

# The new E.U. regulation of flavours



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# Content of the presentation

1. New framework legislation
2. EU list of flavouring substances
3. Common authorisation procedure
4. Smoke flavourings

# Framework legislation on flavourings

- Council Directive **88/388/EEC** of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production

*has been replaced by*

- Regulation (EC) No **1334/2008** of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC
- Regulation (EC) No **1331/2008** of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings

# Objective

- To ensure **effecting functioning of internal market** whilst assuring the **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**.
- These Regulations provide for:
  - General and specific requirements for the use of flavourings
  - Procedure for evaluation and authorisation of flavourings
  - Labelling rules for flavourings



## Scope of the Regulation 1334/2008

- Applies to:
  - 1) Flavourings
  - 2) Food ingredients with flavouring properties
  - 3) Food containing 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
  - 2) Raw foods
  - 3) Non-compound foods and mixtures such as, but not exclusively, fresh, dried or frozen spices and/or herbs, mixtures of tea and mixtures for infusion as such as long as they have not been used as food ingredients.

# General requirements

- 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.

# Definitions 1

- **Flavourings** shall mean products:
- not intended to be consumed as such, which are added to food in order **to impart or modify** odour and/or taste;
- made or consisting of the following categories:
  - flavouring substances
  - flavouring preparations
  - thermal process flavourings
  - smoke flavourings
  - flavour precursors
  - or other flavourings or mixtures thereof;

## Definitions 2

- **Food ingredient with flavouring properties** shall mean a 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;
- **source material** shall mean 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;



## Flavourings and food ingredients with flavourings properties for which evaluation and approval are **not required**:

1. **flavouring preparations** obtained from food
2. **thermal process flavourings** obtained from food which comply with the conditions for the production of thermal process flavourings and maximum levels for certain substances in thermal process flavourings 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 **is required**

- 1. flavouring substances**
- 2. flavouring preparations, thermal process flavourings, flavour precursors** obtained from non-food
- 3. thermal process flavourings** obtained from food but which do not comply with the criteria in Annex V
- 4. smoke flavourings**
- 5. other flavourings**
- 6. source materials** other than food

# Labelling

- Labelling of flavourings **not intended for sale** to the final consumer
- Labelling of flavourings **intended for sale** to the final consumer
- Designation of flavourings in the **list of ingredients**
  - **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**



## Reporting by the food business operators

- Information on the amount of the substance added to foods
- For already approved flavouring which is prepared by production methods or starting materials **significantly different** from those included in the risk assessment of the Authority, data should be submitted to allow an evaluation of the flavouring by EFSA with regard to the modified production method or characteristics.
- Obligation to inform the Commission immediately of any new scientific or technical information

# Annexes

- I: Union list of flavourings and source materials approved for use in and on foods
- II: List of traditional food preparation processes
- III: Presence of certain substances
  - **Part A:** Substances which shall not be added as such to food
  - **Part B:** Maximum levels of certain substances, naturally present in flavourings and food ingredients with flavouring properties, in certain compound food as consumed to which flavourings and/or food ingredients with flavouring properties have been added
- IV: List of source materials to which restrictions apply for their use in the production of flavourings and food ingredients with flavouring properties
- V: Conditions for the production of thermal process flavourings and maximum levels for certain substances in thermal process flavourings

# Implementing measures

- Union list of flavourings and source materials (Annex I)
  - Flavourings substances: Regulation (EC) No **2232/96** of the European Parliament and the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs.
  - Other categories of flavourings and non-food source materials
  
- Guidance on common methodology for gathering intake data

## EU list of flavouring substances

- Register of flavouring substances  
(Commission Decision 1999/217)
- Substances evaluated by
  - Scientific Committee on Food
  - Council of Europe
  - Joint FAO/WHO Expert Committee on Food Additives (JECFA)
  - The European Food Safety Authority
- Will contain about 2 400 substances

## 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
- Procedure for updating the Union list
  1. Adding the substance on the list
  2. Removing the substance from the list
  3. Addition, removing or changing of the conditions, specifications or restrictions which are associated with the presence of the substance on the list
- Does not apply to smoke flavourings



## Main stages of the common procedure (1)

- May be started either on the initiative of the Commission or following an application. Applications may be made by a Member State or by an interested party. Applications shall be sent to the Commission.
  - On receipt of an application to update the Community list, the Commission:
    - (a) shall acknowledge receipt of the application in writing to the applicant within 14 working days of receiving it;
    - (b) where applicable, shall as soon as possible notify EFSA of the application and request its opinion



## Main stages of the common procedure (2)

- Consultation of the European Food Safety Authority except if the updates in question are not liable to have an effect on human health.
  - EFSA shall give its opinion within nine months of receipt of a valid application.
- Ends with the adoption by the Commission of a regulation implementing the update.
  - Within nine months of EFSA giving its opinion, the Commission shall submit a draft regulation updating the Community list.
  - If no EFSA opinion needed, the Commission has nine months from the date of receiving the valid application

# Guidance for applicants

- Regulation 234/2011 on guidance for applicants
  1. The content, drafting and presentation of the application
  2. The arrangements for checking the validity of applications
  3. The type of information that must be included in the opinion of EFSA
- Applicable from 11 September 2011
- Practical guidance on SANCO website

# Smoke Flavourings Regulation 1

- 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 present

## Smoke Flavourings Regulation 2

- 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



## Smoke Flavourings Regulation 3

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

## Smoke flavourings list

- 10 products to consider
- 3 products with “no safety concern at proposed uses and use levels”
- 6 products with “safety concern at proposed uses and use levels”
- 1 product no conclusion on genotoxicity but margins of safety established



Thank you!