTE's website

http://ec.europa.eu/food/safety/food_improvement_agents/common_auth_proc_guid/index_en.htm

2-Article 5 of Reg 234/2011-The applicant shall take into account the latest guidance documents adopted or endorsed by EFSA. Available at EFSA and SANTE's website

- *GMM-derived enzymes*
  http://www.efsa.europa.eu/en/efsajournal/pub/2193.htm
- *Conventional food enzymes*
  http://www.efsa.europa.eu/en/efsajournal/pub/1305.htm

FOOD IMPROVEMENT AGENTS

Additives

Enzymes

EU Rules

EU List and Applications

Flavourings

Extraction Solvents

Common Authorisation Procedure

ALL TOPICS

Enzymes

What are food enzymes and why are they used for?

Enzymes are naturally-occurring proteins that enhance biochemical reactions. They can be obtained by extraction from plants or animals or by fermentation from micro-organisms. They are normally added to perform a technological function in the manufacture, processing, preparation and treatment of a wide range of foods.

Food enzymes (FE) are mainly used in baking industry, for manufacturing fruit juices, in wine making and brewing as well as in cheese manufacturing. An important field of applications in terms of volumes is starch conversion to yield ingredients for foodstuff.

What are the benefits for the food industry?

In food production, food enzymes have a number of advantages:

- They can be used as alternatives to traditional chemical-based technology, and can replace synthetic chemicals in many processes. Such uses can improve the environmental performance of production processes, through lower energy consumption and biodegradability.
- They are more specific in their action than synthetic chemicals. Therefore, processes which utilise enzymes have fewer side reactions and waste by-products, resulting in higher quality purified products.

Are food enzymes safe?

In the past, the safety of some food enzymes was assessed by the Scientific Committee on

What will happen if a new enzyme is developed after March 2015?

- *An application shall be submitted for a safety evaluation. It will not be included in the Register.*
- *The enzyme will not be listed on the first Union list. However, it may be in the updated list.*
- *Until the Union list is applied, the enzyme concerned may be marketed under current national laws. If needed, transitional arrangements can be made.*

What will happen if an enzyme is developed after the establishment of the Union list?.

- *An application shall be submitted for a safety evaluation. It will not be included in the Register.*
- *EFSA has 9 months to make the opinion.*
- *COM has to submit the draft Regulation to the Committee within 9 months*
- *The new enzyme cannot be marketed until the updated Union list is adopted.*

Risk management

Two conditions of use:

- *Reasonable technological need*
- *Its use does not mislead the consumer*

Other tools

Guidance document of categorisation of food enzymes may help to determine whether the enzyme is used as a processing aid or as an ingredient

Food enzyme applications submitted within the deadline

Overall figures

Total No of received applications	GMM source	Non-GMM source	Animal/plant source
301	127 (42%)	136 (45%)	38 (13%)

Main food uses

Food uses
Baking processes
Dairy processing
Cereal-based distilled alcoholic beverages
Brewing process and other cereal-based beverages
Flavouring production
Starch processing
Fruit and vegetable processing

Current state of play

42 EFSA opinions adopted (December 2018)

EU register of valid applications for the 1st Union list practically finalised

The safety assessment will take several years (202?) before it is completed and the 1st Union list can be established.

Extraction solvents

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Extraction Solvents

Directive 2009/32/EC *of the European Parliament and of the Council on the approximation of the laws of the Member States* ***on extraction solvents used in the production of foodstuffs and food ingredients***

Directive – i.e. it needs to be transposed to the national legislation!

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 15 September 2011 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Although not covered by CAP (R. 1331/2008) the procedure for amendment of the Annexes follow CAP to a very large extent.

Until now Directive amended 2 times

Extraction Solvents

What are extraction solvents and what are they used for?

Extraction solvents are solvents used in an extraction procedure during the processing of raw materials, of foodstuffs, or of components or ingredients of these products and which are removed but which may result in the unintentional, but technically unavoidable, presence of residues or derivatives in the foodstuff or food ingredient.

Solvent means any substance for dissolving a foodstuff or any component thereof, including any contaminant present in or on that foodstuff.

The EU Rules on extraction solvents for use in foodstuffs should take account primarily human health requirements but also, within the limits required for the protection of health, economic and technical needs.

Directive 2009/32/EC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients **applies** to extraction solvents used or intended for use in the production of foodstuffs or food ingredients either in the EU or imported into the EU.

This Directive shall **not apply** to:

- extraction solvents or foodstuffs intended for export outside the EU

- extraction solvents used in the production of food additives, vitamins and other nutritional additives, unless such food additives, vitamins or nutritional additives are listed in Annex I (of the Directive).

How to obtain further information?

Further information and training

Web:
https://ec.europa.eu/food/safety/food_improvement_agents_en

Contact emails: SANTE-E2-Additives@ec.europa.eu, SANTE-E2-ENZYMES@ec.europa.eu and SANTE-E2-Flavourings@ec.europa.eu

Legislation: https://eur-lex.europa.eu/

Training: Better Training for Safer Food (BTSF) – Training on the legislation and control of food improvement agents

Course A - Training for control staff on harmonised implementation and enforcement of the EU legislation on food improvement agents – 10 sessions

Course B - Training on the planning of monitoring and official controls of food improvement agents – 4 sessions

Thank you for your attention!

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union'