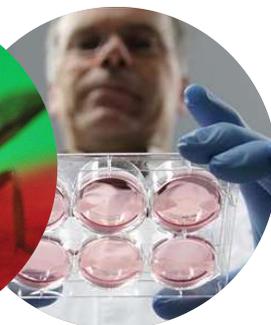


Authorisation requirements

Prior safety assessment of innovative foods – additives, GMOs, novel foods

Bernd van der Meulen



Food Law
Academy

Overview

- Materials
- Urgency
- Food law structure
 - Safety
- Food additives
- Novel Foods
- GMOs
- Experience and problems

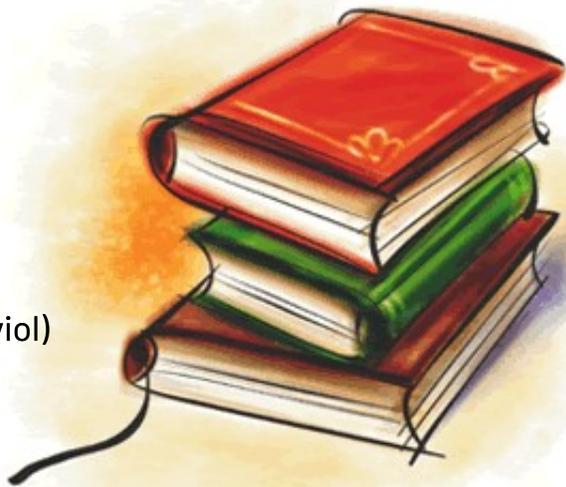


Objectives

- You:
- have an insight in market authorisation schemes
- can recognise situations in which market-authorisation schemes apply.
- can identify the steps to be taken in de different authorisation procedures

Materials I

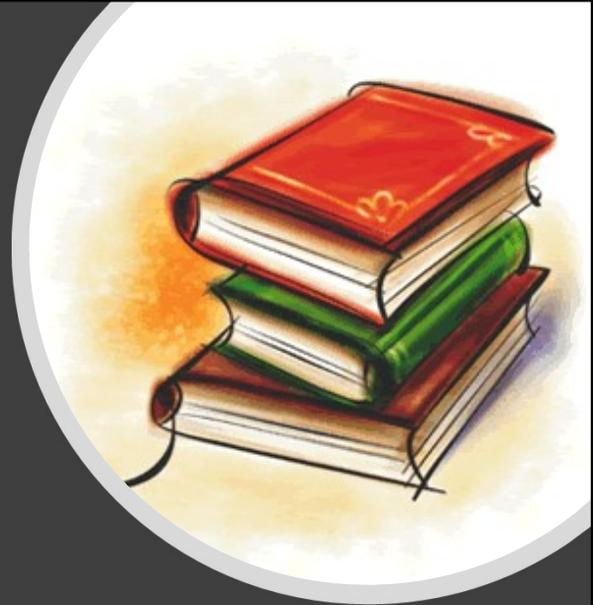
- Literature
 - Handbook chapter 9
- Legislation
 - FIAP 1331-1334/2008
 - NFR regulation 2015/2283
 - (Regulation 1131/2011 on Steviol)
 - GMO regulation 1829/2003
 - (GMO Directive 2001/18)



Food Law
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Materials II

- Case law
 - ECJ 14 April 2011 Case C-327/09 'Stevia'
 - CJEU 9 November 2016 Case C-448/14 'De Tox Forté'
- Suggested further readings
 - ECJ 28 January 2010 Case C-333/08 Cion v. France 'Processing aids'
 - ECJ 6 September 2011, Case C-327/09 Bablok
 - CJEU 25 July 2018, Case C-528/16 Confédération paysanne, et al. v. Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt



Food Law
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5

EU JRC foresight scenarios 2050

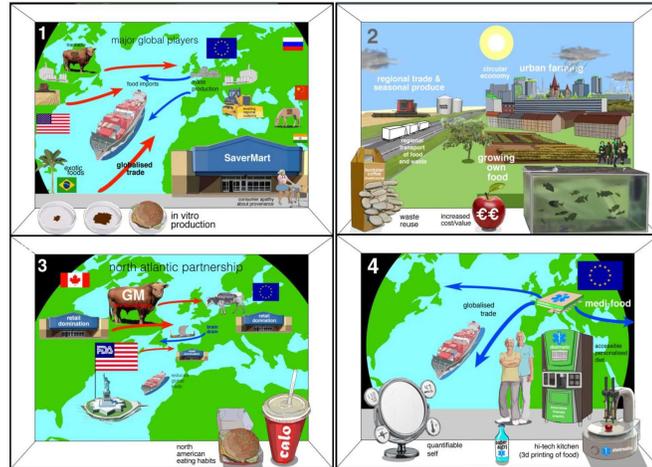
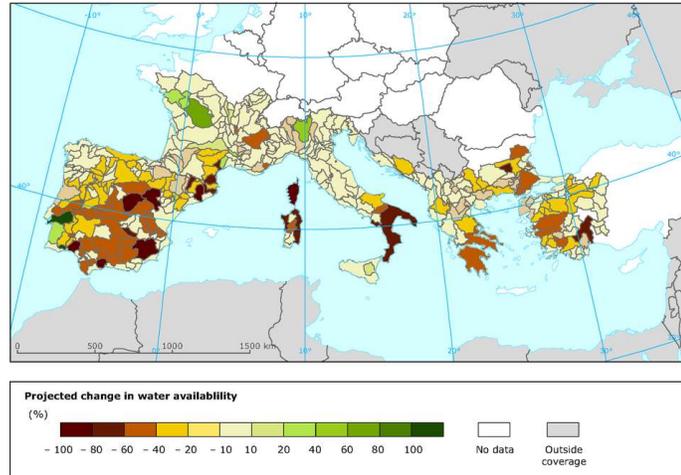


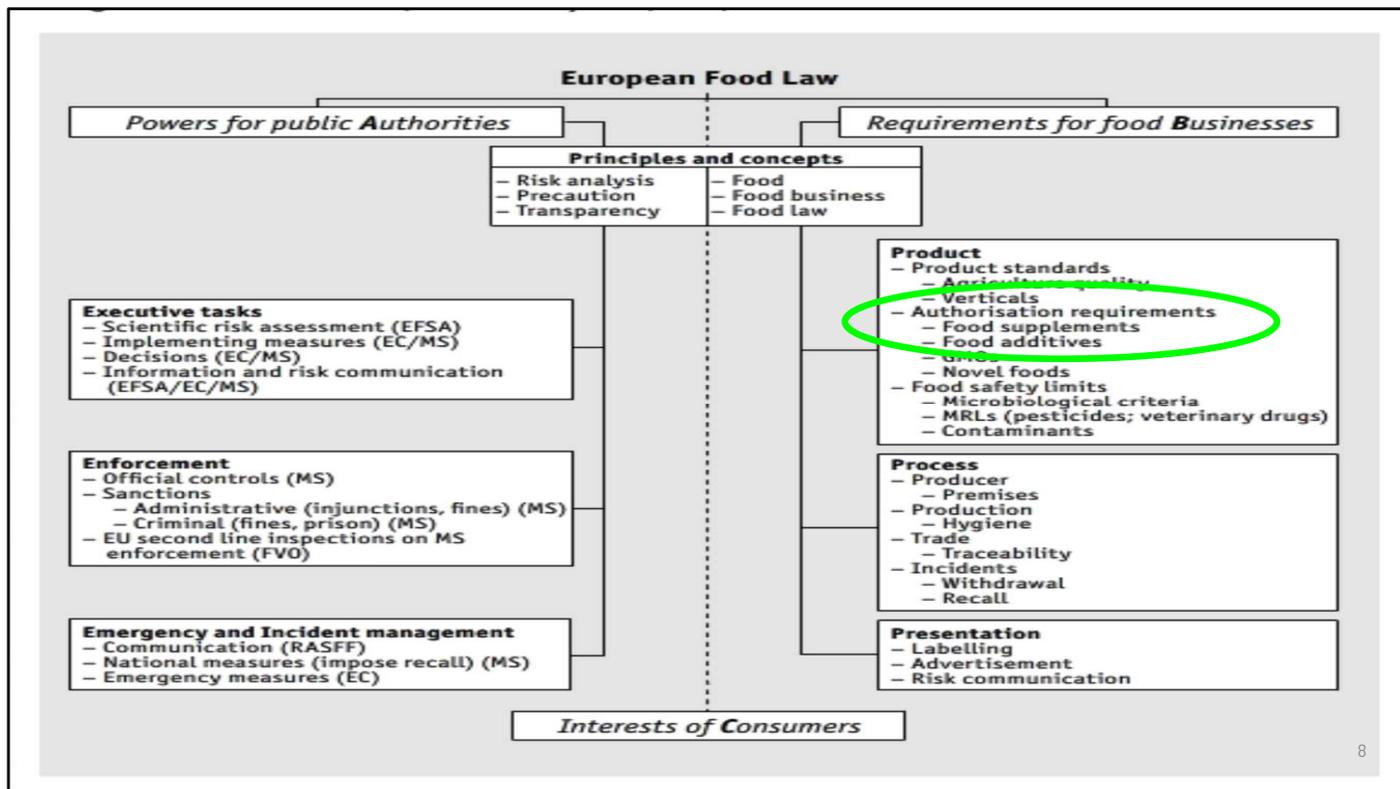
Fig. 1. The four foresight study scenarios

<https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/delivering-eu-food-safety-and-nutrition-2050-future-challenges-and-policy-preparedness>

Projected change in
water availability
for irrigation in the
Mediterranean
region



<https://www.eea.europa.eu/data-and-maps/indicators/water-requirement-1/assessment-1>
Latest version: <https://www.eea.europa.eu/data-and-maps/indicators/water-requirement-2/assessment>



What, who, when?

Safety		Not-regulated	Regulated
	Review		
Inherent properties		14: effect	Category: Additives, GMOs, novel foods
	Ex ante	Self assessment	Authorisation
	Ex post	Enforcement	Enforcement
Condition		14: effect	MRLs, shelf life
	Ex ante	Self assessment	Self assessment
	Ex post	Enforcement	Enforcement



Safety



Structural

Properties of the product

- Toxicity
- Etcetera



Incidental

Condition of a food due to:

- Deterioration
- Contamination
- Etc.



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Structural safety

- Conventional foods
 - Assumed safe on the bases of experience
 - Unless evidence shows otherwise
- Non conventional foods
 - Evidence of safety required
 - → authorisation procedure

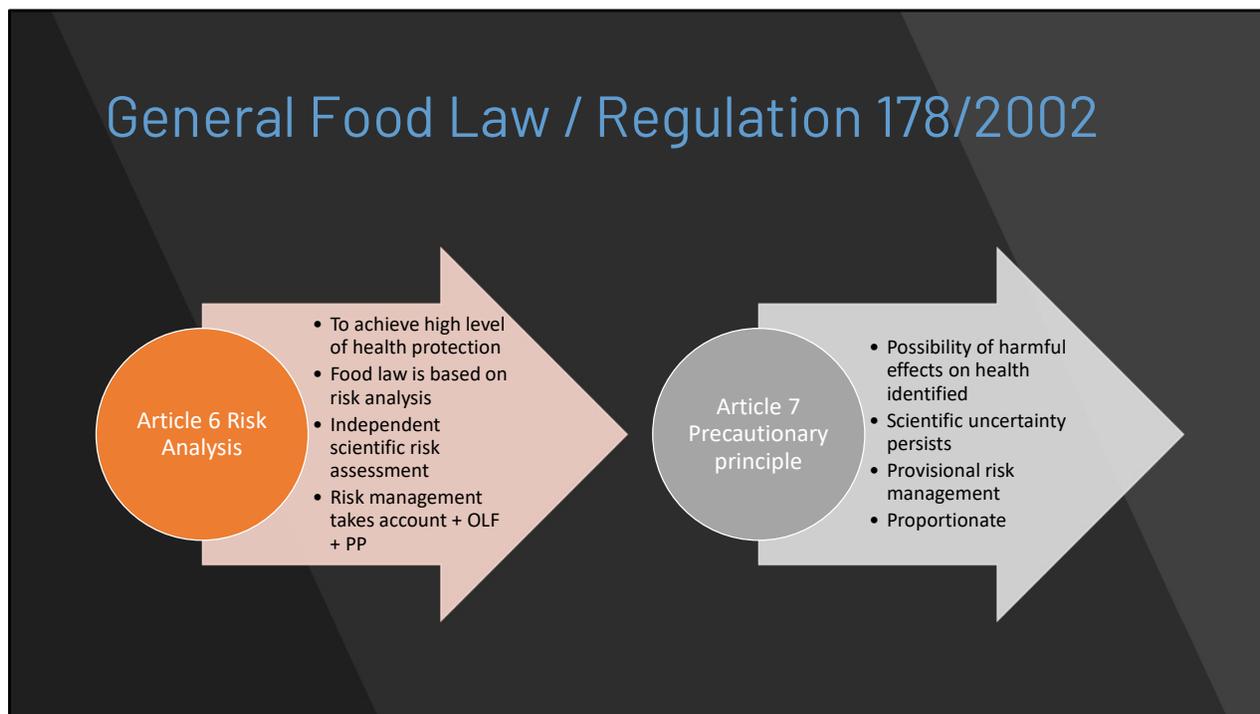


General Food Law / Regulation 178/2002

- Article 2 Concepts
- Risk Analysis process:
 - assessment,
 - communication,
 - management
- Article 22 EFSA
 - Independent platform
- Article 5 Objectives
 - Protect life and health
 - Other consumers interests



Science



Science

Questions to science

- Identify risks
- Is it unsafe?
 - Presumption of safety
- Exclude risks
- Is it safe?
 - Presumption of unsafety ('a priori hazardous')



Science

Science in food law

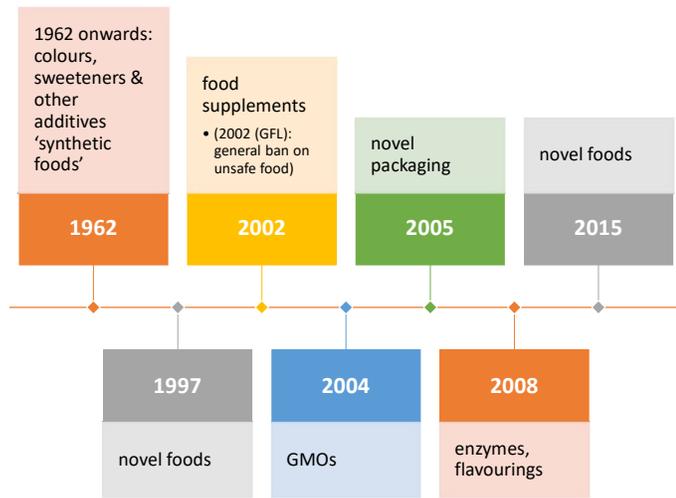
- Identify risks
- Food safety targets
 - Maximum limits in numbers
 - Microbiology
 - Chemicals
 - Zero tolerance
 - Dynamic concepts
→ 'safe' / HACCP
- Incident management
 - Products
 - Producers
 - Areas



Food Law
Academy

Science

Exclude risk: Authorisation requirements



Risk analysis as condition for market access

EC Communication on precaution

Reversal of burden of proof

Ban +

- Permit on application
 - Individual, or → first mover advantage
 - General → second mover advantage
- Science provided by applicant
- Risk assessment = checking the homework



Food Law
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17

Ban +



- Every product that fulfils the definition of
 - Food additive
 - GMO
 - Novel foods
 - Vitamin / mineral
- Is prohibited on the EU market
- Except when explicitly authorised



Food Law
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18

Additives



USA 1958: 'anything added to food' (except...)



Codex Alimentarius: added to food *for a technological purpose*



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19

Additives I

- Principle: prohibited unless authorised
- Additive: any substance **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** in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a **component** of such foods;



Processing aids

- (b) 'processing aid' shall mean any substance which:
- (i) is not consumed as a food by itself;
- (ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and
- (iii) may result in the unintentional but technically unavoidable presence in the final product of **residues** of the substance or its derivatives provided they do not present any health risk **and do not have any technological effect on the final product;**

ECJ 28 Jan. 2010 C-333/08

- Cion. v. France: authorisation requirement processing aids
- 89. A decision to **prohibit marketing**, which indeed constitutes the most restrictive obstacle to trade in products lawfully manufactured and marketed in other Member States, can be adopted **only** if the real risk alleged for public health appears sufficiently established on the basis of the latest scientific data available at the date of the adoption of such decision. In such a context, the object of the **risk assessment to be carried out by the Member State** is to appraise the degree of probability of harmful effects on human health from the addition of certain nutrients to foodstuffs and the seriousness of those potential effects
- the assessment which a Member State is required to make may reveal a high degree of **scientific and practical uncertainty** in that regard. Such uncertainty, which is inseparable from the concept of **precaution**, influences the extent of the discretion of the Member State and thus has an impact on the means of applying the **proportionality principle**.
- In such circumstances, it must be acknowledged that a Member State may, under the precautionary principle, take protective measures without having to wait for the reality and the seriousness of those risks to be fully demonstrated. However, the assessment of the risk **cannot be based on purely hypothetical considerations**



Food Law
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Not discussed in video.

ECJ 28 Jan. 2010 C-333/08 cont'd

- Cion. v. France: authorisation requirement processing aids
- 92. A correct **application of the precautionary** principle presupposes, first, **identification of the potentially negative** consequences for health of the proposed use of processing aids, and, secondly, a **comprehensive assessment of the risk** to health based on the most reliable scientific data available and the most recent results of international research
- 96. It is true that a Member State may base justification on the **precautionary principle** where it proves impossible to determine with certainty the existence or the scope of the alleged risk. However, a correct application of that principle presupposes that the **Member State demonstrates** the existence of the conditions (at 92)



Not discussed in video.



Additives II

- Positive lists
 - Which additive
 - In which food
 - Which purity
 - Which quantity
- EU authorisation procedures
 - Technological need
 - No hazard
 - Not misleading
- Periodic re-evaluation
- Generic authorisation
- E-number



Food Law
Academy

Additives III

Technical classes – follows International Numbering Systems (INS)

E100-E199 Colours

E200-E299 Preservatives,

E300-E399 Antioxidants, acidity regulators

E400-E499 Thickeners, stabilisers, emulsifiers

E500-E599 Acidity regulators, anti-caking agents

E600-E699 Flavour enhancers

E900-E999 Glazing agents, gases, sweeteners

E1000-E1599 Additional additives



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Additives IV

- FIAP – Food Improvement Agents Package
 - Common procedure Reg. 1331/2008
 - Enzymes Reg. 1332/2008
 - Food additives Reg. 1333/2008
 - Flavourings Reg. 1334/2008



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Novel foods

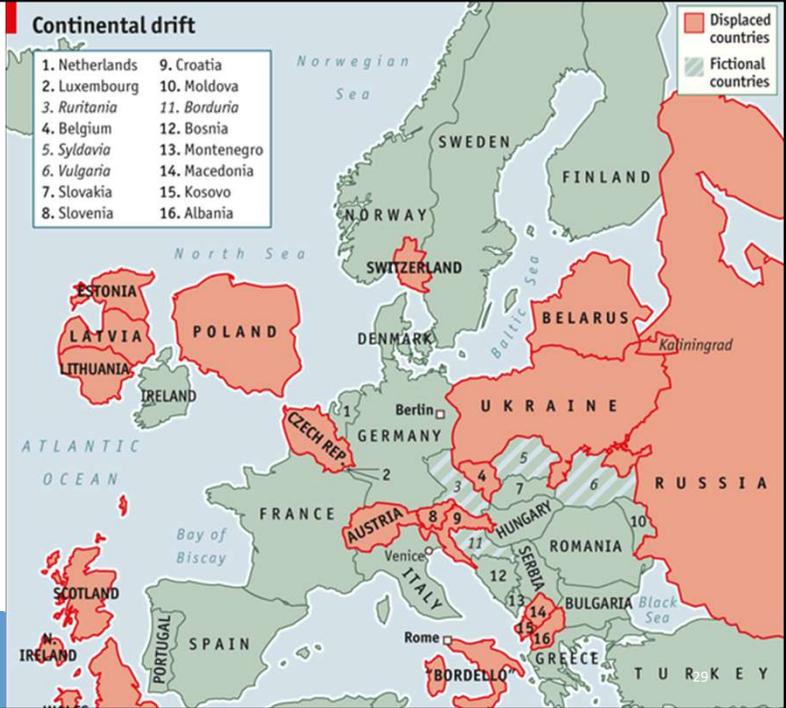
- Not consumed in EU before 1997
 - Modified molecular structure
 - Micro organisms, fungi, algae
 - Mineral origin
 - Plants, Animals
 - Cell culture
 - Nanotechnology
 - New production process
- Example: Becel pro-activ



Food Law
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Any food not used for human consumption to a significant degree within the Union before 15 May 1997, **irrespective of the dates of accession** of Member States to the Union, and that falls under at least one of the following categories



Categories

- Art. 2(a)(i)(i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;
- Old text: foods and food ingredients with a new or intentionally modified **primary** molecular structure
- CJEU case C-448/14 ('De Tox Forte' whose sole ingredient is clinoptilolite, a mineral substance of volcanic origin). ('must be a substance which did not previously exist in nature in that form?'): the expression 'new primary molecular structure' relates to foods or food ingredients which were not used for human consumption in the territory of the European Union before 15 May 1997

CJEU 9 November 2016 Case C-448/14 'De Tox Forte'

- De Tox Forte, a food product whose sole ingredient is clinoptilolite, a mineral substance of volcanic origin
- Is the product "De Tox Forte" marketed by the appellant a food or food ingredient with a new molecular structure within the meaning of Article 1(2) (c) of Regulation No 258/97?
- Answer: must be interpreted as meaning that the expression 'new primary molecular structure' relates to foods or food ingredients which were not used for human consumption in the territory of the European Union before 15 May 1997



Food Law
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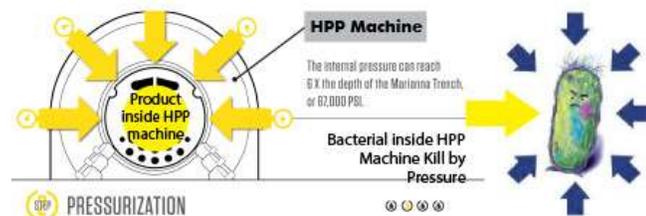
31

Categories

- (iv) food consisting of, isolated from or produced from plants or their parts, **except** when the food has a **history of safe food use** within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by: – **traditional propagating practices** which have been used for food production within the Union before 15 May 1997; or – **non-traditional propagating practices** which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to **significant changes** in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;

Categories

- (vii) food resulting from a **production process** not used for food production within the Union before 15 May 1997, which gives rise to **significant changes** in the composition or structure of a food, **affecting** its nutritional value, metabolism or level of undesirable substances
- HPP?



This Process under low temperature, all the product can keep the nature nutrient, flavor and color.

HPP: high pressure processing a.k.a. cold pasteurisation.

Objectives of the new Novel Food Regulation

- Ensure food safety
- Functioning of the internal market
- Support innovation
- Streamline procedure
 - Clarify definition
 - No substantial changes ...
 - Simplified procedure for traditional foods from 3rd countries (a.k.a. exotic foods)

Not discussed in video.



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Prof. Jan Geuns KU Leuven

Stevia refused as novel food 22.02.2000

- (4) *Stevia rebaudiana* Bertoni: plants and dried leaves, are a novel food in the sense of Regulation (EC) No 258/97. It has not been demonstrated that the product complies with the criteria laid down in Article 3(1) of the Regulation, it shall not be placed on the market in the Community.
- (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

Stevia rebaudiana Bertoni: plants and dried leaves may not be placed on the Community market as food or food ingredient.

Article 2

This Decision is addressed to Professor J. Geuns, KUL, Laboratory of Plant Physiology, Kardinaal Mercierlaan 92, 3001 Heverlee, Belgium.

Done at Brussels, 22 February 2000.

For the Commission
Erkki LIJKANEN
Member of the Commission



Not discussed in video.

ECJ on Stevia 14.4.11

A Commission decision taken on the basis of Article 7 of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients and refusing authorisation to place on the market of the European Union a food or food ingredient is not binding on any persons other than the person or persons whom that decision specifies as its addressees. By contrast, the competent authorities of a Member State must establish whether a product marketed in the territory of that Member State, the characteristics of which appear to match those of the product which was the subject-matter of that Commission decision, is a novel food or novel food ingredient within the meaning of Article 1(2) of that regulation and, where necessary, they must require the person concerned to comply with the provisions of that regulation.



Not discussed in video.

Stevia approved as additive 11.11.11

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(1) in Part B2 the following entry for E 960 is inserted after the entry for E 959:

E 960	Steviol glycosides
-------	--------------------

(2) in Part E the following entries for E 960 are inserted in numerical order in the food categories referred to:

PART E. AUTHORISED FOOD ADDITIVES AND CONDITIONS OF USE IN FOOD CATEGORIES

Category number	Ex-number	Name	Maximum level (mg/kg or mg/kg as appropriate)	Footnote	Restriction/exception
01.4	Flavoured fermented milk products including heat treated products				
	E 960	Steviol glycosides	100	(60)	only energy-reduced products or with no added sugar (60): expressed as steviol equivalents
01.	Edible ices				
	E 960	Steviol glycosides	200	(60)	only energy-reduced or with no added sugar (60): expressed as steviol equivalents
04.2.2	Fruit and vegetables in vinegar, oil, or brine				
	E 960	Steviol glycosides	100	(60)	only sweet-sour preserves of fruit and vegetables (60): expressed as steviol equivalents
04.2.4.1	Fruit and vegetable preparations excluding compote				
	E 960	Steviol glycosides	200	(60)	only energy-reduced (60): expressed as steviol equivalents
04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EC				
	E 960	Steviol glycosides	200	(60)	only energy-reduced jams, jellies and marmalades (60): expressed as steviol equivalents
04.2.5.2	Jam, jelly and marmalade and sweetened chestnut puree as defined by Directive 2001/113/EC				
	E 960	Steviol glycosides	200	(60)	only energy-reduced jams, jellies and marmalades (60): expressed as steviol equivalents

L 324/11

EN

Official Journal of the European Union

L 294/25



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Not discussed in video.

Union list

- Inclusion by European Commission
- Criteria
 - The food does not, on the basis of the scientific evidence available, pose a **safety risk** to human health
 - Does not **mislead** consumer
 - Not nutritionally **disadvantageous**
- Application by business (or initiative EC)
- Safety assessment by EFSA



https://ec.europa.eu/food/safety/novel_food/authorisations/union-list-novel-foods_en
https://ec.europa.eu/food/safety/novel_food/authorisations/list_authorisations_en

Exotic foods

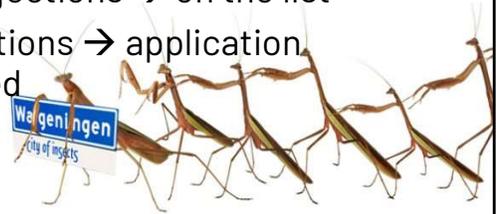
- Globally some 7.000 plant species used for human consumption
- In EU some 300 traditional
- 2,000 insects
- → high potential
- After 1997 just a hand full authorised as novel food (noni, baobab)



Ib Knudsen, Inge Søborg, Folmer Eriksen, Kirsten Pilegaard et al., *Risk Management and Risk Assessment of Novel Plant Foods: Concepts and Principles*, 46 Food & chemical toxicology 1681 et seq. (2008).

Exotic foods

- Simplified procedure
- Notification to EC
 - Name, description, composition, origin
 - Documented history of safe use
 - Instructions of use
- EC to EFSA and MS
 - 4 months science based objections
- No objections → on the list
- Objections → application needed



<https://www.wur.nl/en/Research-Results/Chair-groups/Plant-Sciences/Laboratory-of-Entomology/Edible-insects/Worldwide-species-list.htm>

Governing Nano Foods

Principles-Based Responsive Regulation

EFFoST Critical Reviews #3

Bernd van der Meulen,
Harry Bremmers, Kai Purnhagen,
Nidhi Gupta, Hans Bouwmeester,
L. Leon Geyer



Nanotechnology

- Problem defies definition
- any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.

<https://www.elsevier.com/books/governing-nano-foods-principles-based-responsive-regulation/meulen/978-0-12-420156-9>

Data protection

- Authorisation exclusive for 5 years, if based on
 - Recently developed scientific evidence or data
 - Proprietary
 - Exclusive right of use
 - Necessary for authorisation
- Not applicable to exotic foods
- Request confidentiality
 - Verifiable reasons
 - 6 weeks to withdraw application



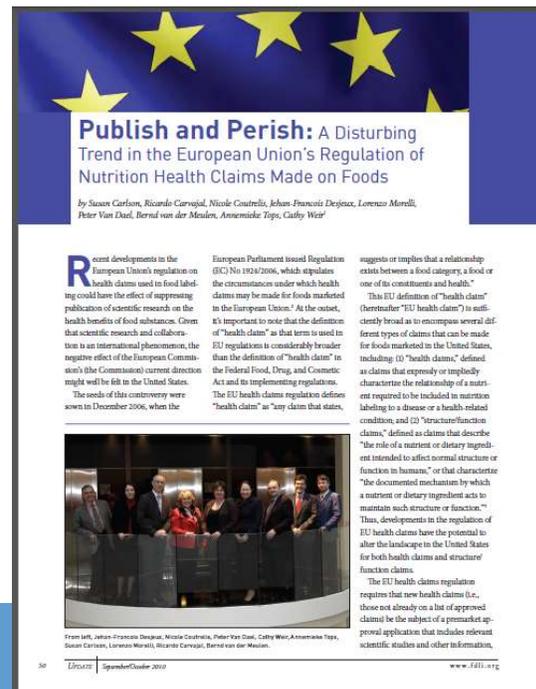
Not discussed in video.

Proprietary?

- Rationale: investment
- Interpretation EC. (at claims): secret
- Problem:
 - Against rationale
 - Unscientific

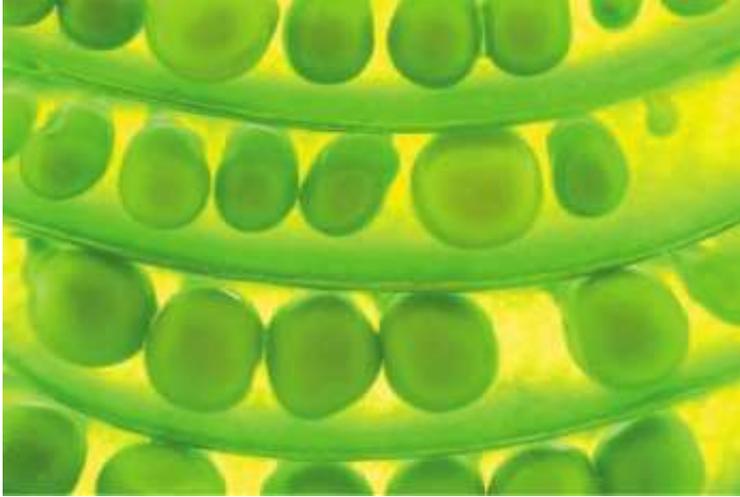


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S. Carlson, R. Carvajal, N. Coutrelis, J.F. Desjeux, L. Morelli, B. van der Meulen, C. Weir, A. Tops, P. van Dael, Publish and perish: a disturbing trend in the European Union's regulation of nutrition health claims made on foods (2010)

< https://www.researchgate.net/publication/48179690_Publish_and_perish_a_disturbing_trend_in_the_European_Union's_regulation_of_nutrition_health_claims_made_on_foods/link/548dcac50cf225bf66a5f5e4/download >. Not discussed in video.



GMOs

Most used commercial applications of GM crops

- **Herbicide-resistant plants**

Advantages: better weed control, less tillage

Soybeans, corn, rice, wheat

- **Pest-resistant plants**

Resistant to certain insects

Advantage: less insecticide required,
better yield, reduce financial loss for farmers

Corn, cotton, potatoes



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Herbicide Resistance



Non-transgenics

Transgenics



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Insect Resistance



Transgenic

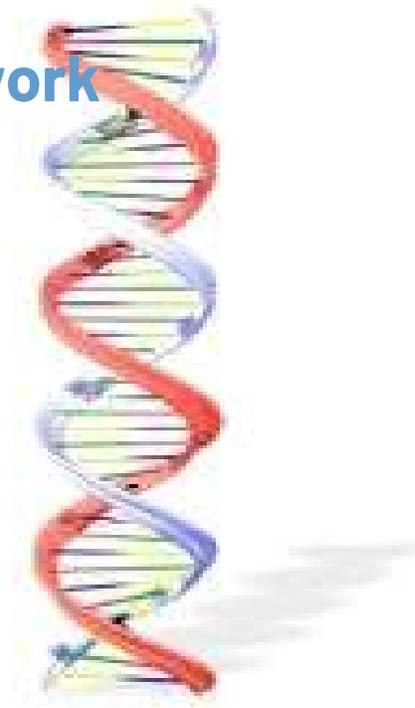
Non-transgenic



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EU regulatory framework

- **Regulation 178/2002**
- **Directive 2001/18**
- **Regulation 1829/2003**
- **Regulation 1830/2003**
- **Regulation 641/2004**
- **Coexistence guidelines**



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Pre-market approval

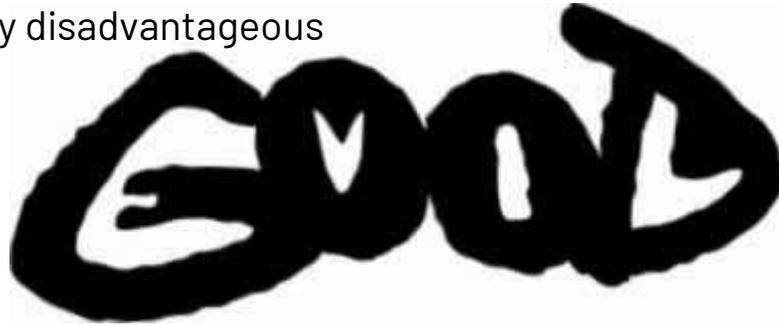
- 'One-door-one-key'
 - EU-wide authorisation
 - Environment & food safety risk assessment
 - Food & feed



https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2605766

Criteria

- No adverse health effects
- Not misleading the consumer
- Not nutritionally disadvantageous



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Authorisation procedure

- Application
 - With national authority: 14 days →
- Risk assessment
 - EFSA (independent scientific) 6 months →
 - Opinion, if favourable
- Commission
 - Draft decision to SCoPAFF
 - Favourable opinion → final decision by Commission
 - Otherwise → Council by qualified majority (3 months)



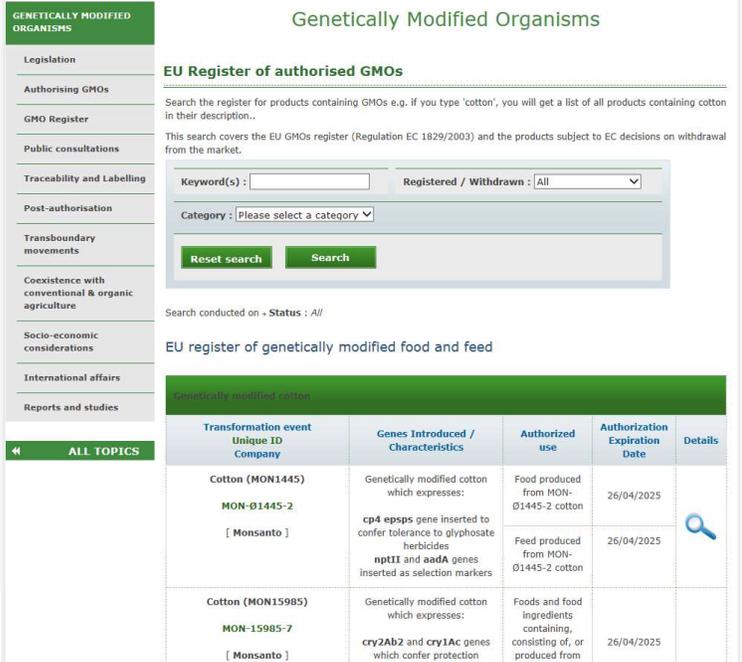
Authorisation

- Valid throughout the EU; for 10 years
- Entry in public registry
- Withdrawal
 - Opinion EFSA
 - Decision Commission
- Renewable
 - 10 years



Positive list

- http://ec.europa.eu/food/dyna/gm_register/index_en.cfm



GENETICALLY MODIFIED ORGANISMS

- Legislation
- Authorising GMOs
- GMO Register**
- Public consultations
- Traceability and Labelling
- Post-authorisation
- Transboundary movements
- Coexistence with conventional & organic agriculture
- Socio-economic considerations
- International affairs
- Reports and studies

Genetically Modified Organisms

EU Register of authorised GMOs

Search the register for products containing GMOs e.g. if you type 'cotton', you will get a list of all products containing cotton in their description..

This search covers the EU GMOs register (Regulation EC 1829/2003) and the products subject to EC decisions on withdrawal from the market.

Keyword(s): Registered / Withdrawn:

Category:

Search conducted on - Status: All

EU register of genetically modified food and feed

Genetically modified cotton

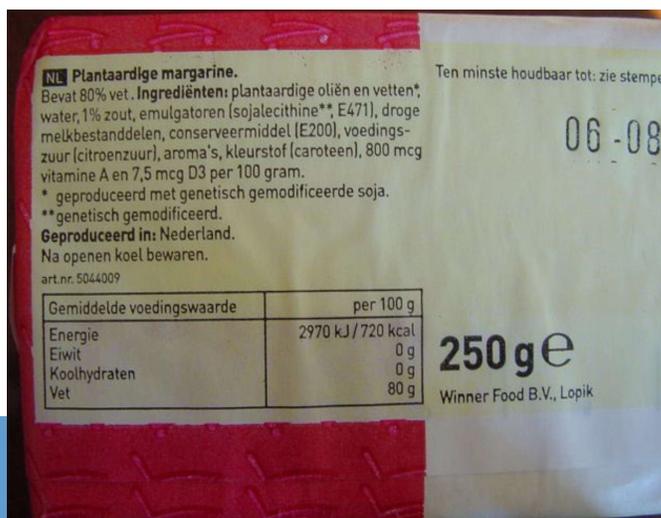
Transformation event Unique ID Company	Genes Introduced / Characteristics	Authorized use	Authorization Expiration Date	Details
Cotton (MON1445) MON-01445-2 [Monsanto]	Genetically modified cotton which expresses: cp4 epsps gene inserted to confer tolerance to glyphosate herbicides npII and aadA genes inserted as selection markers	Food produced from MON-01445-2 cotton Feed produced from MON-01445-2 cotton	26/04/2025 26/04/2025	
Cotton (MON15985) MON-15985-7 [Monsanto]	Genetically modified cotton which expresses: cry2Ab2 and cry1Ac genes which confer protection	Foods and food ingredients containing, consisting of, or produced from	26/04/2025	

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New portal: https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

Labelling requirements

- All ingredients must be mentioned on the label
- Additives: by name or e-number
- Novel foods: specificity regarding
 - Composition
 - Nutrition
 - Intended use
- GMOs: as such



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Regulation (EC) 1829/2003:
- authorisation procedure and labelling

SCOPE is:
GMO, contains a GMO,
produced from a GMO

SCOPE is NOT:
"With" a GMO

"0.9% exemption": "adventitious or technically unavoidable".

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Not discussed in the video.

Ingredient

“Any substance, including additives, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form”

Used = intentional!



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Not discussed in the video.

Honey....

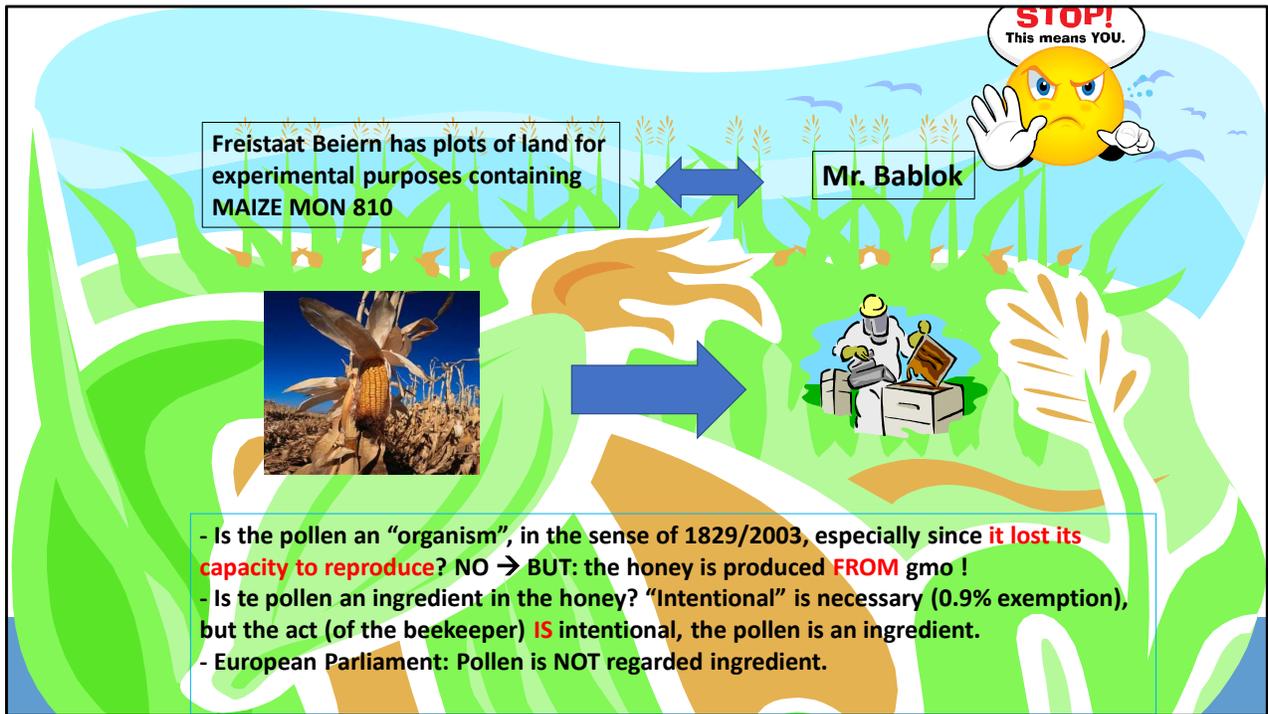


Bablok case.....



Food Law
Academy

Not discussed in the video.



Not discussed in the video.

Wat is a GMO? → Dir. 2001/18

For the purposes of this Directive:

- (1) 'organism' means any biological entity capable of replication or of transferring genetic material;
- (2) 'genetically modified organism (GMO)' means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

Within the terms of this definition:

- (a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;
- (b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

- (1) mutagenesis,
- (2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.



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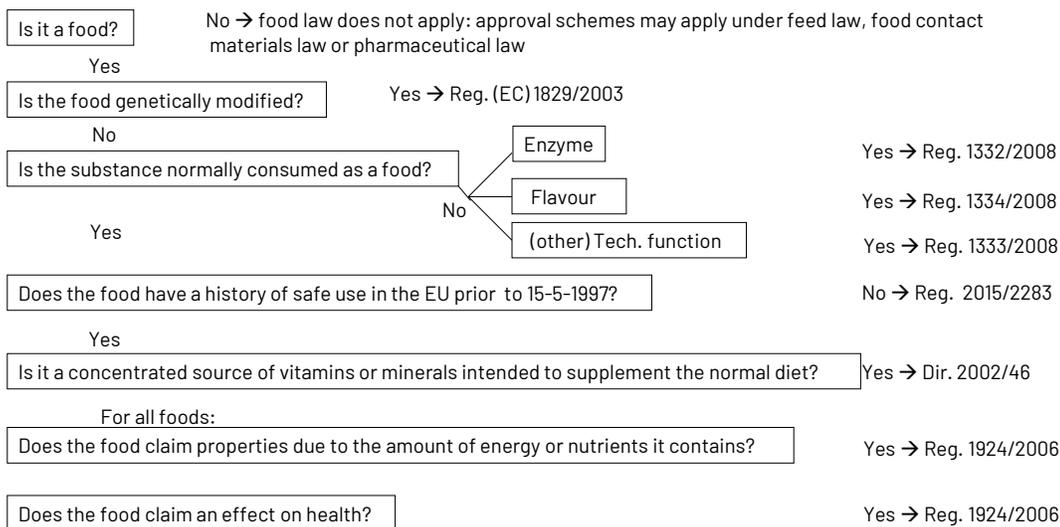
CJEU 25 July 2018, Case C-528/16
Confédération paysanne, et al. v. Ministre de
l'Agriculture, de l'Agroalimentaire et de la Forêt
ECLI:EU:C:2018:583

- Targeted mutagenesis
- 1) GMO → yes
- 2) Excluded → no



See also the opinion of the Advocate General ECLI:EU:C:2018:20

Pre-market authorisation decision tree

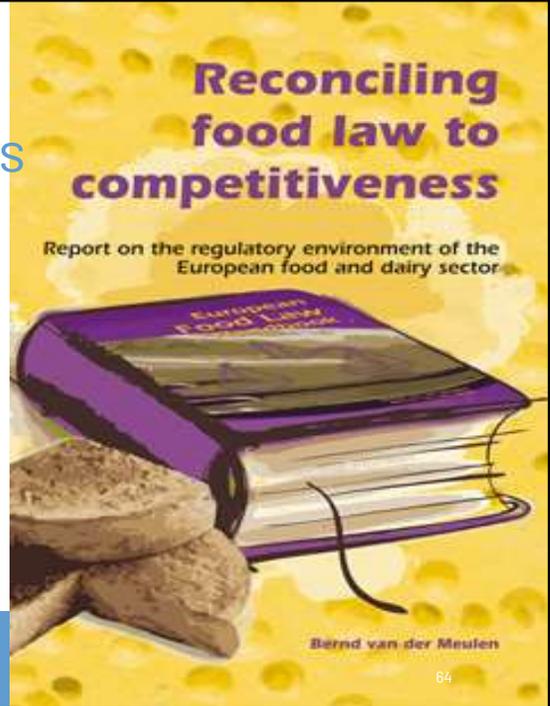


Experiences and problems

- Unclear
- Unpredictable
- Expensive
- Time consuming
- Political application
- Can be manipulated
 - CJEU refusal of authorisation affects only parties (Stevia)



Food Law
Academy



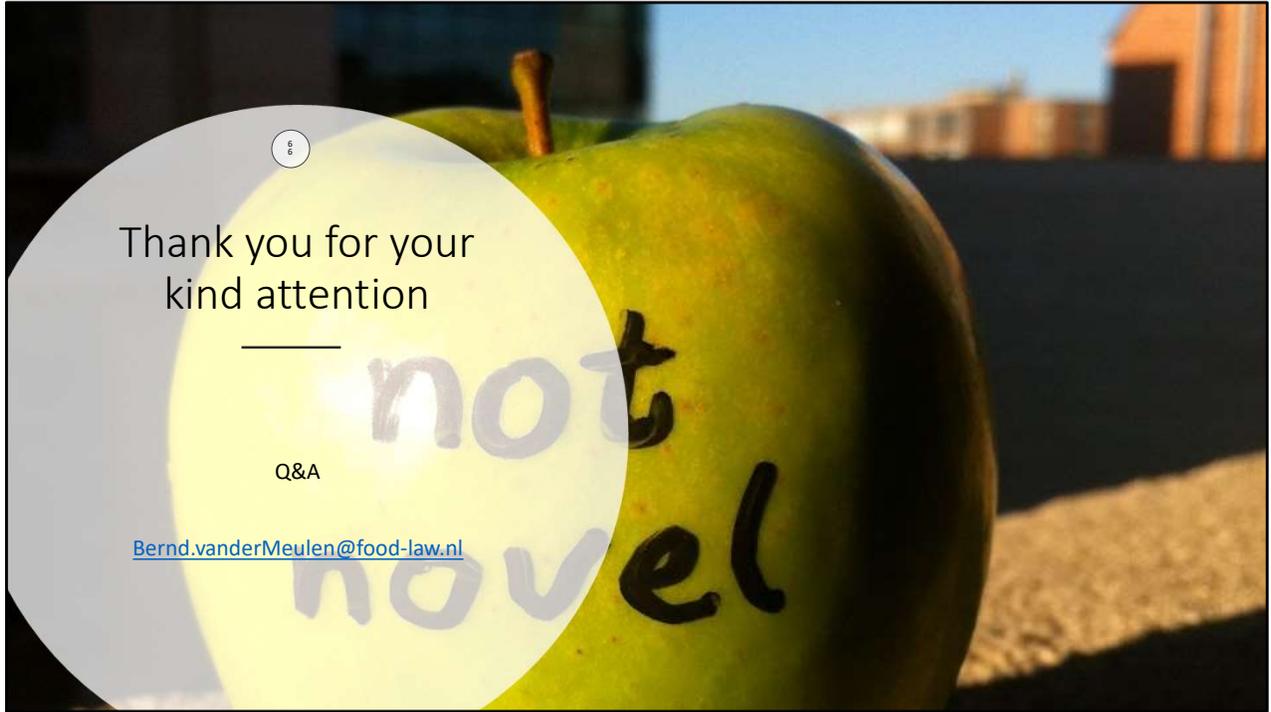
<https://www.wageningenacademic.com/doi/book/10.3920/978-90-8686-679-3>

A photograph of a man with short brown hair, wearing a dark blue suit jacket, a light blue striped shirt, and a dark tie. He is sitting at a chessboard, looking intently at the pieces. The chessboard is in the foreground, with several pieces visible, including a white king and a white pawn. The background is a plain, light-colored wall.

Business strategies

- Avoidance
 - Abandon innovation
- Compliance
- Monopolisation
 - Procedures possible for limited number of businesses
 - Exclusive rights
- Circumvention
 - Do but don't tell...
- Infringement
 - Sell explicitly banned products

Robert Fischer



66

Thank you for your
kind attention

Q&A

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