Authorisation requirements

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

Bernd van der Meulen – Copenhagen Summer 2020

Food Law
Academy

Overview

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

Food Law
Academy

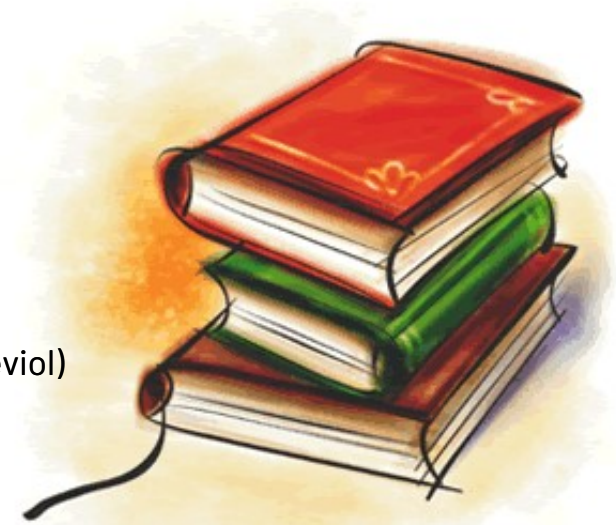
Objectives

- 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
- apply this in your paper

Food Law Academy

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 Academy

Materials II

- Case law
  - ECJ 14 April 2011 Case C-327/09 'Stevia'
  - CJEU 9 November 2016 Case C-448/14 'De Tox Forte'
- 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

EU JRC foresight scenarios 2050

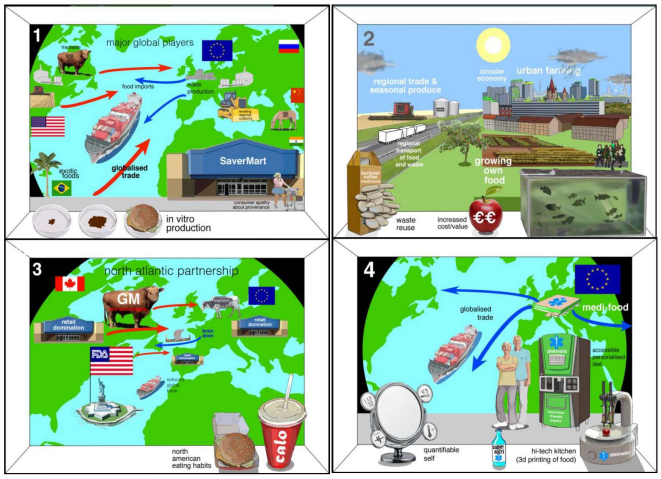


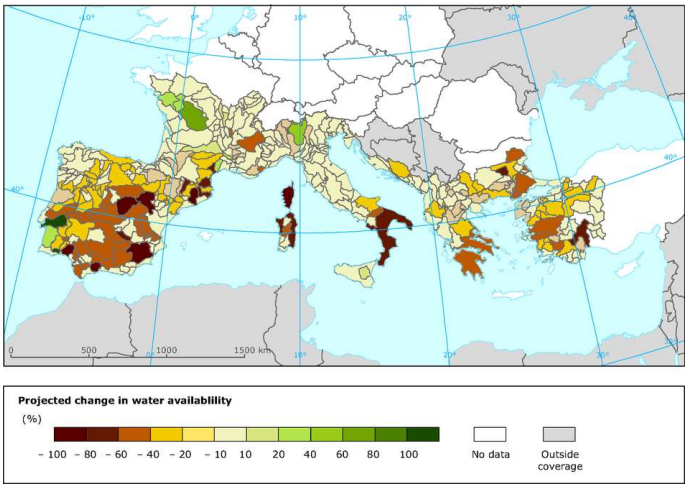
Fig. 1. The four foresight study scenarios

Food Law Academy

6

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

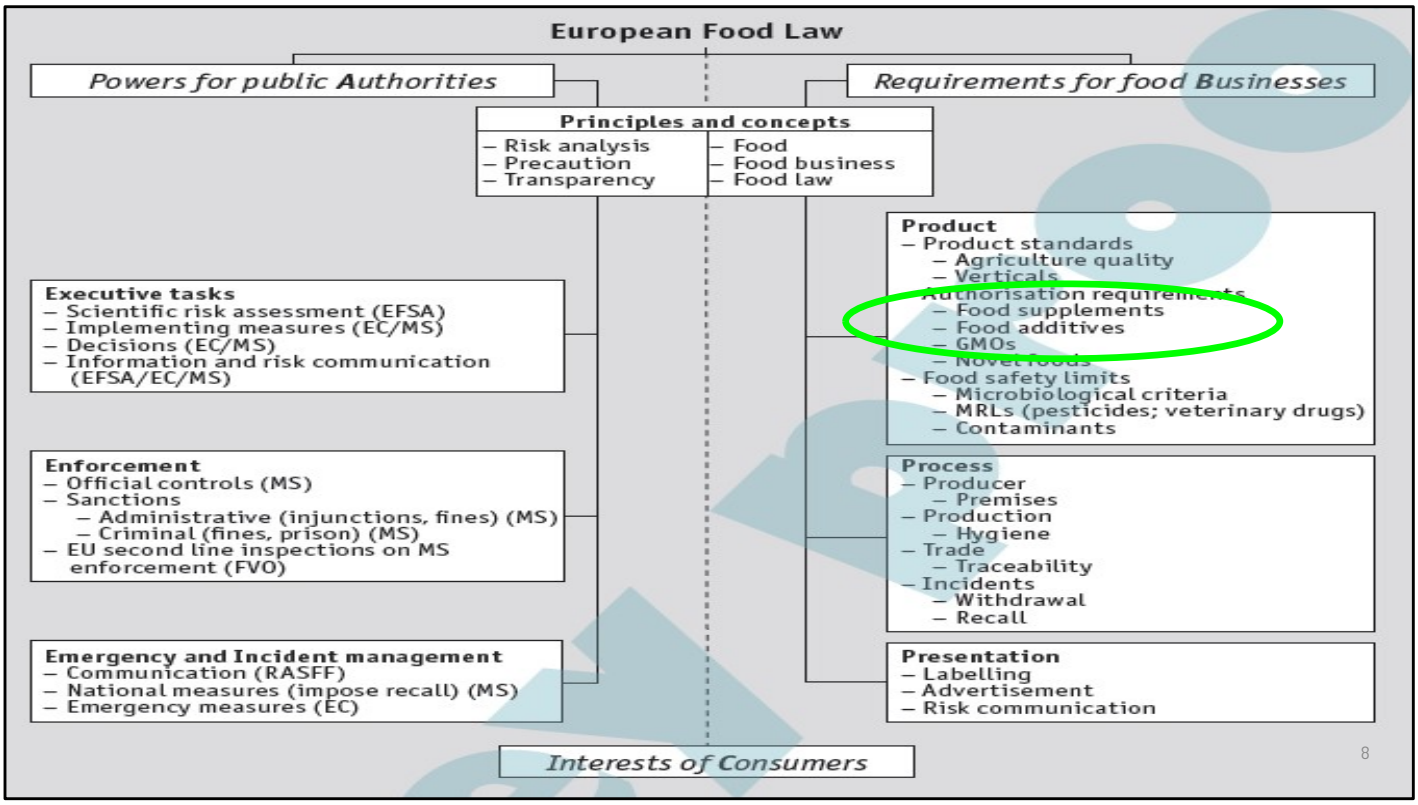
Projected change in water availability for irrigation in the Mediterranean region



Food Law Academy

7

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


European Food Law
Powers for public Authorities
Requirements for food Businesses
Principles and concepts
– Risk analysis
– Precaution
– Transparency
– Food
– Food business
– Food law
Executive tasks
– Scientific risk assessment (EFSA)
– Implementing measures (EC/MS)
– Decisions (EC/MS)
– Information and risk communication (EFSA/EC/MS)
Enforcement
– Official controls (MS)
– Sanctions
– Administrative (injunctions, fines) (MS)
– Criminal (fines, prison) (MS)
– EU second line inspections on MS enforcement (FVO)
Emergency and Incident management
– Communication (RASFF)
– National measures (impose recall) (MS)
– Emergency measures (EC)
Product
– Product standards
– Agriculture quality
– Verticals
– Authorisation requirements
– Food supplements
– Food additives
– GMOs
– Novel foods
– Food safety limits
– Microbiological criteria
– MRLs (pesticides; veterinary drugs)
– Contaminants
Process
– Producer
– Premises
– Production
– Hygiene
– Trade
– Traceability
– Incidents
– Withdrawal
– Recall
Presentation
– Labelling
– Advertisement
– Risk communication
Interests of Consumers
8

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

Food Law Academy

Safety

Structural

Properties of the product

- Toxicity
- Etcetera

Incidental

Condition of a food due to:

- Deterioration
- Contamination
- Etc.

Structural safety

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

Food Law Academy

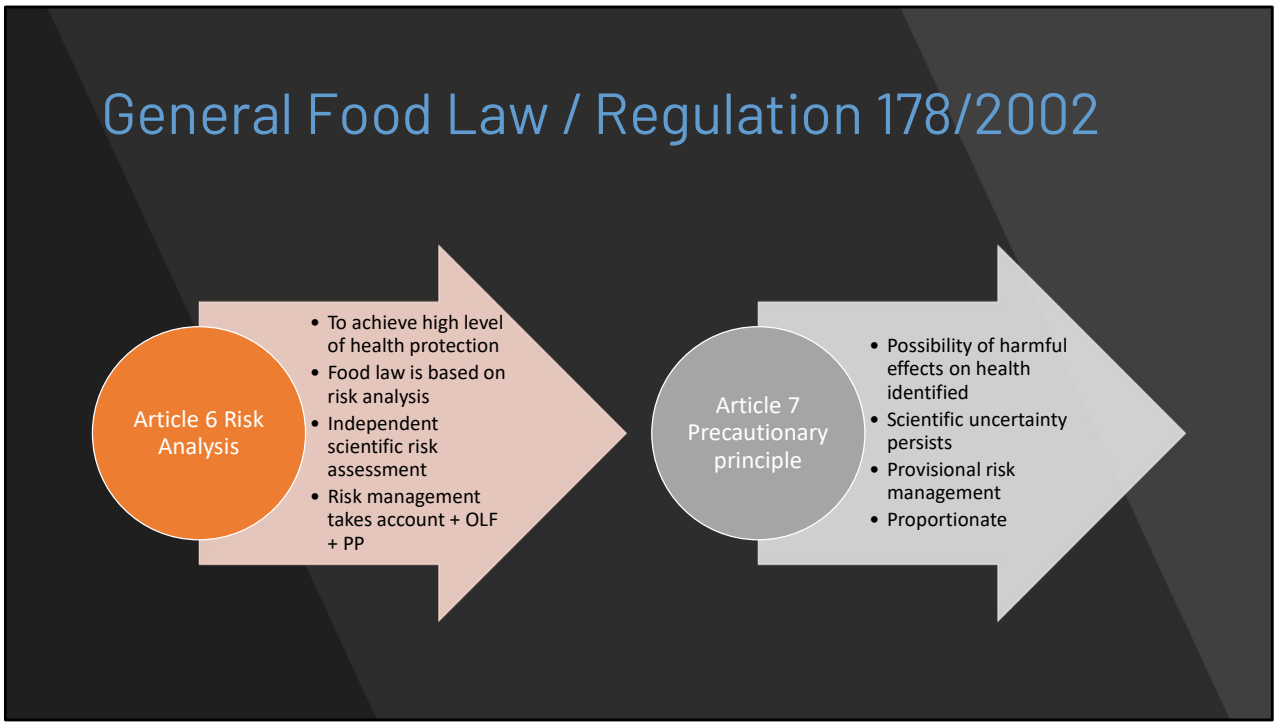
11

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

Food Law Academy

Science


General Food Law / Regulation 178/2002
Article 6 Risk Analysis
To achieve high level of health protection
Food law is based on risk analysis
Independent scientific risk assessment
Risk management takes account + OLF + PP
Article 7 Precautionary principle
Possibility of harmful effects on health identified
Scientific uncertainty persists
Provisional risk management
Proportionate

Science

Questions to science

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

Food Law Academy

Science

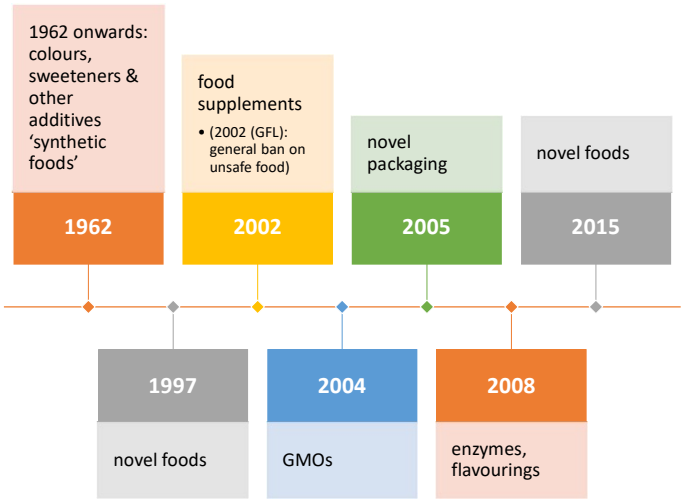
Science in food law

- 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



Academy

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 Academy

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 Academy

Additives

USA 1958: ‘anything added to food’ (except…)

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

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;

Food Law
Academy

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
Academy

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)

Food Law Academy

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

Food Law
Academy

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

Food Law
Academy

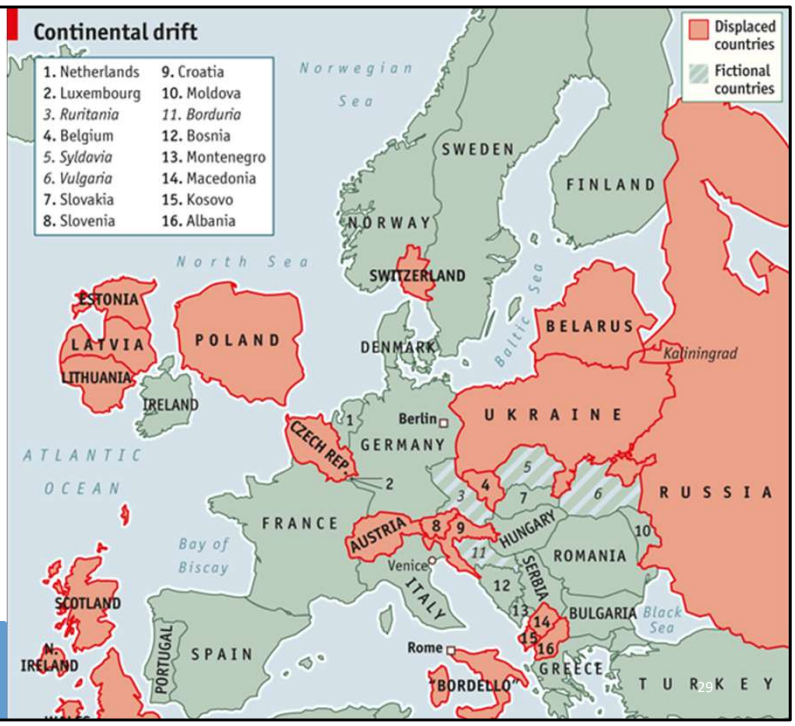
Novel foods

- 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 Academy

Flora

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



Food Law Academy

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 Academy

31

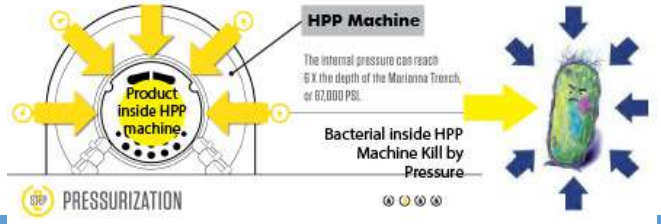
Categories

- (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;

Food Law
Academy

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.

Food Law Academy

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)

Food Law Academy

34

Not discussed in video.

Food Law
Academy

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 LIIKANEN

Member of the Commission

Food Law Academy

Not discussed in video.

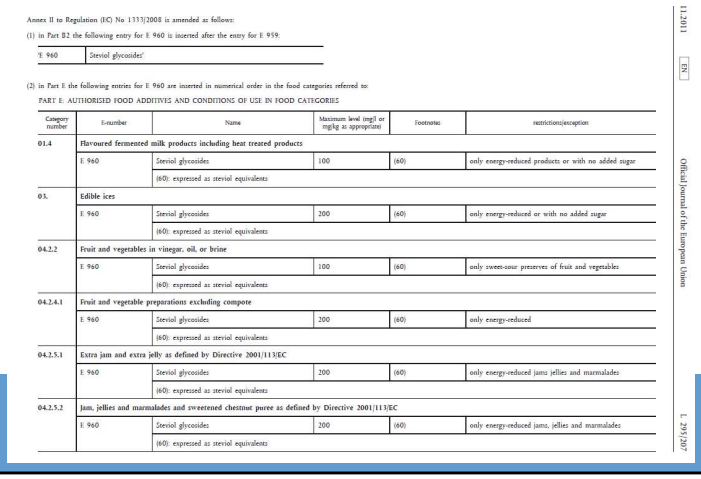
ECJ on Stevia 14.4.11

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.

Food Law Academy

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	E-number	Name	Maximum level (mg/l or mg/kg as appropriate)	Footnotes	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			
03.		**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, jellies and marmalades 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			

11.2011 EN Official Journal of the European Union L 295/207

Food Law Academy

Not discussed in video.

Omslagverhaal 3D-voedselprinter

Technologie Voedingsmiddelen

Keukenmachine die de keuken overbodig maakt

Pizza, snoep, koek: je kunt het allemaal 3D-printen. En het smaakt. Bedrijven en onderzoekers zijn volop bezig met de techniek, die koken overbodig kan maken. 'De grote voedselbedrijven missen de boot als ze hier niets mee doen.'

Jelmer Luimstra

Geprint dj-ijsje

Cartridges

Visuele zorgvoeding

TNO krijgt met mooi geprinte en eetbare aardappels met vlees ouderen in de zorg weer aan het eten

Chipspoeder

Toteco

Wie Eva Bomson (37) & Leonie Smeit (36) | Wat MELT Teaspoge, te Amsterdam | Idee Goedkope mallen produceren

Wie Zoanne Hendriks (48) | Wat By Flow, te Eindhoven | Idee 3D printers makkelijker maken

Wie Kjeld van Bommel (45) | Wat TNO, te Eindhoven | Idee Gemakkelijk kauwfilaar voedsel

Wie Chloé Rutzerveld (33) | Wat Food designer, te Eindhoven | Idee Gezonde geprinte voeding

1928 | 1930 | 1939 | 1947 | 1948 | 1954 | 1980 | 2012

Another example: food printing. 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

Food Law
Academy

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)

Available online at www.sciencedirect.com

ScienceDirect

ELSEVIER

Food and Chemical Toxicology 46 (2008) 1681–1703

www.elsevier.com/locate/foodchemtox

Risk management and risk assessment of novel plant foods: Concepts and principles

Ib Knudsen [a], Inge Søborg [b], Folmer Eriksen [a], Kirsten Pilegaard [a], Jan Pedersen [a,*]

[a] Department of Toxicology and Risk Assessment, National Food Institute, Technical University of Denmark, Mørkhøj Bygade 19, DK-2860 Søborg, Denmark

[b] DHI, Centre for Environment and Toxicology, Agern Allé 5, DK-2970 Hørsholm, Denmark

Received 22 March 2007; accepted 7 January 2008

Abstract

Worldwide 30 food plants deliver 95% of human daily intake of plant food calories and around 300 other plant species are delivering the last 5%. These some 300 food plants are likely to be considered traditional in Europe, while the nearly 5000 other plant species traditionally used in the human food supply in other parts of the world may be considered novel in Europe.

Novel food regulation is already in force in the European Community, Australia/New Zealand and in Canada where the novel plant foods need to go through a premarket assessment procedure. This paper propose criteria and definitions to be used in determining novelty of a plant food and also propose a safety assessment approach for novel plant food with no or limited documented history of safe consumption.

A 2-step management procedure is recommended for a smooth introduction of fruits and vegetables; first to establish the novelty and second to define and commit resources for the safety assessment. The procedure builds upon the use of a worldwide network of global, regional, local and ethnobotanical positive lists for food plants to guide the decisions on novelty at the first step and to enable the safety assessment at the second step.

Keywords: Novel foods; Traditional foods; Plant foods; Regional lists; History of safe use; Positive lists for food plants

1. Introduction

This paper deals with one segment of the novel foods, namely novel plant foods, with the main focus on novel foods derived from plants not known in the country or region. The paper does not deal with foods derived from genetically modified plants, but only foods derived from cultivated plants that may be developed through conventional breeding or plants from wild sources.

For nearly all plant foods it is very difficult to obtain scientific data, which document their history of safe consumption even though they may have been eaten for several hundreds of years. Nevertheless according to the regulation of some countries there is a need to establish the safety of novel plant foods in order to accept their introduction on the market. While there already exist well established paradigms for safety assessment of isolated and extracted plant products like sugars, fats and defined chemical entities e.g. flavours, there are no commonly accepted international approaches to assess the safety of complex foods such as fruits, vegetables and other plant parts derived from novel sources.

The purpose of this paper is to propose a set of basic principles and concepts for safety assessment of plant foods, with a main focus on new fruits and vegetables with no history of safe consumption in a country or region and with the final aim to propose a procedure for the safety assessment based upon up-to-date scientific knowledge. This paper is based upon the work by a working group

* Corresponding author. Tel.: +45 7234 7610; fax: +45 7234 7699.
E-mail address: jp@fvd.dtu.dk (J. Pedersen).

0278-6915/$ - see front matter © 2008 Elsevier Ltd. All rights reserved.
doi:10.1016/j.fct.2008.01.022

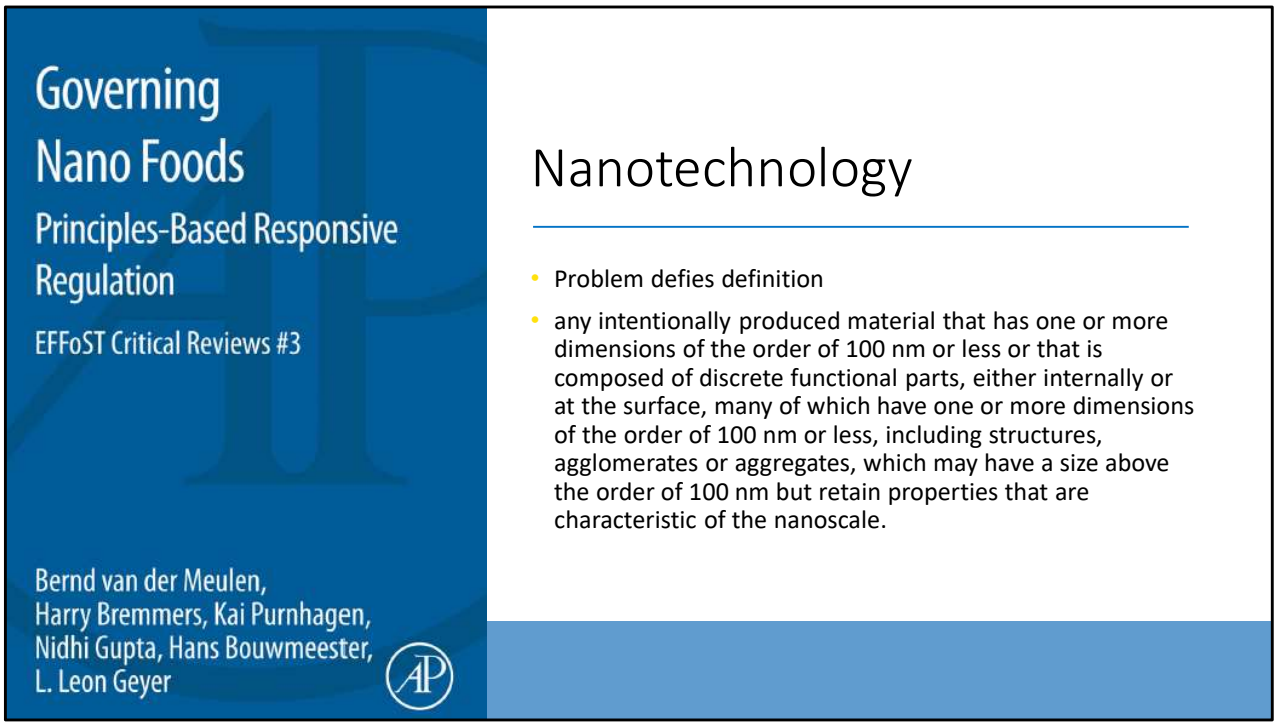
Ib Knudsen, Inge Søborg, Folmer Eriksen, Kirsten Pilegaard et al., *Risk Management and Risk Assessment of Novel Plant Foods: Concepts and Principles*, 46 Food & chemicaL toxicoLogy 1681 *et seq.* (2008).

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

Food Law Academy

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



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

Food Law Academy

Not discussed in video.

Proprietary?

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

Publish and Perish: A Disturbing Trend in the European Union's Regulation of Nutrition Health Claims Made on Foods

by Susan Carlson, Ricardo Carvajal, Nicole Coutrelis, Johan-Francois Desjeux, Lorenzo Morelli, Peter Van Dael, Bernd van der Meulen, Annemieke Tops, Cathy Weir

Recent developments in the European Union's regulation on health claims used in food labeling could have the effect of suppressing publication of scientific research on the health benefits of food substances. Given that scientific research and collaboration is an international phenomenon, the negative effect of the European Commission's (the Commission) current direction might well be felt in the United States.

The seeds of this controversy were sown in December 2006, when the European Parliament issued Regulation (EC) No 1924/2006, which stipulates the circumstances under which health claims may be made for foods marketed in the European Union.[1] At the outset, it's important to note that the definition of "health claim" as that term is used in EU regulations is considerably broader than the definition of "health claim" in the Federal Food, Drug, and Cosmetic Act and its implementing regulations. The EU health claims regulation defines "health claim" as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health."

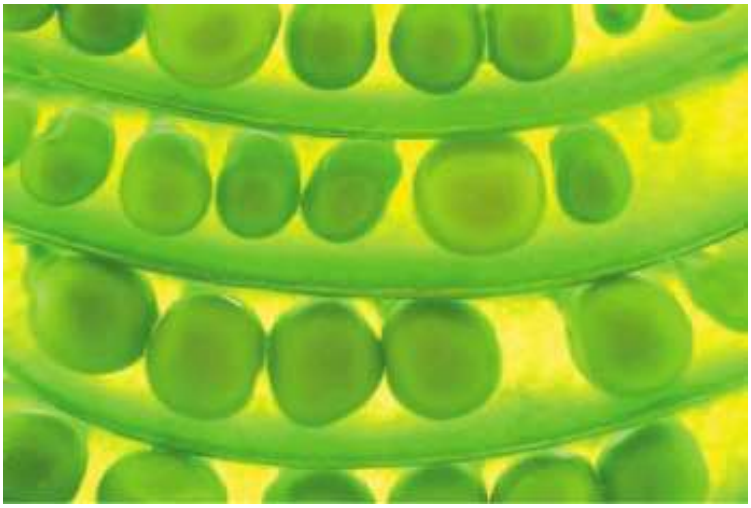
This EU definition of "health claim" (hereinafter "EU health claim") is sufficiently broad as to encompass several different types of claims that can be made for foods marketed in the United States, including: (1) "health claims," defined as claims that expressly or impliedly characterize the relationship of a nutrient required to be included in nutrition labeling to a disease or a health-related condition; and (2) "structure/function claims," defined as claims that describe "the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans," or that characterize "the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function."[2] Thus, developments in the regulation of EU health claims have the potential to alter the landscape in the United States for both health claims and structure/function claims.

The EU health claims regulation requires that new health claims (i.e., those not already on a list of approved claims) be the subject of a premarket approval application that includes relevant scientific studies and other information,

From left, Johan-Francois Desjeux, Nicole Coutrelis, Peter Van Dael, Cathy Weir, Annemieke Tops, Susan Carlson, Lorenzo Morelli, Ricardo Carvajal, Bernd van der Meulen.

Food Law Academy

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

Food Law Academy

Herbicide Resistance

Food Law Academy

Insect Resistance

Transgenic Non-transgenic

Food Law Academy

EU regulatory framework

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

Food Law Academy

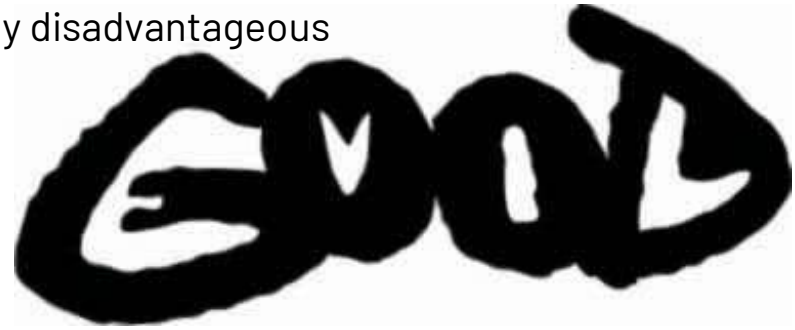
Pre-market approval

- '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



Food Law Academy

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)

Food Law
Academy

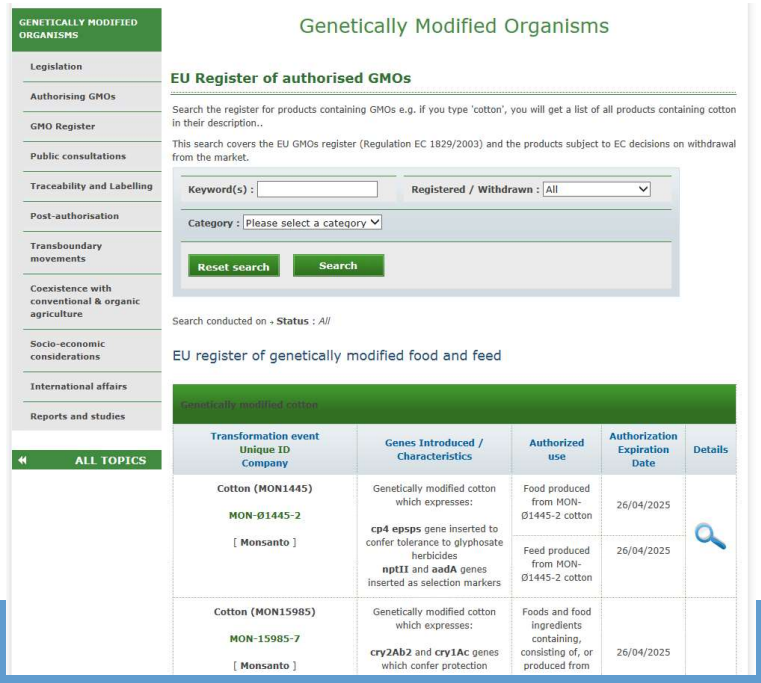
Authorisation

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

Food Law
Academy

Positive list

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

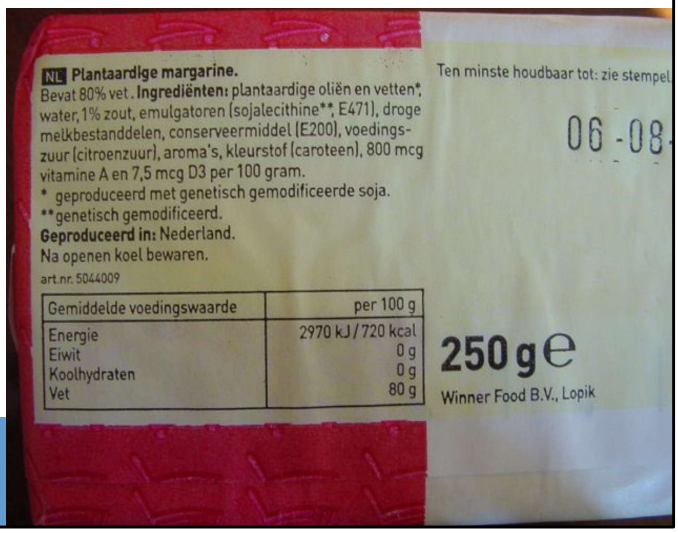


Food Law Academy

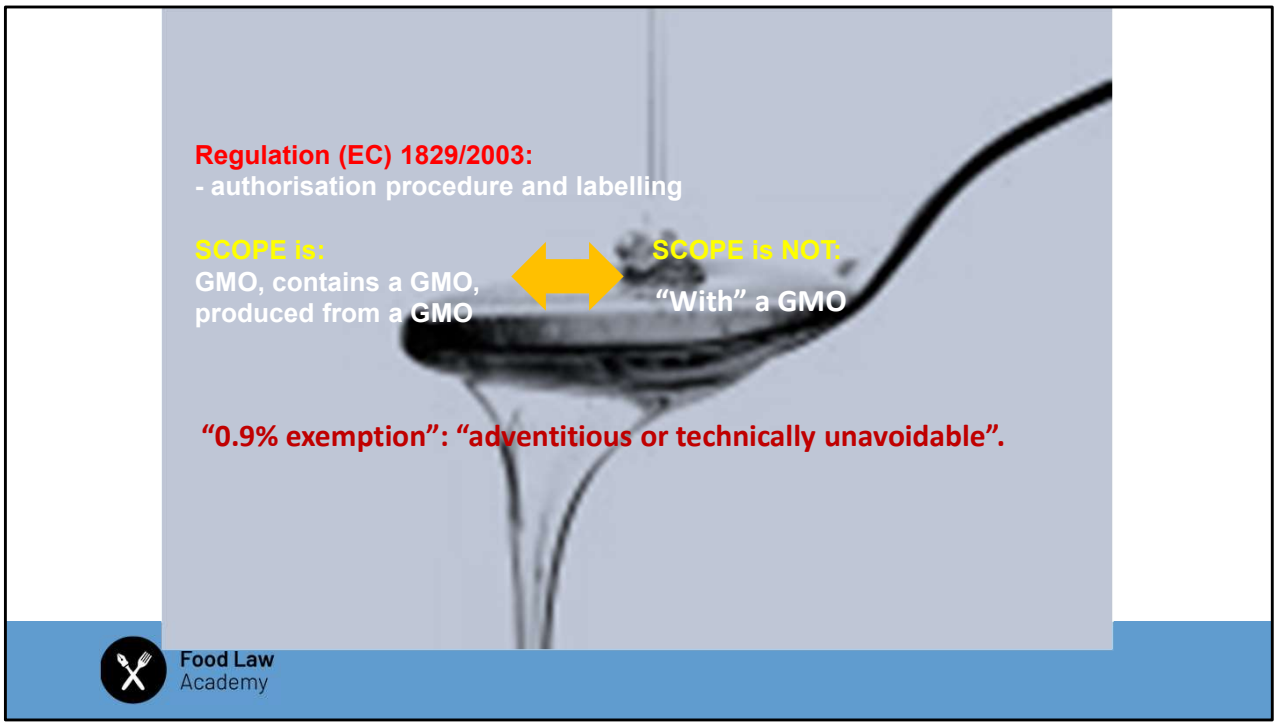
New portal: https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

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



Food Law Academy



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!

Food Law Academy

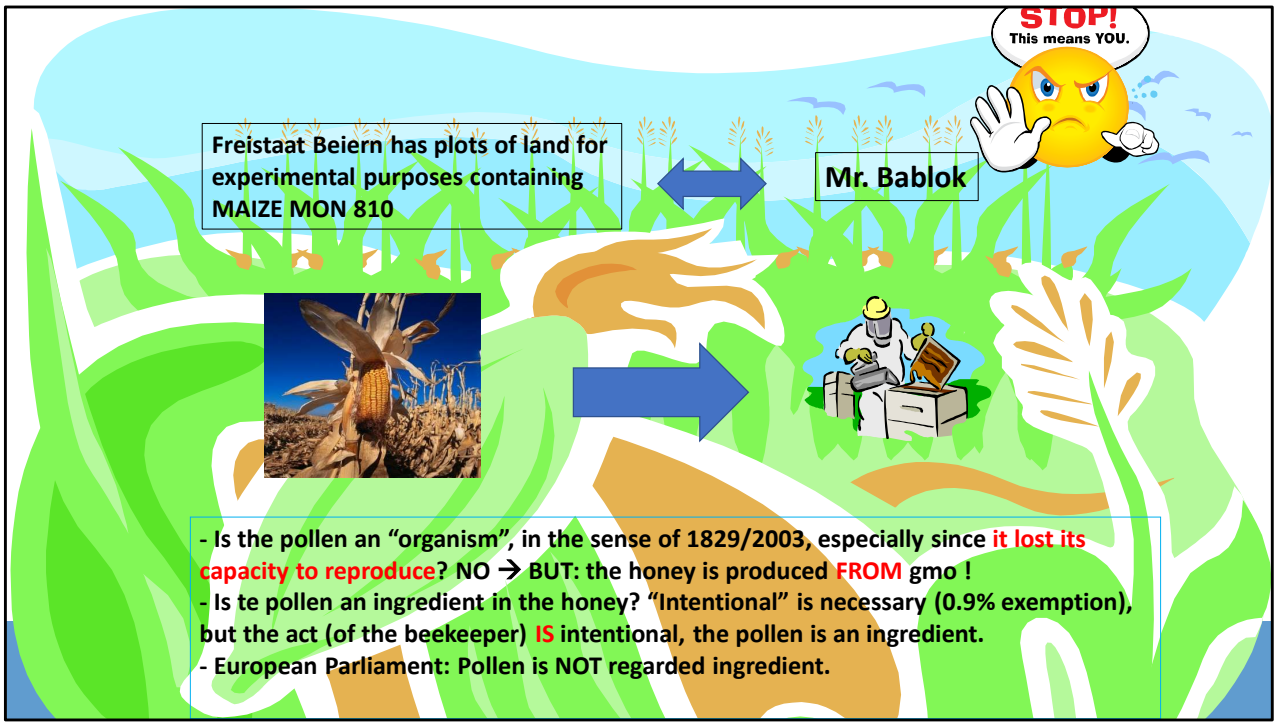
Not discussed in the video.

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.

Food Law Academy

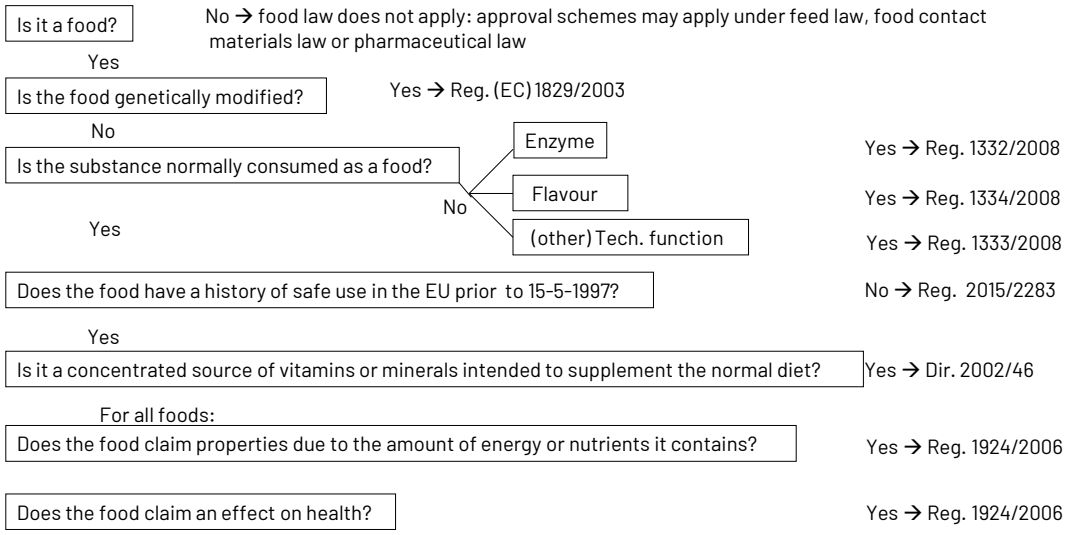
CJEU 25 July 2018, Case C-528/16 Confédération paysanne, et al. v. Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt ECLI:EU:C:2018:583

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

Food Law Academy

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

Pre-market authorisation decision tree



Food Law Academy

Experiences and problems

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

Food Law Academy

64

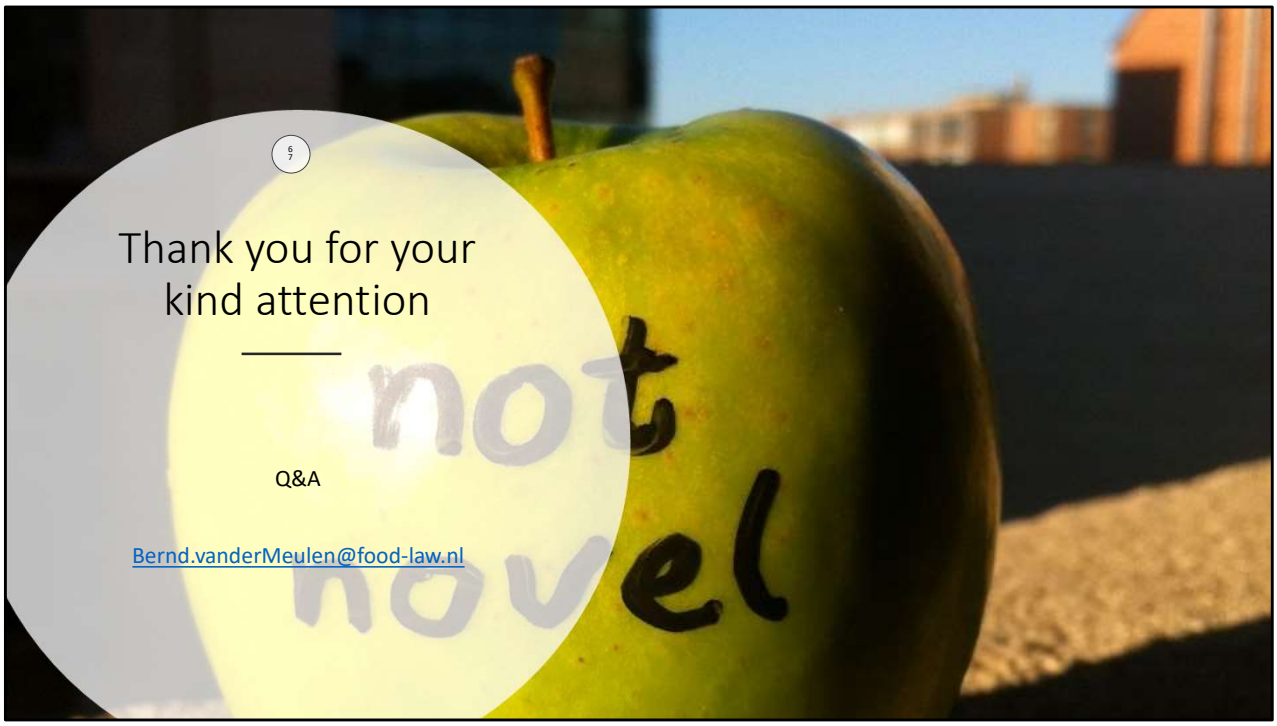
https://www.wageningenacademic.com/doi/book/10.3920/978-90-8686-679-3

Robet Fischer

What do I expect from your paper?

- Recognise situations in which market-authorisation schemes apply.
- Identify the steps to be taken in the authorisation procedure.
- Have an opinion on pros and cons.

Food Law Academy



67

Thank you for your kind attention

Q&A

Bernd.vanderMeulen@food-law.nl