

Community legislation on flavourings

- **Council Directive 88/388/EEC** on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production
- **European Parliament and Council Regulation 2232/96/EC** of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs
- **European Parliament and Council Regulation 2065/2003/EC** of 10 November 2003 on smoke flavourings used or intended for use in or on foods

New Regulation

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

will be replaced by

- **Regulation of the European Parliament and of the Council** on flavourings and certain food ingredients with flavouring properties for use in and on foodstuffs (Com (2006) 427 final)

Need for a new Regulation?

- Clarify the scope;
- allow for future technological developments;
- better inform the consumer about the use of flavourings;
- take into account scientific advice on substances of toxicological concern;
- **adapt to the requirements requested by Regulation (EC) N ° 882/2004 on official feed and food control;**
- formalise the role of the European Food Safety Authority (EFSA).

New Regulation:

■ Risk based approach

■ Annex III: Presence of certain substances

Part b: Maximum levels of certain substances in food and food ingredients with flavouring properties only in certain food categories, which contribute most to the intake.

- Beta-asarone
- 1-Allyl-4-methoxybenzene (estragole)
- Hydrocyanic acid
- Menthofuran
- 4-allyl-1,2-demethoxybenzene (Methyl eugenol)
- Pulegone
- Quassin
- 1-allyl-3,4-methylene dioxy benzene (safrole)
- Teucrin A
- Thujone

Regulation 2232/96/EC, procedure for flavouring substances

- A list of flavouring substances “the use of which is authorized to the exclusion of all others” must be established.
- Member States notified to the Commission the flavouring substances that were allowed in or on foodstuffs marketed on their territory.
- Commission entered flavouring substances “the legal use of which in one Member State must be recognized by the other Member States” in a register
- After completion of the evaluation programme, the positive list of flavouring substances shall be adopted within five years of adoption of that programme.

Commission decision 1999/217 /EC: register of flavouring substances

- About 2600 substances
- Amended 6 times:
 - Introduction of FL numbers and subdivision of all substances into groups of chemically related substances.
 - Delete substances (methyleugenol, estragole, capsaicine, propyl-4-hydroxybenzoate, pentane diketone, acetamide)
 - Addition of substances
 - Corrections

Commission Regulation (EC) No 1565/2000: evaluation programme

- SCF opinion on a programme for the evaluation of flavouring substances (December 1999)
- Substances that do not need to be re-evaluated
 - SCF: Category 1, substances considered safe in use
 - CEFS: Category A, may be used in foodstuffs
 - JECFA: no safety concern at current level of intake with exception of the substances that have been accepted on the sole basis that intake is below 1,5 µg per person per day
 - 655 substances

Regulation (EC) No 1565/2000

- Substances classified by JECFA in the future (since 2000) as to present no safety concern at current levels of intake, shall be considered by EFSA, who may decide that no further evaluation is necessary.

Regulation (EC) No 1565/2000

■ Information to be provided

- Specifications
- Natural occurrence in foodstuffs
- Total amount of the substance that is added to food in the Community
- Normal and maximum use levels in food categories provided, **if available**
- All relevant toxicological and metabolic studies on the substance or closely related substances

- ## ■ The Commission may request additional information within deadlines which are consistent with the overall deadline. For certain substances it might become necessary to submit information on the normal and maximum use levels

Status evaluation programme

- 34 Flavouring Group Evaluations (FGE's) evaluated by EFSA
 - 24 groups adopted; 609/762 substances
- 36 groups evaluated by JECFA
 - 11 groups have been considered EFSA; 354/922 substances
- 128 Newly Notified Substances
 - Allocated to existing FGE's or in 12 additional FGE's

Estimation of intake

■ MSDI

- MSDI is the default approach for the evaluation programme
- MSDI ignores the actual use
- Problems are very obvious with low poundage substances
- Could be correct to estimate average consumption
- MSDI only, makes the evaluation programme questionable
- Positive list based on MSDI could be strongly criticized
- Need for additional methods also recommended by SCF in 1999

Estimation of intake

■ TAMDI

- Based on upper use levels
- Maximum use levels appear to be very (unrealistically) high
- High use levels compared to low poundage would result in very low quantity of food that can be flavoured
- Saturating effect of flavourings
- All flavoured food categories would have same flavour
- Large majority of substances are above the threshold of concern.

Estimation of intake

■ mTAMDI

- Based on normal use levels
- Different approach, more realistic?
- Could be an underestimation
- Identifies substances where there may be a problem with intake
- Levels appear still to be high compared to practices.
- All flavoured food categories would have similar flavour
- Majority of substances above the threshold of concern

Conclusions mTAMDI

■ e.g. FGE 5

- For the 24 flavouring substances the intakes estimated on the basis of the mTAMDI exceed the threshold for the structural class, for which the flavouring has been assigned.
- Therefore, more reliable exposure data are required.
- On the basis of such additional data, these flavouring substances should be reconsidered along the steps of the procedure.
- Following this procedure, additional toxicological data might become necessary.

How to go ahead

- No further delay can be accepted.
- Quality of exposure assessments should be checked.
- Other, more alternative exposure assessments, should be developed
- Risk managers must take into account other legitimate factors:
 - Societal
 - Economic
 - Traditional
 - Ethical
 - Environmental
 - Feasibility of controls
- Risk managers must take into account the precautionary principle

Issue on Coumarin

- Council of Europe set, in 1981, maximum concentration limits.
- Limits were introduced in Council Directive 88/388/EEC
- In 1994 and 1999, the SCF reviewed coumarin, confirmed max limits and requested genotoxicity tests.
- In 2004 EFSA concluded that coumarin was not genotoxic and set a TDI at 0.1 mg coumarin/kg bodyweight.
- Commission removed coumarin from annex III of proposal for new regulation on flavourings. (Com (2006) 427 final)
- Autumn 2006, new analytical findings in Germany demonstrate very high levels of coumarin in certain food categories.
- Member States agree to reintroduce maximum limits for coumarin.
- Approach for estimation of intake differs between Member States, leading to different analyses of the risk.