



Directorate-General for Health & Consumers

- Authorisation procedure of steviol glycosides in the European Union.

Wim Debeuckelaere

Unit E3: Chemicals, contaminants and pesticides

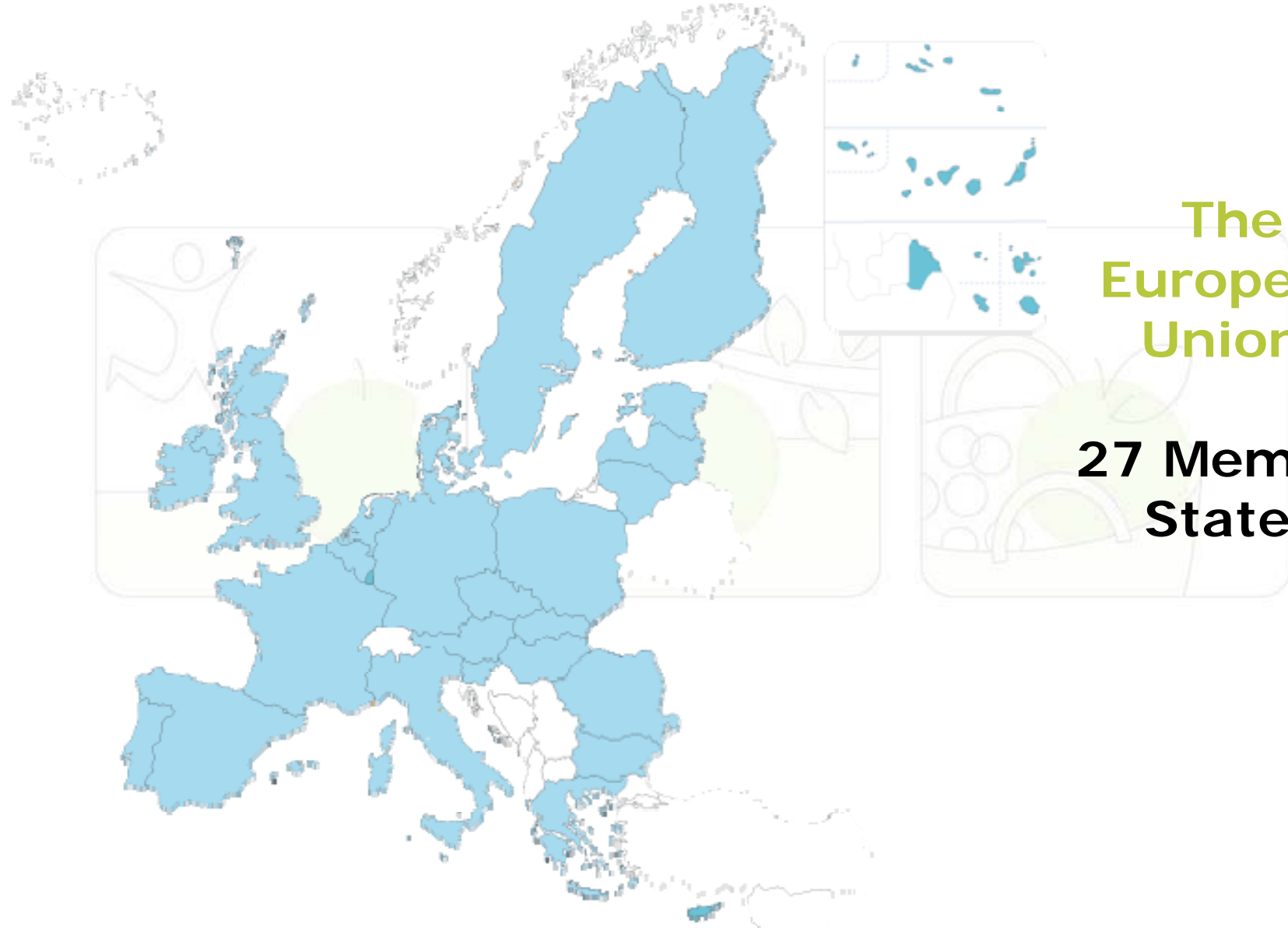


Overview of the presentation

- Who are we
- Food additives legislation
- Authorisation procedure
- Authorisation of steviol glycosides



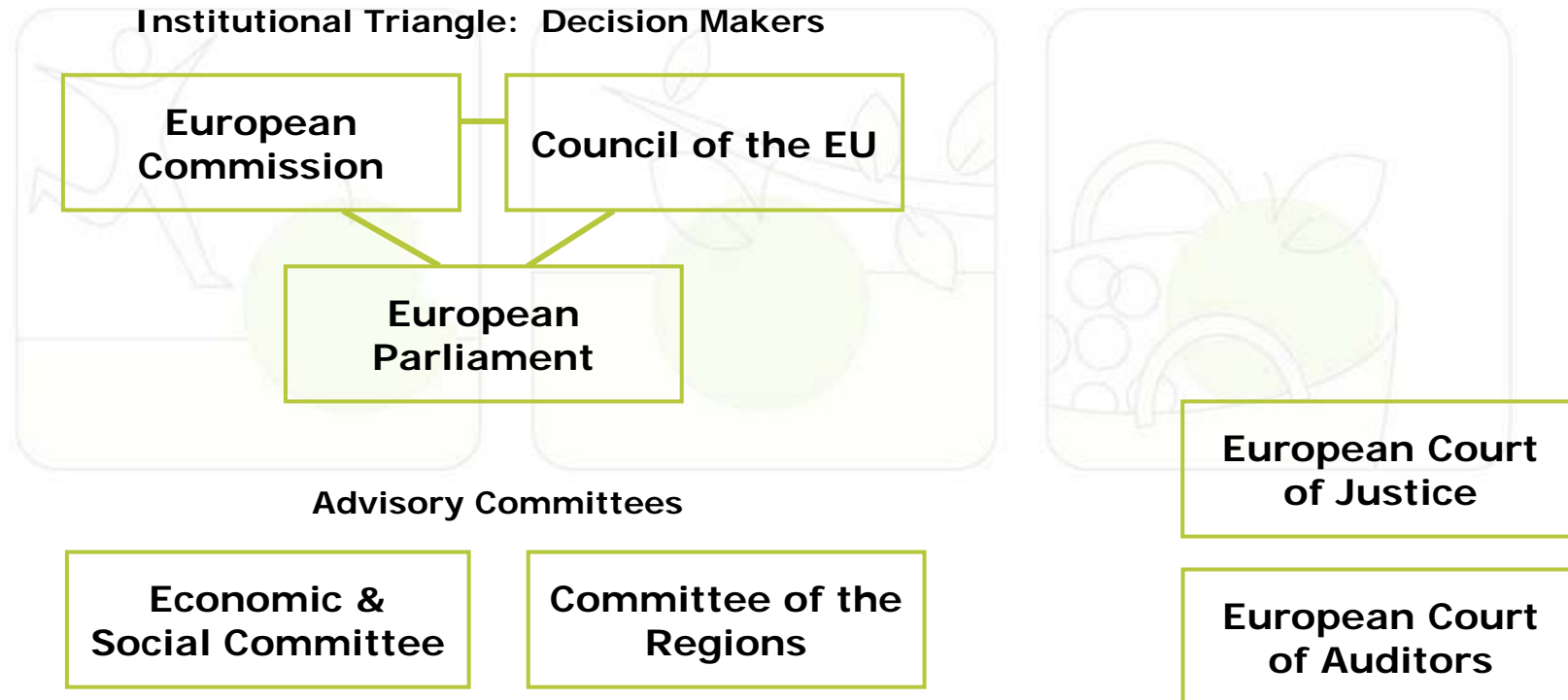
The European Union



The
European
Union:

**27 Member
States**

European Institutions





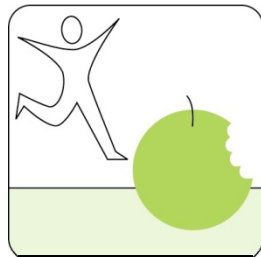
The Role of the Commission

- Initiate & negotiate draft legislation
- Ensure implementation of EU policies
- Apply European Union laws
- Represent the European Union on the world stage

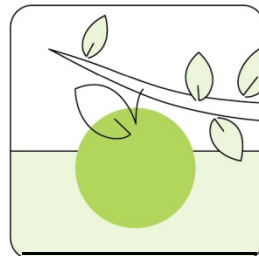


Health and Consumers DG

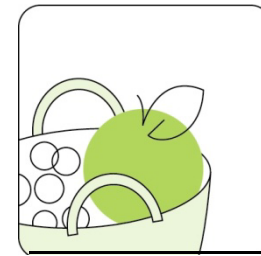
Europe working for healthier, safer,
more confident citizens



Public Health



Food safety



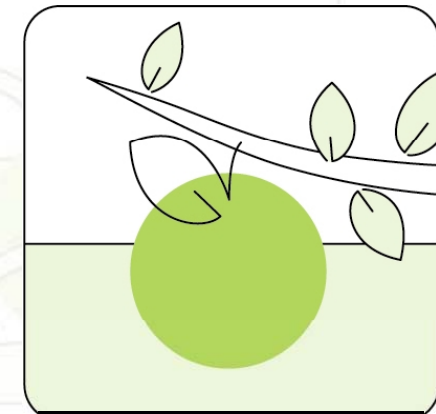
Consumer Affairs



Food Safety

EU laws cover:

- How farmers produce food
- How plants are grown, and how pesticides are used
- How animals are fed, looked after, and transported
- How food is processed, packaged, and sold
- How food is labelled for consumers



Food safety

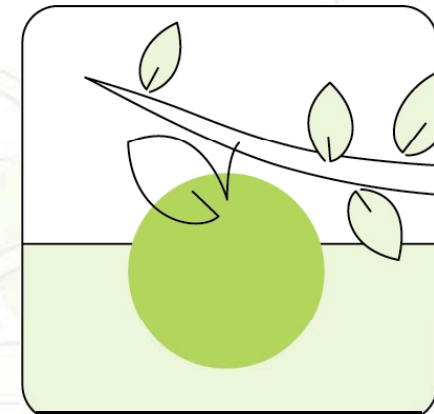
"A World Class Food Safety System from the Farm to the Fork"



UNIT E3

UNIT E3: Chemicals, contaminants and pesticides

- Food additives, food enzymes and flavourings
- Contaminants
- Veterinary residues
- Plant protection products



Food safety

“The EU is the world’s largest food importer”



Food Improvement Agents

- Adopted on 16 December 2008,
 - **Regulation (EC) No 1331/2008** establishing a common authorisation procedure for food additives, food enzymes and flavourings.
 - **Regulation (EC) No 1332/2008** on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97
 - **Regulation (EC) No 1333/2008** on food additives
 - **Regulation (EC) No 1334/2008** on flavourings and certain food ingredients with flavouring properties amending Council Regulation (EEC) no 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC

Legal framework for food additives

Fully harmonized sector

Framework Regulation (EC) No 1333/2008



Annexes to specific Directives for 3 groups of additives still apply
→ Positive lists of additives authorised to the exclusion of all others
+ conditions of use



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



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



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



Regulation (EC) No 1333/2008 on food additives

- Replaces Directive 89/107/EEC
- Most provisions will apply as from 20/01/2010
 - **One single Regulation** on food additives: colours, sweeteners and miscellaneous additives
 - **Comitology**: Simpler regulatory procedure for additive authorisation
 - to set up a **re-evaluation programme** for existing food additives.
 - **Deadlines** for EFSA and the Commission with regard to new authorisations



General conditions of use of food additives

■ Conditions of use:

- Does not pose a safety concern to the health of the consumer at the level of use proposed
- Reasonable technological need for their use which cannot be achieved by other economically and technologically practicable means
- Does not mislead the consumer
- Advantages and benefits for the consumer



Additional conditions for sweeteners

- replace sugars for the production of energy-reduced food (*), non-cariogenic food or food with no added sugars
- replace sugars where this permits an increase in the shelf-life of the food
- produce food intended for particular nutritional use



Reg. (EC) No 1333/2008-Implementation

Implementing measures	Deadline
Application guidelines	16.12.2010
Review of current authorisations	20.01.2011
New Regulation on specifications	20.01.2011
Regulation of additives in additives, enzymes and nutrients.	01.01.2011
Interim measures: Amendments to Directives 95/2, 94/35 & 94/36	Finalised
Specifications for new substances	Finalised
Guidance for appropriate information for table top sweeteners	
Guidance on common methodology for gathering intake data	

This presentation expresses the views of the author and does not, in any case, bind the European Commission



Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings

- Lays down the procedural arrangements for updating the lists of substances the marketing of which is only authorised when included in a Union list.
- 'Updating the Union list' means:
 - (a) adding a substance to the list;
 - (b) removing a substance from the list;
 - (c) adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance

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Main stages of the Common Procedure

- The procedure may be started either on the initiative of the Commission or following an application by a Member State or by an interested party. Applications shall be sent to the Commission..
- The Commission shall seek the opinion of the European Food Safety Authority, unless the updates in question are not liable to have an effect on human health
- The common procedure shall end with the adoption by the Commission of a regulation implementing the update.

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Timing for an authorisation

- Opinion of EFSA: nine months
- Proposal of the Commission at the Standing Committee: nine months
- Regulatory procedure with scrutiny: 2 months
- Time needed for adoption by the Commission and publication in the official journal

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Authorisation of steviol glycosides

Applications

- 2007 – 2008 three separate independent petitions for the authorisation of steviol glycosides
 - Cargill Incorporated,
 - The European Stevia Association (EUSTAS),
 - Morita Kagaku Kogyo Co., Ltd
- European Food Safety Authority requested cross reference
- April 2009, roadmap for combined assessment was introduced on behalf of of these companies.



Opinion of the European Food Safety Authority

- Scientific Opinion on the safety of steviol glycosides for the proposed uses as a food additive, March 2010.
 - Mixture of Stevioside and/or rebaudioside A > 95%
 - Not genotoxic, not carcinogenic, no reproductive/developmental toxicity
 - ADI of 4 mg/kg



Approach exposure assessment

- Maximum proposed use levels in 44 different food categories, similar to aspartame.
- EU food consumption data
 - Combined national data for children
 - UK data for adults.
- High level consumer for one category, average consumer for the other categories.

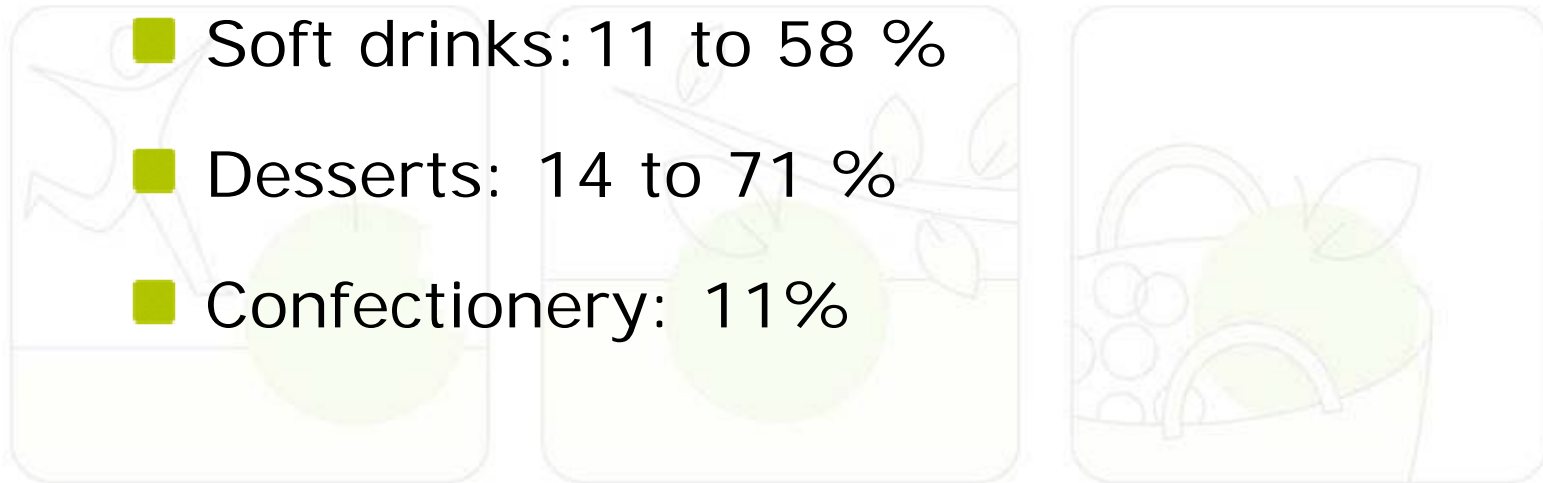
Conclusions exposure assessment

Anticipated exposure to steviol glycosides expressed as steviol equivalents in children and adult populations

	Adult UK population (>18 years old)	Children population (1-14 years old)
	mg/kg bw/d	
Tier 2. Maximum Proposed uses Level		
1. Mean exposure	2.2	0.7-5.9
2. Exposure 95 th * or 97.5 th percentile**	8.0	3.3-14.2

Major contributors to exposure

- Soft drinks: 11 to 58 %
- Desserts: 14 to 71 %
- Confectionery: 11%





Risk management

■ Consultation with Member States April 2010:

Taking into account the conclusion of EFSA that both in adults and children it is likely that the ADI can be exceeded at the maximum proposed use level, the working group requests the applicants to reconsider the proposed uses in order to assure that the ADI will not be exceeded. EFSA can then be requested to perform a new exposure assessment.

■ Commission received revised levels from the applicants in September 2010



Next steps

- New exposure assessment expected by end 2010.
- More details about contribution of each food category to the total exposure should be provided by EFSA
- Proposal of Commission regulation authorising steviol glycosides with conditions of use: first half 2011.
- Possible authorisation of steviol glycosides: end 2011.



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The screenshot shows the homepage of the Directorate-General for Health and Consumers. The header includes the European Commission logo and the text 'Directorate - General for Health and Consumers'. Below the header is a navigation menu with links for 'Overview', 'Who we are', 'Press Room', 'Financing', 'A-Z', and 'Contact Us'. The main content area features a welcome message: 'Welcome to the Directorate General for "Health and Consumers"'. It states: 'Our job is to help make Europe's citizens healthier, safer and more confident. Over the years the European Union has established EU laws on the safety of food and other products, on consumers' rights and on the protection of people's health. The Directorate General for "Health and Consumers" has the task of keeping these laws up to date. It is national, regional or even local governments in EU countries who actually apply the EU's health and consumer protection laws. It is their job to make sure traders, manufacturers and food producers in their country observe the rules. Nonetheless, part of our job is to check that this is really happening and that the rules are being applied properly in all EU countries.' A link is provided to 'Read more about DG SANCO's mission'. A news section titled 'EUROPE IN ACTION FOR HEALTHIER, SAFER, MORE CONFIDENT CITIZENS' features a video player and a link to 'See the brochure, watch the videos'. The right sidebar contains sections for 'Food', 'Consumers', and 'Health', each with links for 'Speeches', 'Press Releases', and 'Events'. At the bottom, there are links for 'Influenza A(H1N1) EU Coordination' and 'Europe for Patients'.

http://ec.europa.eu/dgs/health_consumer/index_en.htm



Thank you for your attention

