



Directorate-General for Health & Consumers

Update on the latest developments of
the EU legislation on food additives
related to the use of colours by the food
and beverage industry

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Key aspects of the presentation

- New Regulation (EC) No 1333/2008 on food additives
 - Review of current authorisations and transfer in the new Regulation
 - Re-evaluation of all authorised food colours
 - Azo colours
 - Nanotechnology

- Timeframe for additional legislation



New Regulation

- Food additives: Regulation (EC) No 1333/2008
 - Adopted 16 December 2008
 - Entry into force 20 January 2009
 - Most provisions will apply as from 20 January 2010

New Regulation Aim

- **One single Regulation** on food additives: colours, sweeteners and miscellaneous additives
- **Comitology**: Simpler regulatory procedure for additives authorisation
- to set up a **re-evaluation programme** for existing food additives.
- **Deadlines** for EFSA and the Commission w.r.t. applications



New Regulation: Transfer of current annexes

- The Commission assisted by the SCOFCAH to review the current additive authorisations by 20 January 2011 and transfer them into the annexes of the new regulation



New Regulation: Transitional measures

Until the transfer of the current authorisations into the annexes of the new Regulation is completed, the Annexes to Directives 94/35, **94/36/EC** and 95/2/EC remain in force and can be amended, where necessary, by comitology



New Regulation: Re-evaluation of approved food additives (1)

- EFSA to undertake a new risk assessment on all currently authorised food additives
- The re-evaluation of food colours is already on-going

New Regulation: Re-evaluation of approved food additives (2)

- One opinion adopted on Red 2G
- Priority on the re-evaluation of the **“Southampton colours”** (E104, E122, E129, E102, E124) by **July 2009**
- **Other azo** colours (E 123, E 151, E 154, E 155, E 180) by **March 2010**
- **Remaining colours** by **end 2010**
- Opinion on **potential allergenicity** of azo colours by the **end of 2009**

New Regulation: “Southampton study” colours

Foods containing one or more of the food colours:

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

shall include the additional information:

**‘name or E number of the colour(s)’: may have
an adverse effect on activity and attention in
children.**

New Regulation: "Southampton study" colours

- Labelling requirements for food containing these colours
- Will apply from 20 July 2010
 - Only exclusions relate to the use of the colours in meat marking and egg decoration/stamping
 - Future exclusion of spirit drinks by implementing measure

New Regulation: Nanotechnology(1)

*“When a food additive is already included in a community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through **nanotechnology**, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market”.*



New Regulation: Nanotechnology(2)

- This will be also clarified in the new regulation on specifications
- By the time food additives are placed in the annexes of Regulation 1333/2008, the current specifications will be included in a new Regulation after a review of their format and content.
- Chance to update and revise current specifications where this is necessary
 - e.g. In light of international developments in JECFA
 - Changes required following EFSA re-evaluations
 - Other changes.....

Timeframe for additional legislation (1)

- List of pending requests for new food additives and/or extensions of use
- Discussion with Member States
- Wider consultation with relevant stakeholders (launched 20/3-30/4/2009)
- Suitable measures for adoption sometime 2009
 - Amendment to Directives 94/35/EC, 94/36/EC and 95/2/EC
 - Specifications for any new food additives

Timeframe for additional legislation(2)

- Amendment to Directive 94/36/EC
 - Revision of uses of lycopene on the basis of the ADI = 0.5 mg/kg bw/day established by EFSA on 30.01.08
 - Deletion of Red2G
- Revision of specifications to include synthetic lycopene and lycopene from *Blakeslea trispora*
- *Follow up, where necessary, on EFSA's re-evaluation of food colours....*

Red 2G

- Colour was permitted in certain burgers and sausages
- EFSA opinion of 5th July 2007
 - EFSA stated that aniline, a metabolite of Red 2G, is considered to be a carcinogen, based on rat studies, and therefore may contribute to the development of cancer.
 - EFSA therefore withdrew the ADI previously established and stated that it would be prudent to consider the substance as a safety concern.
- 28/07/07 Banned from use in foods

Thank you for your attention

