B2C Labelling of Food Additives
The ELC is the voice of the Specialty Food Ingredients Industries in Europe. We aim to create a safe and suitable regulatory environment and represent the industry with EU-decision-makers.

It is our objective to ensure that all stakeholders – from manufacturers and retailers to regulatory authorities and consumers – are correctly informed of the use and safety of specialty food ingredients and their advantages.
More than 200 EU companies represented either by direct membership or through a member association.
Specialty ingredients are valuable – not just for the food industry but for everybody who enjoys tasty, safe, affordable food and choice.

Manufactured food has a place in today’s health balanced diet.

The ingredients used are there for a reason. With their technological, nutritional and health related functions, they help deliver tasty, safe, affordable food and food choices, hence they are an integral part of our food supply.

To name but a few: vitamins, minerals, enzymes, specific proteins, fibres, additives, specific carbohydrates, cultures etc.
- 3-8 % of EU specialty food ingredients manufacturers’ turnover is dedicated to R&D, depending on the sectors. Overall the average investment is between 4-5 % of revenue.

- The specialty food ingredients industry represents around €35 billion of the global food ingredients market – of which 40 % (around €15 billion) is in Europe.
Today’s agenda

- Setting the scene: the new EU legislative framework for FA
- General labelling requirements
- Particular requirements
- Challenges
Setting the scene:
the new EU legislative framework for FA
Overview

Directive 89/107/EEC
Framework Directive

Directive 94/35/EC
Sweeteners Directive

Specifications Dir 2008/60/EC

Directive 94/36/EC
Colours Directive

Specifications Dir 2008/128/EC

Directive 95/2/EC
MAD Directive

Specifications Dir 2008/84/EC

Regulation (EC) 1331/2008
Common authorisation procedure for FA, FE & FF

Regulation (EC) 1333/2008
Food Additives

Regulation (EU) …/2012
Specifications

Regulation (EU) 1169/2011
Food Information to Consumers
Application Dec. 2014
Annex III of Regulation (EC) 1333/2008

- Carriers
- Additives including carriers
- Additives other than carriers
- Additives
- Flavourings
- Enzymes
- Nutrients

NEW

(except for nutrients for use in foodstuffs for infants and young children)
Definitions & general rules

« Ingredient » means any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if an altered form; residues shall not be considered as ingredients. (Art. 1 (f) Reg. (EU) 1169/2011)

Ingredients shall be listed, however certain constituents of foods can be omitted from the list of ingredients:

[...]

(b) **food additives** and food enzymes

(i) whose presence in a given food is solely due to the fact that they were contained in one or more ingredients of that food, in accordance with the carry-over principle, provided that they serve no technological function on the finished product

(ii) which are used as **processing aids**

[...]

(Art. 20 Reg (EU) 1169/2011)
Food additive

« Food additive » shall mean any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods»

List of a number of substances that are not considered to be food additives: e.g. caseinates and casein, inulin, chewing gum bases etc.

Art. 3.2. (a) Reg. (EC) 1333/2008
Processing aids

« Processing aid » shall mean any substance which:
(i) is not consumed as a food by itself;
(ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and
(iii) may result in the unintentional but technologically 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.

Art. 3.2. (b) Reg. (EC) 1333/2008
Carry-over

The presence of a food additive shall be permitted:

(a) In a compound food other than as referred to in Annex II of Reg. (EC) 1333/2008, where the food additive is permitted in one of the ingredients of the compound food.

(b) In a food to which a food additive, food enzyme or food flavouring has been added, where the food additive:
   (i) is permitted in the food additive, food enzyme or food flavouring in accordance with Regulation (EC) 1333/2008; and
   (ii) has been carried over to the food via the food additive, food enzyme or food flavouring; and
   (iii) has no technological function in the final food.

(c) In a food which is to be used solely in the preparation of a compound food and provided that the compound food complies with Reg. (EC) 1333/2008.
The carry-over principle via a compound food shall not apply to:
- foods listed in Table 1 of Annex II of Regulation (EC) 1333/2008 as regards food additives in general (i.e. unprocessed foods, butter, honey etc)
- foods listed in Table 2 of Annex II of Regulation (EC) 1333/2008 as regards food colours (i.e. unprocessed foods, chocolate milk, pasta and gnocchi etc)

Reg. (EC) 1333/2008 – Annex

- The carry-over principle shall not apply to infant formulae, follow-on formulae, processed cereal-based foods, baby-foods and peanuts except where specifically provided for.

Reg. (EC) 1333/2008 – Art. 18.2
Summary: case-by-case basis!

Food additive + Technological role in final food = Labelling

Food additive + No technological role in final food = NO Labelling except for allergens

Processing aids + Carry-over (incl. Annex III) = With exceptions
General labelling requirements
Food additives and food enzymes must be designated by the name of their category, followed by their specific name or, if appropriate, E number. If an ingredient belongs to more than one of the categories, the category appropriate to the principal function in the case of the food in question shall be indicated (Annex VII – part C – Reg. (EU) 1169/2011)

Category examples
- Anti-caking agent
- Bulking agent
- Emulsifier
- Colour
- Gelling agent
- Sweetener
- Thickener
- Modified starch (specific name or E number shall not be required to be indicated)
- etc

Emulsifier: lecithin OR Emulsifier: E 322

Sweetener: maltitol OR Sweetener: E 965
Food additives sold singly or mixed with each other and/or other food ingredients:

- Name and E number in respect of each food additive, or a sales description which includes the name and E number of each food additive
- The statement « for food » or « restricted use in food » or a more specific reference to its intended food use

(Art. 23 of Reg. (EC) 1333/2008)

Food additives are exempted from the requirement of the mandatory nutrition declaration

(Annex V of Reg. (EU) 1169/2011)
Specific provisions for table-top sweeteners

- The sales description shall include the term « …-based table-top sweetener », using the name(s) of the sweetener(s) used in its composition.

- Additional warnings may be required:
  - Polyols: « excessive consumption may induce laxative effects »
  - Aspartame/Aspartame-acesulfame salt : « contains a source of phenylalanine »

- Manufacturers of TTS shall make available by appropriate means the necessary information to allow their safe use by consumers.

(Art. 23 of Reg. (EC) 1333/2008)
Particular requirements
Two categories of particular requirements

Foods for which the labelling must include one or more additional indication:

**General**
- Allergens
- GMOs
- Nano-materials
- Nutrition

**Specific**
- Packaging gases
- Some colours
- Sweeteners
- Formed meat/fish
Allergen labelling

- A number of exemptions granted to additives derived from the list of substances or products causing allergies or intolerances (Annex II of Reg. (EU) 1169/2011), e.g.
  - Polyols and caramel colours obtained from wheat/wheat based glucose syrups
  - Emulsifiers obtained from fully refined soybean oil and fat
  - Lactitol obtained from milk

- Processing aids that can cause allergies or intolerances must be labelled
  - 2011 EFSA opinions did not rule out potential allergenicity of
    - Wine fined with casein/caseinate/milk
    - Wines fined with ovalbumine/egg white products
    - Wines treated with lysozyme
GMOs

- Foods containing material which contains, consists of or is produced from GMO in a proportion higher than 0.9% of the food ingredients considered individually or food consisting in a single ingredient (Reg. (EC) 1829/2003)

  ➔ GM-crop derived food additives: « genetically modified … » or « produced from genetically modified (name of the ingredient) »
Additional requirements – general (cont’d)

GMOs (cont’d)

- “Food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified micro-organism (GMM) which is kept under contained conditions and is not present in the final product are not included in the scope of Regulation (EC) No 1829/2003. These food and feed have to be considered as having been produced with the GMM, rather than from the GMM.

- Food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified micro-organism (GMM) which is present in the final product, totally or partially, whether alive or not, are included in the scope of Regulation (EC) No 1829/2003, in regard of both authorisation and labelling.”
  
  (Minutes SCFCAH meeting (section on GM food and feed) - September 2004)
Nano-materials

« All ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word « nano » in brackets » Art. 18.2 of Reg. (EU) 1169/2011

The scope of the definition triggers the labelling

The definition in Art. 2(t) of Reg. (EU) 1169/2011 is under review to take into account the definition provided in the Commission Recommendation 2011/696/EU

ELC supports that such labelling shall be reserved to new substances that do exhibit nano-characteristics that do not exist in their bulk counterparts.
Nano-materials (cont’d)

- The nano-labelling is perceived by the consumers as a warning labelling

- To the question « Would you buy products from the following groups if they contain nanomaterials? », the answer is NO for food for 80% of respondents (2007 survey).

“Acceptance is lowest for foods. The differences within this area can be attributed to various reasons: acceptance is greater in the case of food packaging than in the case of an application which leads directly to a change in the food. Furthermore, benefit considerations seem to play a role. The differing acceptance of nanotechnology when it comes to encapsulating vitamins and improving the appearance of food seems to point in this direction.”

BfR Wissenschaft report « Public perception about nanotechnologies »
Nutrition

- Dual use additives e.g. additives and vitamins
  - Labelling is determined by intention of use

- Nutrition declaration
  - Food additives = fibres, carbohydrates, starch, polyols
  - Polyols taken into account for the calculation of energy

- Relation to Regulation (EC) 1924/2006
  - A number of Nutrition and Health Claims are related to food additives (ca 20)
Foods packaged in certain gases

« packaged in a protective atmosphere »

Certain foods containing some food colours


Sunset yellow - E 110
Quinoline yellow - E 104
Carmoisine - E 122
Allura red - E 129
Tartrazine - E 102
Ponceau 4R - E 124

« Name or E number: may have an adverse effect on activity and attention in children »

Mandatory labelling except in:

- Foods where the colour(s) has been used for the purposes of health or other marking on meat product or for stamping or decorative colouring on eggshells
- Beverages containing more than 1,21 % by volume of alcohol (Reg. (EU) 238/2010)
**Foods containing sweeteners**


- **« with sweetener(s) »:** this statement shall accompany the name of the food.
- **« with sugar(s) and sweetener(s) »:** this statement shall accompany the name of the food.
- **Aspartame/aspartame-acesulfame salt: ** « **contains aspartame (a source of phenylalanine) » shall appear on the label in cases where aspartame/aspartame-acesulfame salt is designated in the list of ingredients only by reference to the E number.
- **« contains a source of phenylalanine »** shall appear on the label in cases where aspartame/aspartame – acesulfame salt is designated in the list of ingredients by its specific name.
- **More than 10 % added polyols** « **excessive consumption may produce laxative effects »**.
Formed meat/formed fish

Meat products, meat preparations and fishery products which may give the impression that they are made of a whole piece of meat or fish, but actually consist of different pieces combined together by other ingredients, including food additives and food enzymes or by other means, shall bear the following indication: « formed meat » and « formed fish ».

Annex VI- Part A -7 of Reg. (EU) 1169/2011
Challenges:
From food additives to food improvement agents
A distorted perception of the E number

- E number: the safety stamp of the EU legislator.
- However in practice: poor public perception.
  - « Natural » additives are not legally defined at EU level
    - Subject to national guidelines in certain MS
    - Marketing practices
    - Baseline: shall not mislead the consumer
  
- Eurobarometer 2005/2010 on food related risk perception

  “Concerns have increased regarding […] food additives, colours and preservatives (9%, +2 points vs. 2005).”
A distorted perception of the E number (cont’d)

QF3. Could you tell me in your own words, what are all the things that come to your mind when thinking about possible problems or risks associated with food and eating? Just say out loud whatever comes to mind and I will write it down. Anything else?

- Chemical products, pesticides, toxic substances: 19%
- Food poisoning, Bacteria (e.g. salmonella, listeria): 12%
- Diet-related diseases (high cholesterol, cardiovascular problems, diabetes, ...): 10%
- Obesity, overweight: 9%
- Lack of freshness, expiry dates: 9%
- Food additives, colouring, preservatives: 9%
- GMOs - genetically modified organisms: 8%
- Diet too high in fat, sugar or calories/ Unbalanced diet: 7%
- We do not know what we are eating/traceability of the products, origin of products: 7%
- Food is not natural/ industrial/ artificial: 6%
- Lack of sanitary controls/ hygiene: 5%
- Poor food quality: 5%
- Cancer: 5%
- Allergies/Allergic to certain food: 4%
- Prices (prices too high/ food too expensive): 3%
- Environmental concerns: 3%
- New viruses and diseases (bird flu, swine flu): 3%
- Digestive problems and discomforts (indigestions, ulcers, etc.): 3%
- Bovine spongiform encephalopathy (BSE - mad-cow disease): 2%
- Problem of poverty/ lack of food/ hunger in the world: 2%
- New technologies (e.g. animal cloning, nanotechnology, irradiation): 1%
- Anorexia/ Bulimia: 1%
- No problem: 9%
- Don’t know: 8%

Worry about “additives like colours, preservatives or flavourings used in food or drinks” ranks third in the ‘medium levels of worry’ issues. This worry is most pronounced in Lithuania (87%), Greece (85%) and Cyprus (82%). With regard to this issue there is a large increase in worry levels since 2005 in the Netherlands (56%; +16) and Sweden (54%; +14). The United Kingdom is again the only country with a clear decline in concern (51%; -11).
Commendable EC’s efforts

DG SANCO website: section Food Improvement Agents
EUROPA - Food Safety - Food Additives, Enzymes and Flavourings

Youtube clip:
«No need to scan your food for additives.
Their safety has been scanned for you.
There are strict laws on food additives in the European Union»
Next step ➔ towards a simpler labelling of food additives?

ELC supports that food additives that express strong similarities (chemically, technologically and toxicologically) could be replaced in the list of ingredients by a group name instead of by their specific name.

E.g. «sorbates» for sorbic acid, potassium sorbate and calcium sorbate.

<table>
<thead>
<tr>
<th>Current labelling rules</th>
<th>ELC proposed labelling rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turkey fillet 97%; salt; dextrose; glucose syrup; saccharose; spice; spice extracts; stabilisers: trisodium citrate, tripotassium citrate, diphosphates, triphosphates; antioxidants: sodium ascorbate, E 316; preservative: sodium nitrite</td>
<td>Turkey fillet 97%; salt; dextrose, glucose syrup; saccharose; spice; spice extracts; stabilisers: citrates, phosphates; antioxidants: ascorbates; E 316; preservative: sodium nitrite</td>
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</table>
Food additives are there for a reason!

- Food additives serve specific technological purposes in food

- Their safety is assessed as part of the pre-market authorization

- They are labelled ➔ the consumer is informed about both their presence and their role in foods and drinks
Thank you for your attention

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