CZECH AGRICULTURE AND FOOD INSPECTION AUTHORITY

New EU legislation on food additives

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Czech Agricultural and Food Inspection Authority (CAFIA)

Introduction

Czech Agricultural and Food Inspection Authority (CAFIA)

- state administration body (subordinate to the Ministry of Agriculture)

- state authority responsible for supervision of safety, quality and labelling of foodstuffs.

EU legislation – useful basics

EU legal acts can come in three different forms:

- **Regulation**

has direct effect; becomes immediately enforceable as law in all member states simultaneously

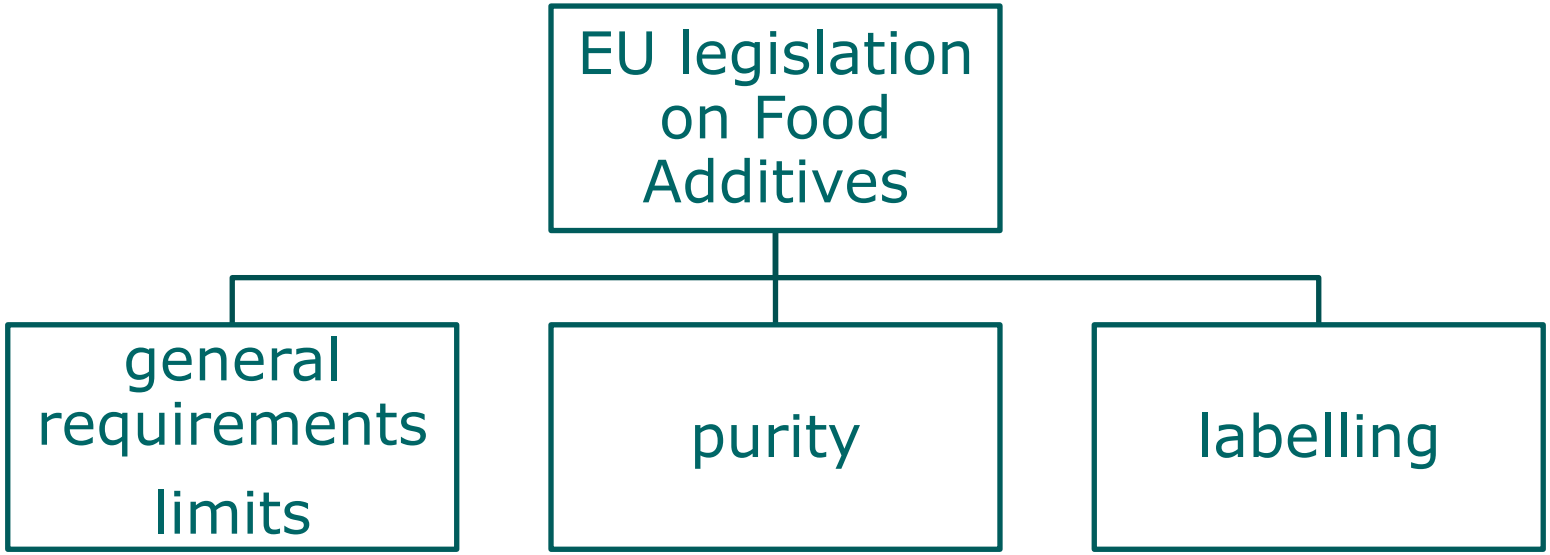
- **Directive**

needs to be transposed, within certain limits, into national law; which requires member states to achieve a particular result without dictating the means of achieving that result

- **Decision**

has direct effect, but only relating to a specific person or entity, and there are also various other non-binding instruments. Decisions may be addressed to member states or individuals.

EU legislation on Food Additives



EU acts concerning Food Additives

- Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning **food additives** authorized for use in foodstuffs intended for human consumption
- European Parliament and Council Directive 95/2/EC on food **additives other than colours and sweetener**
- European Parliament and Council Directive 94/35/EC on **sweeteners** for use in foodstuffs
- European Parliament and Council Directive 94/36/EC on **colours** for use in foodstuffs
- Commission Decision 2002/247/EC suspending the placing on the market and import of jelly confectionery containing the food additive E 425 **konjac**
- Commission Decision 2004/374/EC suspending the placing on the market and import of jelly mini-cups containing the food additives E 400, E 401, E 402, E 403, E 404, E 405, E 406, E 407, E 407a, E 410, E 412, E 413, E 414, E 415, E 417 and/or E 418
- Commission Regulation (EC) No 884/2007 on emergency measures suspending the use of E 128 **Red 2G** as food colour

EU legislation concerning Food additives – purity criteria

- Commission Directive 2008/60/EC laying down specific purity criteria concerning sweeteners for use in foodstuffs
- Commission Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners
- Commission Directive 2008/128/EC laying down specific purity criteria concerning colours for use in foodstuffs

EU legislation concerning Food additives – labelling

- Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
- Commission Regulation (EC) No 50/2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms

Additives EU legislation - access

Where is it possible to find EU legislation?

www.eur-lex.europa.eu

- easy and free access
- available in all EU languages

EU legislation - search

difficult orientation in EU law – not easy to find current act including all amendments

consolidated text – all amendments included

Additives EU legislation – implementation (transposition) in the Czech republic

All EU directives concerning food additives in the Czech republic excep purity criteria implemented into one Decree. Regularly amended.

Directive 89/107 EEC (General)

- Concerning all additives
- Definitions:

food additive - 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

Shall not apply to:

- processing aids
- subsatnces used for protection of plants and plants products
- nutrients (for example minerals, trace elements or vitamins)

- General criteria for usage
- Labelling (not intended for sale to the ultimate consumer and intended for sale to the ultimate consumer)

Directive 89/107 EEC

- Categories of food additives

Colour	Flavour enhancer	Glazing agent
Preservative	Acid	Flour treatment agent
Anti-oxidant	Acidity regulator	Firming agent
Emulsifier	Anti-caking agent	Humectant
Emulsifying salt	Modified starch	Sequestrant
Thickener	Sweetener	Enzyme
Gelling agent	Raising agent	Bulking agent
Stabilizer	Anti-foaming agent	Propellent gas and packaging gas

Directive 94/35/EC (Sweeteners)

- Definitions (no sugar added and sugar free)
- General criteria for usage
- Limits (maximum usable doses) for:
- Polyols (sorbitol, manitol, isomalt, maltilol, lactitol, xylitol, erythitol) - *quantum satis* for all food
- acesulfame K, aspartame, cyclamates, saccharine, sucralose, thaumatin, neohesperidine DC, salt of aspartame-acesulfame, neotame - limits

Directive 94/35/EC (Sweeteners)

Ilustration

E 951	Aspartame	**Non-alcoholic drinks**	
		— Water-based flavoured drinks, energy-reduced or with no added sugar	600 mg/l
		— Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar	600 mg/l
		Desserts and similar products	
		— Water-based flavoured desserts, energy-reduced or with no added sugar	1 000 mg/kg
		— Milk- and milk-derivate-based preparations, energy-reduced or with no added sugar	1 000 mg/kg
		— Fruit- and vegetable-based desserts, energy-reduced or with no added sugar	1 000 mg/kg
		— Egg-based desserts, energy-reduced or with no added sugar	1 000 mg/kg
		— Cereal-based desserts, energy-reduced or with no added sugar	1 000 mg/kg
		— Fat-based desserts, energy-reduced or with no added sugar	1 000 mg/kg
		— 'snacks': certain flavours of ready to eat, prepacked, dry, savoury starch products and coated nuts	500 mg/kg
		Confectionery	
		— Confectionery with no added sugar	1 000 mg/kg
		— Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar	2 000 mg/kg
		— Starch-based confectionery, energy-reduced or with no added sugar	2 000 mg/kg

Directive 94/36/EC (Colours)

- Definitions of colours and substances not be considered colours
- List of substances which may be used as colours
- Foodstuffs which may not contain added colours
- Foodstuffs which may contain only selected colours
- Colours permited only for certain uses
- Limits (maximum usable doses)

Directive 95/2/EC on food additives other than colours and sweetener

- Definitions of categories
- List of substances which may be used as additives
- Foodstuffs which may not contain additives
- Additives generally permited for use in foodstuffs
- Foodstuffs in which a limited number of additives may be used
- Limits (maximum usable doses)

Purity criteria (e.g. Directive 2008/128/EC)

E 127 ERYTHROSINE

Synonyms	CI Food Red 14
Definition	Erythrosine consists essentially of disodium 2-(2,4,5,7-tetraiodo-3-oxido-6-oxoxanthen-9-yl) benzoate monohydrate and subsidiary colouring matters together with water, sodium chloride and/or sodium sulfate as the principal uncoloured components.
	Erythrosine is described as the sodium salt. The calcium and the potassium salt are also permitted.
Class	Xanthen
Colour Index No	45430
Einecs	240-474-8
Chemical name	Disodium 2-(2,4,5,7-tetraiodo-3-oxido-6-oxoxanthen-9-yl)benzoate monohydrate
Chemical formula	$C_{20}H_6I_4Na_2O_5.H_2O$
Molecular weight	897,88
Assay	Content not less than 87 % total colouring matters, calculated as the anhydrous sodium salt
	$E_{1\ cm}^{1\ \%}$ 1 100 at ca 526 nm in aqueous solution at pH 7
Description	Red powder or granules.
Identification	
A. Spectrometry	Maximum in water at ca 526 nm at pH 7
B. Red solution in water	
Purity	
Inorganic iodides calculated as sodium iodide	Not more than 0,1 %
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters (except fluorescein)	Not more than 4,0 %
Fluorescein	Not more than 20 mg/kg
Organic compounds other than colouring matters:	
Tri-iodoresorcinol	Not more than 0,2 %
2-(2,4-dihydroxy-3,5-diodo-benzoyl) benzoic acid	Not more than 0,2 %
Ether extractable matter	From a solution of pH from 7 through 8, not more than 0,2 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 40 mg/kg
Aluminium Lakes	The hydrochloric acid insoluble matter method is not applicable. It is replaced by a sodium hydroxide insoluble matter, at not more than 0,5 %, for this colour only.

Modernising the rules on food additives

- More complex legislation – based on two basic regulations – aim to simplify the rules, update and bring them into line with the latest scientific findings
- New rules for authorising of food additives
- will assist the free movement of food within the EU
- will give better health and consumer protection
- clearer labelling of certain food colourings.

New legislation

- Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings
  - lays down a common procedure for the assessment and authorisation on EU level

Authorisation done

- in a transparent, centralised manner
- on the basis of a scientific opinion by European Food Safety Authority (EFSA)

New legislation

- Regulation (EC) No 1333/2008 on food additives

- harmonises the use of food additives in foods in the Community
- includes also use of additives in foodstuffs intended for particular nutritional uses

and the use of certain food colours for the health marking of meat and the decoration and stamping of eggs

- harmonises the use of food additives in food additives, aromas and food enzymes (has not been regulated on Community level)

Regulation (EC) No 1333/2008

- lays down rules on food additives used in foods
  - view to ensuring the effective functioning of the internal market
  - ensuring a high level of protection of human health
  - ensuring a high level of consumer protection
  - and also (where appropriate) the protection of the environment

Regulation (EC) No 1333/2008 - content

- scope, definintions

- what a food additive is
- which substances should not be considered food additives
- other definitions e.g. ‘unprocessed food’, ‘food with no added sugars’ etc.
- Community lists of Food Additives on the basis of food categories(will be included to annexes
- general and specific conditions for inclusion and use of food additives in Community lists

Regulation (EC) No 1333/2008

- food additives banned in unprocessed food and in food for babies and small children
- new roles on labeling azo-dyes - (colourings E 110, E 104, E 122, E 129, E 102 and E 124) must be labelled also with the words "may have an adverse effect on activity and attention in children"

Regulation (EC) No 1333/2008 - conclusions

- Should replace all directives and decisions mentioned above excluding purity criteria

but

- some time will be necessary for preparing of the lists of authorised additives including maximum usable doses

The latest act

- Commission Regulation (EU) No 257/2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 on food additives
- sets up a programme for the re-evaluation by the European Food Safety Authority (EFSA) of food additives approved before 20 January 2009

Regulation (EU) No 257/2010

- list of already re-evaluated additives
- priorities for re-evaluation
- re-evaluation procedure
- data from the interested business operators and/or other interested parties

Thank you for your attention