



Food Improvement Agent Regulatory Package Challenges & Changes

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Framework Directive 89/107/EC

Specific Directives

Dir. 95/2/EC: Roughly 300 additives other than Colours and Sweeteners
Ex. E 260 (acetic acid), E 220 (sulphur dioxide)...

Dir. 94/35: Roughly 15 Sweeteners
Ex. E 950 (Acesulfame K),
E 951 (Aspartame)...

Dir. 94/36: Roughly 30 Colours authorized
Ex. E 160d (lycopene),
E 129 (allura red)...

Purity Criteria

Sweeteners

Colours

Other additives

+

Flavourings Directive - National rules

+

Enzymes - not EU legislated - National rules

+

National laws prohibiting the use of certain additives in the production of certain specific foodstuffs.



New Regulations for a new Framework

Adopted in December 2008

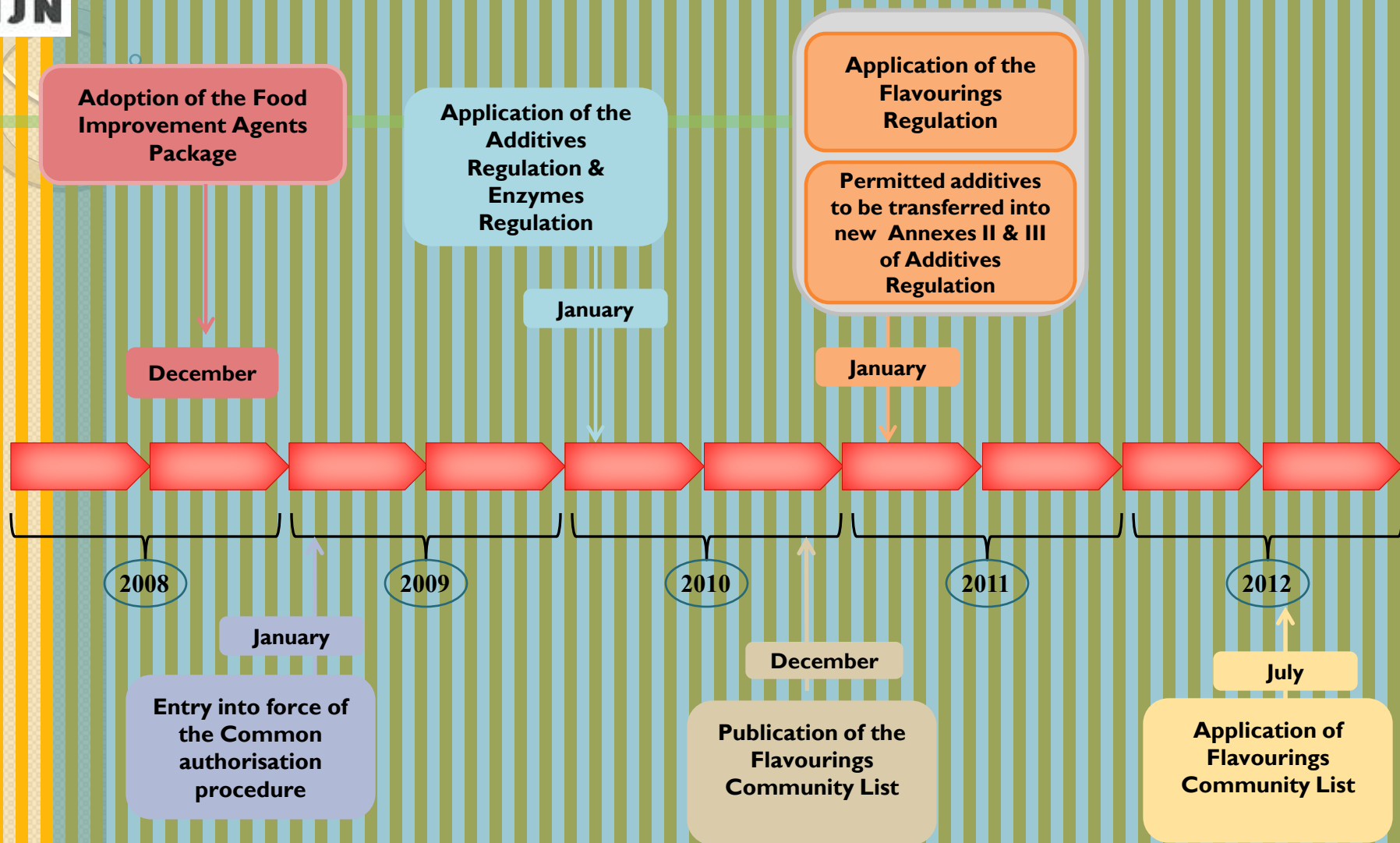
- **Regulation (EC) No 1331/2008** establishing a common authorisation procedure for food additives, food enzymes and flavourings.
- **Regulation (EC) No 1333/2008** on food additives
- **Regulation (EC) No 1334/2008** on flavouring and certain food ingredients with flavouring properties
- **Regulation (EC) No 1332/2008** on food enzymes

The package aims to provide a simplified regulatory framework for food improvement agents with more legal clarity but has resulted in a complex system with various application dates.

But not completely applicable yet.....



Implementation Timing





Common Authorisation Procedure

Procedure initiation

- Commission
- MS
- Interested party

'Acknowledgment of application receipt' within 14 days

Commission

- Acknowledges the receipt
- Notifies EFSA where applicable

Without delay, communicates application to MS

EFSA

- Opinion within 9 months
- Extension possible for more info
- Forwards opinion and reasons to EC, MS and applicant

Commission

Within 9 months submits a draft regulation
(Justified if not in accordance with EFSA)

Standing Committee

- Regulatory procedure with scrutiny
- After opinion of the SC, Council and EP vote within 3 to 4 months

Commission

Without delay, informs the applicant of the decision taken and publishes it in Official Journal of the EU



New Regulations on Additives

- Food additives in Annex II shall be listed on the basis of the categories of food to which they may be added.
- The review shall not include a new risk assessment by the Authority.
- The review shall be completed by 20 January 2011.
- Food additives and uses which are no longer needed shall not be entered in Annex II.
- Until the establishment of the Annex II current authorisations annexed to Directives 94/35/EC, 94/36/EC and 95/2/EC continue to apply.



New Categories of food

- 1 Dairy
- 2 Fats and Oils
- 3 Ice cream
- 4 Fruit and Vegetables
- 5 Confectionery
- 6 Cereals and Cereal Products
- 7 Bakery Wares
- 8 Meat and Meat Products
- 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

Current draft of the Annex II

14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices		restrictions/exceptions
Group I	Additives	(30)	only vegetable juices
E 170	Calcium carbonates	QS	only grape juice
E 200 - 213	Sorbic acid - sorbates; Benzoic acid - benzoates	2000 (1) (4)	only grape juice, unfermented, for sacramental use
E 220 - 228	Sulphur dioxide - sulphites	2000 (3)	only concentrated grape juice for home wine-making
E 220 - 228	Sulphur dioxide - sulphites	50 (3)	only orange, grapefruit, apple and pineapple juice for bulk dispensing in catering establishments
E 220 - 228	Sulphur dioxide - sulphites	350 (3)	only lime and lemon juice
E 220 - 228	Sulphur dioxide - sulphites	70 (3)	only grape juice, unfermented, for sacramental use
E 296	Malic acid	3000	only pineapple juice
E 300	Ascorbic acid	QS	
E 330	Citric acid	3000	
E 336	Potassium tartrates	QS	only grape juice
E 440	Pectins	3000	only pineapple and passion fruit
E 900	Dimethyl polysiloxane	10	only pineapple juice

AIJN worked closely with the Commission to secure current status of possible additive usages in fruit/vegetable juices and nectars.

FRUIT / VEGETABLE JUICES

Current draft of the Annex II

14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetal	restrictions/exceptions	
Group I	Additives	(30) only vegetable nectars	
E 270	Lactic acid	5000	
E 300	Ascorbic acid	QS	
E 330	Citric acid	5000	
E 440	Pectins	3000	only pineapple and passion fruit
E 950	Acesulfame K	350	only when energy-reduced or with no added sugar
E 951	Aspartame	600	only when energy-reduced or with no added sugar
E 952	Cyclamic acid and its Na and Ca salts	250	only when energy-reduced or with no added sugar
E 954	Saccharin and its Na, K and Ca salts	80	only when energy-reduced or with no added sugar
E 955	Sucralose	300	only when energy-reduced or with no added sugar
E 959	Neohesperidine DC	30	only when energy-reduced or with no added sugar
E 961	Neotame	20	only when energy-reduced or with no added sugar
E 962	Salt of aspartame-acesulfame	350	(11) a or b only when energy-reduced or with no added sugar

FRUIT / VEGETABLE NECTARS



Next steps and timeline

October
2010

- Final consultations with Member States and stakeholders

November
2010

- Preparation of a proposal for a Regulation establishing the Community list of food additives

January
2011

- Draft proposal expected for vote

Market application – as soon as the list is published (1st semester 2011)



EFSA re-evaluation program

- EFSA to re-evaluate from the safety perspective all food additives which were authorised before 20 January 2009
- Regulation No 257/2010 sets up a programme for the re-evaluation of approved food additives.
- Future potential issues on additives, e.g. suggested change regarding the recommended ADI .
- The review is currently ongoing and is scheduled until December 2018.
- Priorities:
Colours by 2015, Preservatives and antioxidants by 2015, Emulsifiers, stabilisers & gelling agents by 2016, others by 2018



Foods with colouring properties

EU Commission drafted guidelines:

Principles that can be applied to any product that might be considered for use as a colouring foodstuff / food and that will enable to decide whether it has been selectively extracted (i.e. basically natural juice – or more processed and synthetic colour).

Need to prove the functionality of the addition of particular juice!!!

UK FSA (Food Standards Agency) is to provide a report to the European Commission and Member States (autumn 2010) on the principle developed in the guidance:

The specific examples for testing the principles are:

Orange carrot	Turmeric/ Curcumin
Black carrot	Paprika
Elderberry	Pumpkin
Hibiscus	Beetroot
Red cabbage	Nettle extract
Safflower	Gardenia concentrates
Spirulina	

It will then be for that Member States and the Commission to decide how to proceed.



Foods with colouring properties

FIC – European Parliament amendment creating a new category

Amendment 235

Annex VI - Indication and designation of ingredients

Part B - Designation of certain ingredients by the name of a category rather than a specific name

15a. Natural extracts from fruit, vegetables and edible plants or parts of plants obtained by means of mechanical/physical procedures and used in concentrated form to colour food.



'Colouring food'

The working document of the European Council does not include this element yet.

The position of the Council to be adopted in the coming months will clarify the position of the Member States on this issue.



New requirements on Enzymes

- Enzymes are now regulated on EU level and rules apply as of 20 January 2011
- Legislation covers enzymes added to food to perform a technological function in the manufacturing, processing, preparation, treatment, packaging, transport and storage including enzymes used as processing aids.
- A community list with all permitted enzymes including conditions of use will be established. This process will take another 2-3 years as of now.
- If you are using enzymes as ingredients (and not processing aid or additive) you are out of the scope of this Regulation. In this case however, you would have to label the used enzyme in the ingredient list.



New requirements on Enzymes

By 20 January 2013 interested parties should submit applications for existing and new products.

- EFSA to evaluate all enzymes for which an application was submitted
- Within 9 months after evaluations completed the Commission to establish the Community list
- Until the establishment of the community list, new enzymes used as processing aids may be placed on the market and used, in accordance with existing national rules
- Enzymes used as food additives will continue to be regulated under the food additives legislation until the establishment of the Community list of enzymes.
- Novel food dimension to be closely monitored



Questions?



Thank you