

Food Safety and the Precautionary Principle

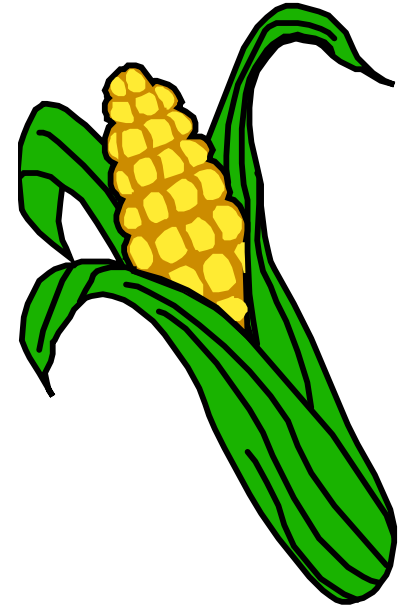
Professor Michael Blakeney

Outline

- Starlink Corn
- Food Scares
- EU-Framework Legislation Feed and Food Safety



Starlink Corn



Starlink corn with Cry9C based Bt toxin protein

63FR28258 Bacillus Thuringiensis Subspecies tolworthi Cry9C Protein and the Genetic Material Necessary for its Production in Corn;

Exemption from the Requirement of a Tolerance May 22, 1998



Starlink Corn problem

- Starlink corn produced by Adventis Corp (Research Triangle NC) with Cry9c Bt toxin protein
- Approval given by EPA in 1998 but restricted to animal feed as noted by potential for allergenic response in humans based on four criteria
- September 2000 Consumer group (FOE) analyzes taco shells and finds Cry9c Bt protein. Sept 11, 2000 calls on EPA to remove
- Taco Bell begins recall of tacos from supermarkets, as does Safeway product made by Kraft



U.S. probes Taco Bell's alleged use of biotech corn

September 18, 2000

WASHINGTON (Reuters) -- The U.S. government said Monday it was investigating a strain of bioengineered corn not approved for human food that may have crept into Taco Bell shells sold in grocery stores.

News about the alleged unlicensed use of the corn variety in human food comes at a time when the Clinton administration is finalizing guidelines to use in approving new varieties of bio-engineered foods.



Taco Bell sees no need for recall

CNN

September 24, 2000

IRVINE, California -- Taco Bell has decided to continue selling taco shells obtained from the same supplier as those recalled by Kraft Foods.

Kraft Foods is recalling millions of Taco Bell home-brand packages because they may contain a possibly harmful variety of genetically engineered corn.

Voluntary Recall of Taco Bell Taco Shells containing StarLink Corn, Which Had Been Approved for Animal Feed but Not for Human Consumption

September 25, 2000

On Friday, September 22, Kraft Foods announced a voluntary recall of Taco Bell Home Originals taco-shell products sold in grocery stores throughout the United States. Kraft's recall decision came less than one week after a group, Genetically Engineered Food Alert, announced that in testing performed at their request they had identified the presence of a product, StarLink corn, in Taco Shells being sold in US Grocery stores.

Seeds of Dissent

- WASHINGTON (Reuters) Wednesday, October 11, 2000 4:48 PM EST
- - A biotech corn variety found last month in Taco Bell taco shells and intended only for use as a livestock feed has been detected in a second human food product, a consumer advocacy group said on Wednesday.
- Genetically Engineered Food Alert, a coalition of health, consumer and environmental groups, said it would announce the product at a news conference on Thursday. "It'll be a product that people have heard about," said Matt Rand, biotechnology specialist for the National Environmental Trust and co-coordinator of the GE Food Alert campaign.
- The group's announcement last month that Taco Bell taco shells sold in grocery stores contained the Starlink corn variety prompted manufacturer Kraft Foods, a unit of Philip Morris Cos. Inc. (MO.N), to announce a voluntary recall.
- Starlink corn, which is made by Aventis SA (AVEP.PA), has been approved for animal feed but not for use in human food because of concerns about the potential for allergic reactions.
- The U.S. Agriculture Department has said it would buy all of the estimated 45 million bushels of Starlink corn produced this year to get it off the market. Aventis will reimburse the department for the expected \$90 to \$100 million cost of that action.

Starlink Corn problem

- Kellogg's shuts down corn flakes cereal plant (10/18/2000) as precaution against potential for allergenic response
- 10/19/00 Adventis says problem is farmers co-mingled corn into human food destined corn. Of 260 grain elevators, about 106 sent out to food processors which is 12% of Starlink corn or 9 million bushels

Millers and Grocers Reuters 10/10/00

Kroger and Albertsons remove cereal and tacos

Mission Foods recalls all Tacos (largest US maker)

Azteca Milling will take back all yellow 2 corn flour

ConAgra stops operations at Kansas corn flour mill - will not disclose customers

Nov 3 FDA announces over 300 products with potential risk

More to the story....

- Sept. 27 Aventis suspends sales and offers to buy back from farmers
- Oct. 2 FDA says it will demand a recall from Taco Bell
- Oct. 11 activists announce that Safeway store brand taco shells test positive
- Fourteen people claim adverse allergic reactions
- Tyson Foods won't use StarLink as chicken feed
- Discovery that Aventis has planted StarLink in other countries
- Iowa says half of its corn may be mixed with StarLink varieties
- December, 2000, Japan rejects a U.S. shipment of corn

The Issue

Green Party (NZ) health spokeswoman Sue Kedgley was cited as saying on Monday (Oct 30) that Starlink corn was feared to cause allergic reactions and digestion problems in some humans, adding, "Unless the government sets up an immediate program to randomly monitor genetically engineered ingredients in our food supply, it cannot guarantee consumers that their food is safe."

Steve Taylor Univ. Nebraska

- Statement to EPA
 - Would need repeated long time exposure to Starlink to develop allergy to it
 - Cry9C accounts for 0.013% of corn grain while most allergens at 1 to 40% in food
 - “this clearly would not produce proteins levels of any health concern”

Status of StarLink

- The registration for StarLink corn was withdrawn in the USA by Aventis CropScience
- StarLink corn is no longer available for sale nor being planted in the US
- U.S. seed companies have destroyed their stocks of StarLink corn seed
- The use of StarLink corn in livestock feed and industrial, non-food uses remains fully approved by EPA
- Aventis CropScience became Bayer CropScience



Banished Biotech Corn Not Gone Yet

Dec. 1, 2003 *San Jose Mercury News*:

Three years after a genetically engineered corn banned from human consumption turned up in taco shells and was pulled from the market, contaminated grain is still showing up in the nation's corn supply.

A federal testing program found traces of the banished grain, called StarLink, in more than 1 percent of samples submitted by growers and grain handlers in the past 12 months, government records show.

Aventis, a French drug company that sold off its crop seed subsidiary, will not comment on how much it has spent on the StarLink recall and its aftermath. Neil E. Harl, a professor of economics at Iowa State University, estimates that the company has paid out more than \$500 million to farmers, food processors and grain handlers.

Genetic Wheat Faces Snag

Jan. 14, 2004 *Kansas City Star*:

In the grain trade, StarLink serves as shorthand for the folly of trying to sort one kind of corn from another.

Almost immediately, a ban stopped the deliberate planting of StarLink in American fields. But three years later it still pops up in the country's corn supply.

Now critics are citing StarLink...as an argument against a herbicide-proof wheat on the verge of approval for planting in the Midwest and Canada . Already controversial, the new wheat must now overcome the StarLink legacy.

Monsanto Pulls Plan To Commercialize Gene-altered Wheat

May 11, 2004 *Washington Post*:

Monsanto Co. yesterday scrapped plans to commercialize genetically engineered wheat, the biggest defeat yet for advocates of agricultural biotechnology – and a victory for skeptics who said the company was trying to foist on the world a crop it did not want or need.

Proposed 21 CFR 192

PBN Premarket Biotechnology Notice

- Identity
- Function
- Level
- Dietary exposure
- Allergenicity
- History of use of food in diet
- FDA response within 120 days

The Final Step

Labeling - Informed Consent

- Required warnings
 - Saccharin
 - Aspartame
 - Sulfite
 - Alcohol
 - Meat handling
 - irradiation



FDA Labeling Guidance Document

- 66 FR 4839 (Jan 18, 2001)
- Guidance Document
 - <http://vm.cfsan.fda.gov/~dms/biolabgu.html>
 - Labeling is voluntary
 - Food labeling must be truthful ie no GMO need proof
 - If GMO significantly different, common and usual name should state so
 - If allergen present must state so
 - Example GMO statements



Recent Food Scares

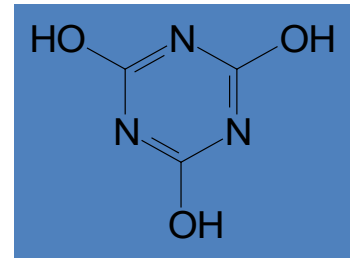
Economic drivers

- prions (BSE – mad cow) in beef
- dioxins in animal feed (2008 Ireland)



Deliberate adulteration

- melamine in pet food and baby food
- sudan dye in spices



Recent food scares

Technology changes

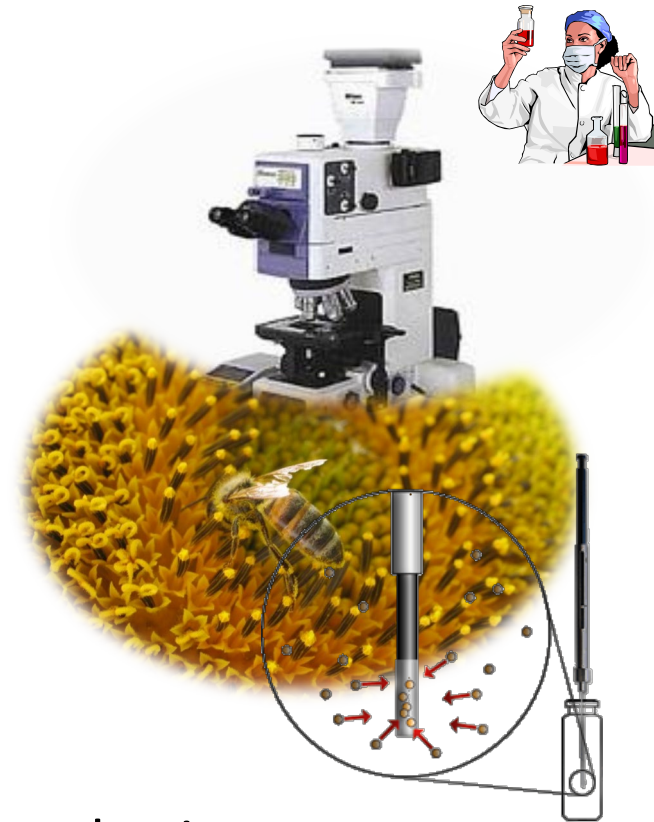
- E-coli (O157) in spinach salad (USA)

Failure to observe regulations

- nitrofurans in shrimps
- chloramphenicol in honey

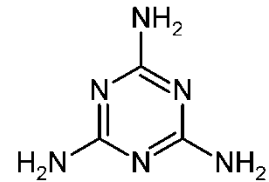
Improved analytical techniques

- acrylamide and furan in cooked foods
- 2- isopropyl thioxanthone (ITX) in food packaging
- Bisphenol-A-diglycidyl-ether (BADGE) in can coatings



Melamine

- A chemical we know from inexpensive dinnerware, tabletop, etc...
- Is rich in nitrogen
- Nitrogen in food will be registered as protein (Kjeldahl analysis)
- Added to food it will disguise a low protein content



Chronology of Events

December 2007:

- One dairy producer (Sanlu) began receiving complains from consumers

July 2008:

- Sixteen babies in Hebei province were found with kidney stones. They were fed with infant formula made by Sanlu



WHO/Sari Setiogi

Chronology of Events

October 2008 : Extension to the feed industry :

- 16 - Japan reported melamine in egg products from China
- 20 – 1,500 racoon dogs in China died after eating contaminated feed
- 30 - Chinese state media reported melamine in animal feed

Chronology of Events

September 2008:

- 11 - WHO was informed by the Chinese authorities
- 15 - Sanlu apologizes to the public. 11000 tons of milk powder seized or recalled.
- 17 – Contaminated products originating from China found in Singapore.
- 18 - Melamine found in fresh milk
- 22 - Director of China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) resigned
- 23 - China confirmed delay in informing the public
- 25 - WHO issued "Melamine and Cyanuric Acid: Toxicity Preliminary Risk Assessment and Guidance on Levels in Food"



Contaminated Infant Formula

- Melamine was added in milk collection centres to disguise diluted milk with water
- 22 of 79 Chinese powdered infant formula producers affected
- Powdered Infant formula products from affected producers exported to 5 countries
- Levels detected range from <0.1 – 2600 mg/kg

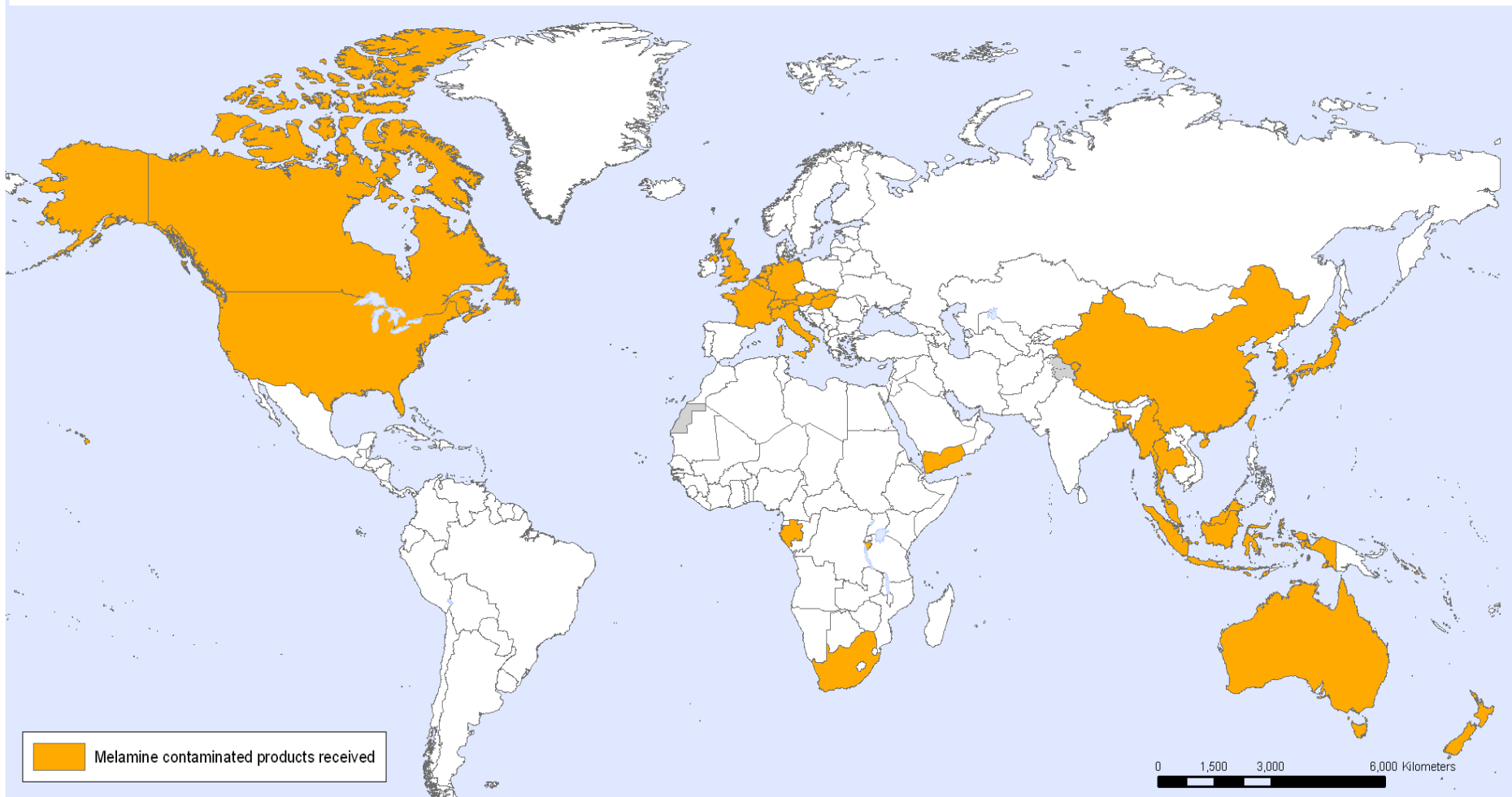


Other products contaminated

- milk (powder), yoghurt, biscuits, instant & liquid coffee preparations, candies, frozen desserts, novelty products...
- egg powder, fresh eggs, animal feed
- Sodium bicarbonate (raising agent)
- Protein powders



Country received melamine contaminated products



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: Public Health Information
and Geographic Information Systems (GIS)
World Health Organization



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Children affected in China

- More than 290 000 children affected
- 51 900 hospitalized
- 6 deaths reported
- 22.4 million children screened



Levels of Melamine

Product category	Melamine levels (mg/kg)
Infant formula	0.09 – 2 563
Liquid milk and yoghurt	0.6 - 648
Powdered milk and cereal products	<1 – 6 196
Biscuits, cakes & confectionary	0.6 - 945
Frozen desserts	4.4 - 60.8
Snackfood	0.5 - 54
Processed food	0.7 - 13.6
Non-dairy creamer	1.5 – 6 694
Ammonium bicarbonate	33.4 - 508
Dried egg powder	0.1 - 5.03
Eggs	2.9 - 4.7
Animal feed	116.2 - 410

Measures Taken: National Authorities

- Traceability of imported and exported products
- Test for melamine (and cyanuric acid)
- Withdrawal of confirmed and suspected melamine contaminated products
- Alert to other countries if products exported
- Regulatory actions, e.g. import bans
- Preliminary risk assessments and interim limits for melamine in food and feed

Limits set by National Authorities

Country/Region	Product	Limit (mg/kg)
Australia	Infant formula	1
	Dairy-based foods and foods containing dairy-based ingredients	2.5
Canada	Infant formula and sole source nutrition products, including meal replacement products	1*
	Other food products containing milk and milk-derived ingredients	2.5*
China	Infant formula	1
	Liquid milk, including milk as raw material, milk powder, and other milk formula products	2.5
	Other milk products (products containing 15% of milk and above)	2.5
European Union	Composite products containing milk and milk products, intended for infants and young children (including infant formula and follow-on formula) originating in or consigned from China	Import into the EU prohibited
	Products containing milk and milk products originating in or consigned from China	2.5

Limits set by National Authorities (2)

Country/Region	Product	Limit (mg/kg)
Hong Kong SAR, China	Milk; any food for infants under 36 months old, pregnant and lactating women	1
	Other food products	2.5
Malaysia	Infant food	1
	Other food products	2.5
New Zealand	Infant formula	1
	For foods in their final form, other than infant formula	2.5
United States of America	Infant formula	Too much uncertainty to set a level and rule out any public health concern
	In food products other than infant formula	2.5°

Toxicology of melamine

- On its own melamine is not extremely toxic (but in high concentrations can cause kidney and bladder affections (calculi) – leading to cancer in animals)
- Melamine has a low acute toxicity, with an oral LD50 in the rat of 3161 mg/kg body weight (OECD 1998).
- Together with cyanuric acid (break-down product of melamine) it forms kidney stone
- Effects presumably more serious in infants (because of dramatic exposure when only fed infant formula with high melamine concentration)

Home > Breaking News > Asia > Story
Jan 23, 2009
TAINTED MILK SCANDAL

Ex-Sanlu boss jailed for life

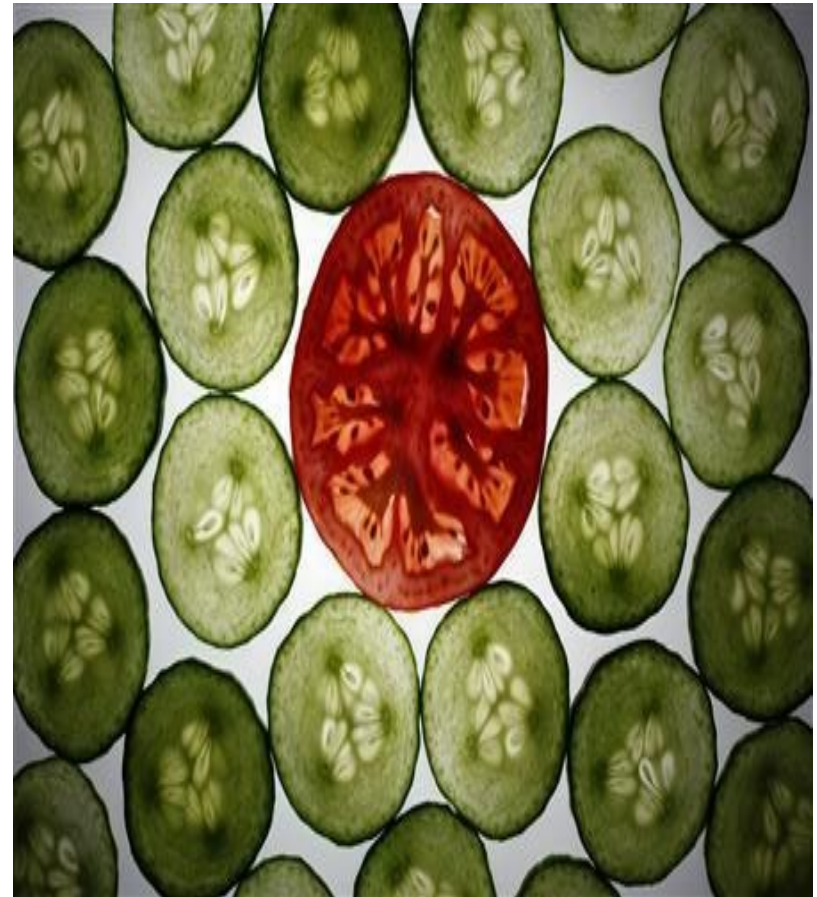
Death sentence for two men who made and sold melamine; stiff prison terms for nine others

By Peh Shing Huei, China Bureau Chief



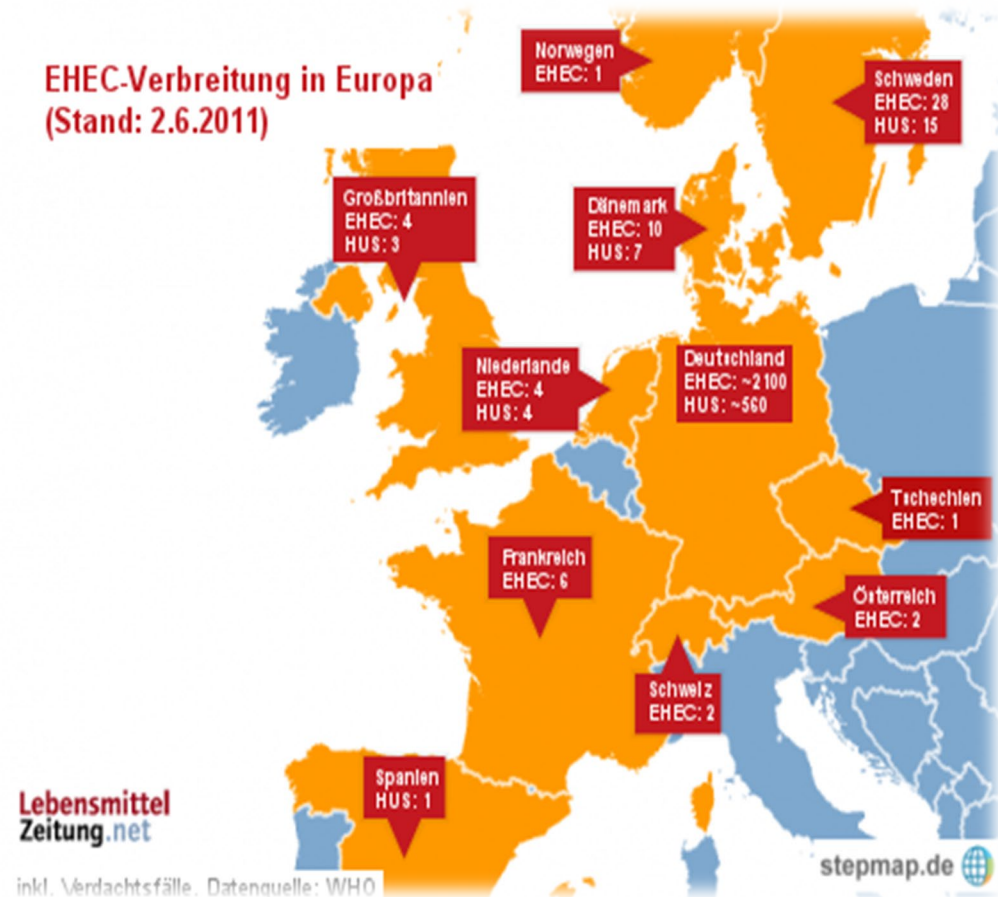
Shiga toxin-producing *Escherichia coli* (STEC)

- Shiga toxin-producing *Escherichia coli* (STEC) can cause severe enteric infections and the potentially life threatening hemolytic uremic syndrome (HUS). Prompt diagnosis of these infections is important to implement early clinical management that minimizes the likelihood of developing HUS, to reduce the risk of transmitting the infection to others, and to detect outbreak
- **Commonly consumed vegetables are source of spread.**



New report on E.coli O104 h4 outbreak

- Large outbreak of Shiga toxin-producing *Escherichia coli* O104:H4 (STEC O104:H4) infections ongoing in Germany. The responsible strain shares virulence characteristics with enter aggregative *E. coli* (EAEC). As of June 2, 2011, case counts confirmed by **Germany's Robert Koch Institute*** include 520 patients with hemolytic uremic syndrome (HUS) – a type of kidney failure that is associated with *E. coli* or STEC infections – and deaths.



EU-FRAMEWORK LEGISLATION FEED AND FOOD SAFETY

Regulation (EC) 178/2002 of the European Parliament
and of the Council of 28 January 2002

laying down the general principles and requirements
of food law, establishing the European Food Safety
Authority and laying down procedures in matters
of food safety

“The General Food Law (GFL)”

General objectives and principles

General Food Law

- The principles and the objectives of the general food law apply to all stages of the production, processing and distribution of food and also of feed produced for, or fed to, food producing animals: **“farm to fork” approach**
- The objectives of a **high level of protection of human health** and the protection of consumers’ interests and of, where appropriate, the protection of animal health and welfare, plant health and the environment shall be pursued by food legislation

General objectives and principles

General Food Law

- Food legislation shall aim to achieve the **free movement** in the Community of feed and food manufactured or marketed according to the general principles and requirements of food law
- When **international standards** exist or their completion is imminent, they shall be taken into consideration in the development of food law, except where such standards would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law

The main pillars (1): **General Food Law**

Regulation 178/2002

- **Article 17 – Liability**
All operators must ensure safety of food and feed.
- **Article 18 – Traceability**
All food, feed and animals: One step up, one step down.
- **Article 20 – Recall**
All recalls must be reported to authorities.
- **Article 11 - Imports**
Food and feed imported into the Community complies with food law or conditions recognised as equivalent.
- **Article 12 - Exports**
Food and feed exported shall comply with the food law.

The main pillars (2): **Animal Health**

- **Main, horizontal legislation**
 - **Live animals**
 - For example, for bovine species
Council Directive 64/432 and Dir. 2004/68 for imports
 - **Identification**
 - For example, Regulation (EC) 1760/2000.
 - **Germplasm**
 - For example, Council Dir. 88/407 for bovine semen
 - Council Directive 89/556 for bovine ova and embryos
 - **Products of animal origin**
 - For example, for fresh meat or poultry meat
Council Directive 2002/99
 - Meat products Council Directive 72/462

The main pillars (3): **Animal Health**

- Main, horizontal legislation
 - Animal welfare
 - Council Directive 98/58 for farming purposes
- Specific rules
 - Specific rules for animal diseases
 - For example, FMD, avian influenza
 - Specific animal welfare rules
 - For example, Regulation 1099/2009 for animal protection during slaughter
- Implementing rules

The main pillars (4): **Plant Health**

- **Main, horizontal legislation**
 - Authorisation of plant protection products
 - Pesticide residues Regulation (EC) No 396/2005
 - Harmful organisms Directive 2002/29
 - Seeds and propagating material
- **Implementing rules (example)**
 - Decision 2004/4 on potatoe diseases - emergency measures against the dissemination of *Pseudomonas solanacearum*

The main pillars (5): Zoonoses

- Main, horizontal legislation
 - Control of Salmonella and other zoonotic agents:
Regulation 2160/2003
 - Bovine spongiform encephalitis
Regulation 999/2001
- Implementing rules
 - Decision 2007/843 on Salmonella control programs in breeding flocks
 - Decision 2007/848 for laying hens

The main pillars (6): **Hygiene**

- Main, horizontal legislation
 - General hygiene for all food and feed
Regulation 852/2004
HACCP (*Hazard Analyses Critical Control Points*)-based self controls in all businesses
 - Hygiene for products of animal origin
Regulation 853/2004
Specific requirements for high risk foods
 - Inspection and control practices
Regulation 854/2004
- Implementing rules
 - Microbial criteria
Regulation 2073/2005
 - Testing methods Reg. 2074/2005

The main pillars (7): Contaminants

- Main legislation
 - Council Regulation 315/93 for contaminants in food
 - Residues of veterinary drugs
Council Regulation (EC) 2377/90
 - Hormone ban Directive 96/22/EC
- Implementing rules (Dir. 96/23)

The main pillars (8): **Additives, flavourings,
contact materials**

- **Main, horizontal legislation**
 - **Regulation (EC) No 1331/2008**
establishing a common authorisation
procedure for food additives, food
enzymes and food flavourings
 - **Food contact materials**
Regulation 1935/2004

The main pillars (9): **Labelling**

- **Main Legislation**
 - Directive 2000/13
Labelling of foods
 - Directive 90/496
Nutritional labelling
 - Specific rules for dietary foods
and special needs

The main pillars (10): **Official Controls**

- **Regulation 882/2004**
 - Coherent principles for all authorities:
 - Adequate staff, resource, training.
 - Accredited labs, international standards.
 - Risk-based controls in all sectors
 - based on multi-annual plans.
 - delegation of official inspection is possible.
 - pre-export inspection is possible.

Certification

- Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
- Rules to be observed in issuing certificates
 - **Certifying officers must not certify data of which they have no personal knowledge or which cannot be ascertained by them.**
 - **Certifying officers must not sign certificates relating to products which they have not inspected or which have passed out of their control.**
 - **Where a certificate is signed on the basis of another certificate or attestation, the certifying officer shall be in possession of that document before signing.**
 - **The competent authorities shall take all necessary steps to ensure the integrity of certification.**
 - **Certifying officers have a status which ensures their impartiality and have no direct commercial interest.**

EU oversight – the FVO (**Food and Veterinary Office**)

http://ec.europa.eu/food/fvo/index_en.html

The mission of the Food and Veterinary Office is, through its audits, inspections and related activities, to:

- Check compliance with the EU food law within the European Union and in countries exporting to the EU,
- Contribute to the development of EU policy in food safety, animal health and welfare and plant health,
- Contribute to the development and implementation of effective control systems,
- Inform stakeholders of the outcome of its audits and inspections.

European Food Safety Authority (EFSA)

<http://efsa.europa.eu>

- The **European Food Safety Authority**, as the point of reference for **risk assessment** on food and feed safety should:
 - ▶ provide **independent scientific advice** to policy makers
 - ▶ timely and clearly **communicate opinions** to all interested parties and the public,
 - ▶ with the aim to improve EU-food-safety-level and consumer confidence

Documentation on the web

General Information:

http://ec.europa.eu/food/index_en.htm

International Quality Systems

The most important quality systems:

- Hazard Analyses Critical Control Points (HACCP)
- ISO 9000 (at this moment ISO 9000:2000)
- EUREP-GAP
- British Retail Consortium (BRC)
- Safe Quality Food.

Hazard Analyses Critical Control Points (HACCP)

- The HACCP system is the system that is required for any food business or organisation in most countries by legislation.
- The joint FAO / WHO Codex Alimentarius Commission recommends the HACCP approach to enhance Food Safety.

HACCP

Food safety assurance system

- **H:** Hazard
- **A:** Analysis
- **C:** Critical
- **C:** Control
- **P:** Point
- Risk management strategy for prevention, elimination or reducing of hazards to the acceptable level
- **Proactive approach: to prevent food contamination rather than trying to identify and control contamination after it has occurred**

HACCP: required by regulations of 'hygiene package'

- regulation **852/2004 article 5**
 - Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.
 - Principles: *Codex Alimentarius* CAC/RCP 1-1996, rev. 4-2003.
 - Different foods, production technologies → guidance document
- regulation **852/2004 chapter XII**
 - adequate training in the application of the HACCP principles
- regulation **853/2004 annex II, II jagu**
- regulation **854/2004 article 4 p 3**
 - auditing

HACCP info:

- GUIDANCE DOCUMENT. Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf



GUIDANCE DOCUMENT

Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses

ISO 9000

(at this moment ISO 9000:2000)

ISO systems are:

- **Generic** {for all types of organisations producing all kinds of products or services in any sector of activity (profit, non-profit or public)}
- **Management systems** (there is a minimum of operational order so that time, money and other resources are utilised efficiently)
- **Standards** (providing the organization with a model for setting up and operating the management system).

ISO 9000:2000

The revised system consists of:

- ISO 9000 Quality Management System (QMS): Principles and Definitions
- ISO 9001 QMS: Requirements
- ISO 9004 QMS: Guidelines for performance improvement
- ISO 19011 Guidelines for auditing QMS.

www.iso.org

www.lrqqa.nl

ISO 9000:2000

Sanctions can be used for misleading practices such as:

- Misuse of the ISO logo, which is a registered trademark
- Giving the false impression, through expression such as “ISO certification”
- Giving the false impression that ISO 9000 is a product quality label.

British Retail Consortium (BRC)

BRC took the initiative to formulate common standards to inspect suppliers providing retailers with food.

Aim:

With a BRC-certificate producers satisfy all demands that British supermarkets require at once. Because this lowers the cost for customers and producers both with regard to inspection cost this concept is valued broadly.

British Retail consortium (BRC)

Set up of the system:

BRC requires suppliers to have a quality system operational, the application of HACCP, including process, staff and product, and finally environmental demands should be met

It consists of:

- Inspection protocol (used by the organizations controlling the suppliers)
- Elaborated checklist for the suppliers itself.

A supplier can achieve two levels; foundation and a higher level.

Safe Quality Food (SQF)

SQF is an Australian initiative that focuses on Food safety, product quality and the stimulation of improvement strategies.

Aim:

1. To raise standards of Food Safety and quality **across the food chain**
2. To continuously improve and deliver high standards of customer services
3. To continue to pursue increased recognition of SQF Management Systems by customers and client in new existing markets
4. To maintain and protect the high level of integrity of SQF Codes.

www.sqfi.com

Safe Quality System (SQF)

Set up of the system:

- SQF 1000 Quality Code: a simple HACCP-based supplier approved system for primary producers
- SQF 2000 Quality Code: a user-friendly quality assurance system specifically tailored for food businesses
- SQF 3000 Quality Code: a system focused on retailers, especially for biological, chemical and physical contamination.

General Food Law Import / Export (Art. 11, 12)

- **Food and feed imported into the EU shall comply with the EU requirements of food law**
- Food and feed exported or re-exported from the EU for placing on the market of a third country shall comply with the EU food law
- EC Reg. 882/04 – Official controls
- EC Reg. 854/04 – Official controls, products of animal origin
- **EC Draft Reg. (2008) – Specific measures for High Risk products of non-animal origin**

RESPONSIBILITIES (Art. 17)

- **All those who participate** to the **food/feed chain** are **responsible** for
 - the **hygiene** of their process and
 - the **safety** of their output
- **No exemption** or limitation of responsibility
- The **safety assurance must be continuous**, from primary production (animal or vegetal) to final distribution (including catering)

FOOD HYGIENE - MUST

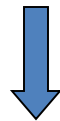
EC Reg. 852/04, sub. 2, lett. a

“**Measures** and **conditions necessary** to

- **control hazards** and to

- **ensure fitness for human consumption**
of a **foodstuff**,

taking into account its **intended use**”



HACCP

TRACEABILITY - What

- **Food & Feed**, agricultural raw materials (including animals), and every related component (ie. ingredients, additives)
- **Food Contact Materials** (traceability is provided, under identical rules, by EC Reg. 1935/04, Art. 17)

TRACEABILITY - How

Art. 18 GFL sets a **basic rule**: all those who join the food chain

must

➤ be able to identify their suppliers – Who supplied What

➤ be able to identify the business operators to whom they have delivered their products - Who has received Which product

TRACEABILITY - Why

- The general traceability system aims to allow the **control authorities** to retrace the path of food, feed and their related substances, along every phase of the chain (ie. dioxins in milk, Holland 2004, Italy 2008)

Traceability– sector obligations

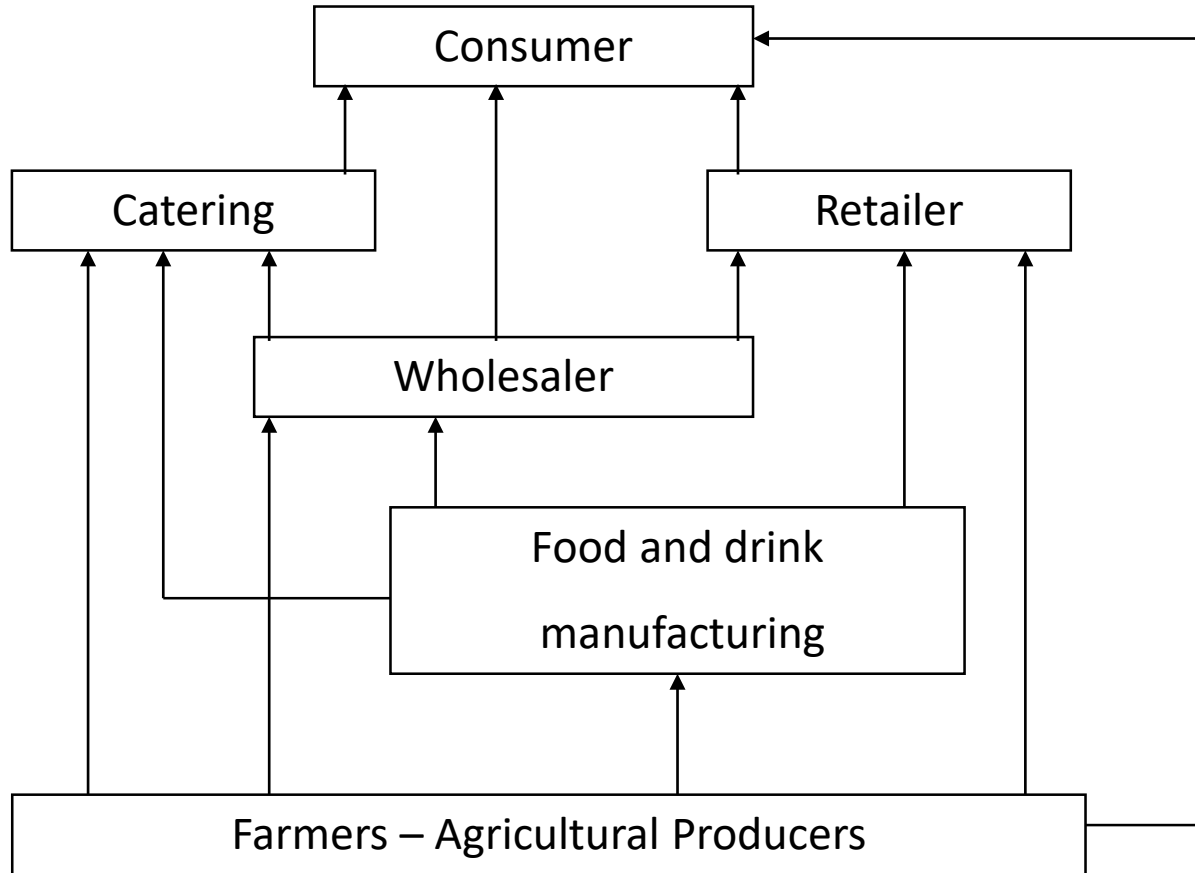
- Cattle and bovine beef (EC Reg. 1760, 1825/00)
- Other animals and meat products (Dir. 92/102/EEC, 92/5/EEC, *etc.*)
- Fish (EC Reg. 2065/01)
- GMOs (EC Reg. 1830/03)
- Eggs (EC Reg. 2295/03)
- EC draft Regulation, concerning **all foods of animal origin** – diary products included (2008)
- EC draft Regulation, concerning **high risk foods of non-animal origin** (2008)

Traceability

- The ability to track and/or trace product flows in a production and distribution chain
- It implies that product flows are uniquely identifiable and at critical points in the production and distribution processes, the identity of product flows is logged
- This information is systematically collected, processed and stored.

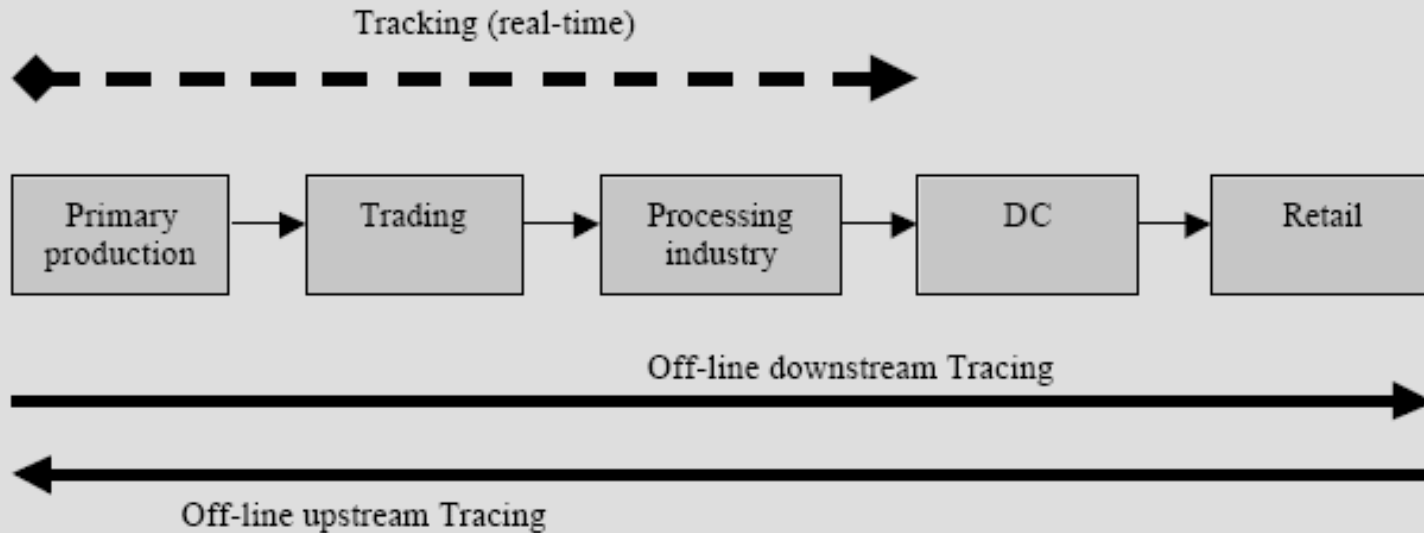
Vernède, R., Verdenius, F. and Broeze, J., (2003) Traceability in Food Processing Chains. KLICT Position Paper, Agrotechnology & Food Innovations, Wageningen.

The Food Supply Chain



Traceability

Tracking & up/downstream Tracing



Traceability

Groups of identification techniques

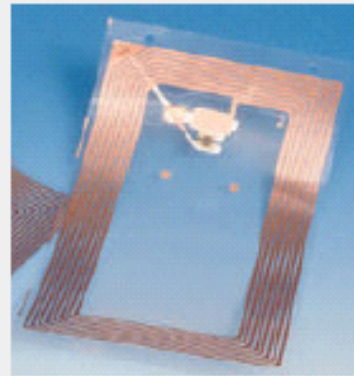
(1) Optical



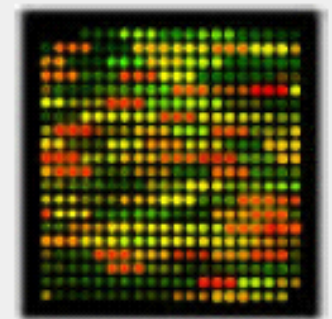
(2) Magnetic



(3) Electronic



(4) Biological



TRACB - allergens (1)

Dir. 2003/89/EC, the “Allergens Directive”, requires to **indicate on food labels**

- **the presence, even if just in traces, of**
 - **allergenic substances**, and/or
 - **materials derived thereof** (except those mentioned in Dir. 2007/68/CE)

TRACB - allergens (2)

List of allergens

- **Cereals containing gluten** (ie. wheat, rye, barley, oat, spelt, and their hybrids)
- **Milk**
- **Eggs**
- **Fish, shellfish, molluscs**
- **Soy**
- **Dry fruit with shell** (ie. almond, hazelnut, nut, peanut, cashew nut, pecan nut, brazil nut, pistachio, macadamia nut)
- **Sesame**
- **Mustard**
- **Celery, Celeriac**
- **Sulphurous anhydride (SO₂)**, at concentration higher than 10 mg/kg or 10 mg/litre
- **Lupin**

TRACB - allergens (3)

Impact on process

- ✿ HACCP analysis must consider the risk of (cross-) contamination with allergens and/or their derivatives, in all phases of
 - buying (suppliers' warranties)
 - stocking
 - manufacturing
 - packaging
 - deposit
 - transport
 - distribution

Allergens – labels - example

Dark chocolate (F-I)



It may contain traces of peanuts, nuts, almonds, milk and soy lecithine

INCIDENT MANAGEMENT

(GFL, Art. 19, food – Art. 20, feed)

- GFL sets the **operators'** duties in case of
 - real, or suspected - food/feed **safety risk** concerning products out of their direct disposal
- These rules do *not operate* in cases of qualitative non-compliance that do not affect the product safety (see Art. 14, 15)

OPERATOR's MUST (A) (art. 19 - Food)

- ✿ In case of a food safety risk:
 - ➔ immediate ***recall*** of the product, so as to stop the distribution and to prevent the placing on consumers' market
 - ➔ ***inform the competent authorities.***
Immediately, specifying the adopted measures, when there is a danger for the human health

OPERATOR'S MUST (B)

(art. 19 - Food)

- ➡ In case of product recall, give an effective and detailed **information to consumers**, explaining the reasons for the **withdrawal** (ie. physical contamination with ..., food non suitable for consumption, yes/no health danger)
- ➡ *'when other measures aren't enough to achieve an high health level'*, public **recall** of products from the market

Information to consumer: example

PRODUCT RECALL

Batchelors Super Noodles Chicken Flavour: 100g

A small number of the above foil packs may contain small pieces of hard white plastic, and are being recalled as a precautionary measure.

These packs can be identified by the coding detail found in the Best Before End information box on the back of pack as set out below:

APR08 6307 WF xx:xx

OR

APR08 6308 WF xx:xx

OR

APR08 6309 WF xx:xx

Where xx:xx denotes time of manufacture

Only batch codes referenced 6307, 6308 and 6309 are affected by this recall. No other Super Noodles products or other Batchelors products are affected by this recall notice.

What you should do

If you have purchased a pack of Batchelors Super Noodles Chicken flavour 100g coded 6307, 6308 or 6309 please do not consume the product, and return the pack to the address below where a full refund will be given:

**Consumer Relations Dept.
FREEPOST PE377
Hardwick Road
Kings Lynn
Norfolk
PE30 4BR**

We apologise for any inconvenience caused.

**If you have any queries please contact our
freephone consumer help line on: 0800 0853959**

OPERATOR'S MUST (c)

(art. 19 - Food)

- ➡ supply the competent authorities with all the useful information to assess the nature of the risk and to find the product
- ➡ cooperate with the other operators involved, within the food chain.

OPERATOR's MUST - Feed (art. 20)

In case of a feed *safety risk*:

- ➔ immediate product ***withdrawal***, providing clients with the relevant info (inclusive of the reasons)
- ➔ ***inform*** the competent authorities
- ➔ ***destroy*** risky feed, except upon different authority's orders
- ➔ when other measures are insufficient to achieve a high level of health safeguard, ***recall***

Precautionary Principle

Community law definition: Article 7(1) of Regulation
178/2002

“In specified circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment”

➤ **Accepted conditions for application of precautionary principle:**

- ✓ **Scientific uncertainty**
- ✓ **Latest science suggests existence of potential public health risk and possibility of harmful effects**
- ✓ **Risk assessment**
- ✓ **Measures based on precautionary principle must be temporary (pending more conclusive scientific evidence)**
- ✓ **Proportionate**

- a) **1992 Maastricht Treaty amends Treaty of European Community:**
“Community policy on the environment ... shall be based on the precautionary principle ...” – precautionary principle not defined
- b) **ECJ Judgment in BSE case (C-180/96 *United Kingdom v. Commission* [1998] ECR I -2265) catalyst for spread into Public Health (including Food) Area:**
“When there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks becomes fully apparent” (paragraph 99)

- **1997 Commission Green Paper: ‘The general principles of food law in the European Union’**
 - ✓ **“Conservative approach” to food safety through application of precautionary principle.**
 - ✓ **Food legislation must be based on science through a risk assessment.**

- **1999 WTO Appeal Body *Beef Hormones* decision - legitimacy of EU ban under precautionary principle Article 5.7 of SPS Agreement:**
 - ✓ **Precautionary measures must be “sufficiently suggested or reasonably warranted by a risk assessment”**
 - ✓ **10 year ban not “provisional”**

- **Alpharma Case (T-70/99 *Alpharma v. Council of the European Union* [2002] ECR II-3495): “preventive measure cannot properly be based on a purely hypothetical approach to risk, founded on mere conjecture which has not been scientifically verified”**
(paragraph 156)

- **February 2000 Commission Communication on Precautionary Principle main points:**
 - ✓ **Confirms application in public health (food) area**

 - ✓ **Strict separation between risk assessment (on which basis precautionary measure must be taken) and risk management (political decision on how to respond to risk)**

- **Regulation 178/2002 laying down the general principles and requirements of food law:**
 - ✓ **Established European Food Safety Authority (EFSA) to carry out risk assessments independently of risk management decisions of Commission**

- **New risk management approach based on precautionary principle is key to regaining Public Confidence in food safety – 2 main elements:**
 - ✓ **Overriding need of Community to re-engage with public “civil society” after food crisis of 1990’s: BSE, dioxins in chicken, etc.**
 - ✓ **Lack of conclusive scientific evidence should never, in itself, be a barrier to adoption of restrictive measures.**

General objectives and principles

General Food Law

- In order to achieve the general objective of a high level of protection of human health, **EU feed/food legislation shall be based on *risk analysis*** (process consisting of three interconnected components: risk assessment-risk management-risk communication) except where this is not appropriate to the circumstances or the nature of the measure
- Risk assessment shall be based on the ***available scientific evidence*** and undertaken in an **independent, objective and transparent manner**

General objectives and principles

General Food Law

- The **risk management shall take into account the results of risk assessment, other factors legitimate** to the matter under consideration and the precautionary principle where appropriate
- The **precautionary principle**: where, following an assessment of available information, the **possibility of harmful effects** on health has been identified but **scientific uncertainty** persists, **provisional risk management measures** necessary to ensure the high level of health protection chosen in the EU may be adopted, **pending further scientific information for a more comprehensive risk assessment**

The Precautionary Principle in EU Food Law

- **Pre-market authorisation: proving that product is safe**
 - ✓ Directive 2002/46 on food supplements legislation
 - Regulation 2232/96 on flavourings
 - ✓ Regulation on addition of vitamins and minerals and other substances to foods (COD/2003/0262)
 - ✓ Regulation on nutrition and health claims made on food (COD/2003/165)
- **Safeguard clauses in majority of food legislation**
 - ✓ Case 236/01 *Monsanto v. Presidenza del Consiglio de Ministri* [2003] ECR I-8105: “... protective measures adopted under the safeguard clause [of the Novel Foods Regulation 258/98] may not properly be based on a purely hypothetical approach to risk, founded on mere suppositions which are not yet scientifically verified.” (paragraph 106)

What constitutes a valid risk assessment on which a food safety precautionary measure may properly be based?

✓ Case C-192/01 *Commission v. Kingdom of Denmark* : “a proper application of the precautionary principle presupposes ... a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research.” (paragraph 51)

Case C-24/00 *Commission v. French Republic*: “the French Republic may decide at what level it wishes to ensure the protection of human life and health” (paragraph 68) even if “there is no argument based on mainstream toxicology” suggesting a risk (paragraph 67)

Sufficiently specific: “it merely refers vaguely to the possibility of a general risk of excessive intake, without specifying the vitamins concerned, the extent to which limits would be exceeded or the risk raised thereby” (paragraph 61)

- ✓ **Case C-192/01 *Commission v. Kingdom of Denmark*: “The criteria of the nutritional need of the population of a Member State can play a role in its detailed assessment of the risk which the addition of nutrients to foodstuffs may pose for public health. However, the absence of such a need cannot, by itself, justify a [precautionary measure]” (paragraph 54)**
- ✓ **Food Supplements Directive 2002/46: “maximum vitamin and mineral levels established by scientific risk assessment ... taking into account ... as appropriate the varying degrees of sensitivity of different consumer groups.” (Article 5(1)(a))**

General objectives and principles

General Food Law

- An **open and transparent public consultation** must be ensured, directly or through representative bodies, during the preparation, evaluation and revision of food legislation, except where the urgency of the matter does not allow it
- **Food shall not be placed on the market if it is unsafe**
- **Traceability**

RASFF

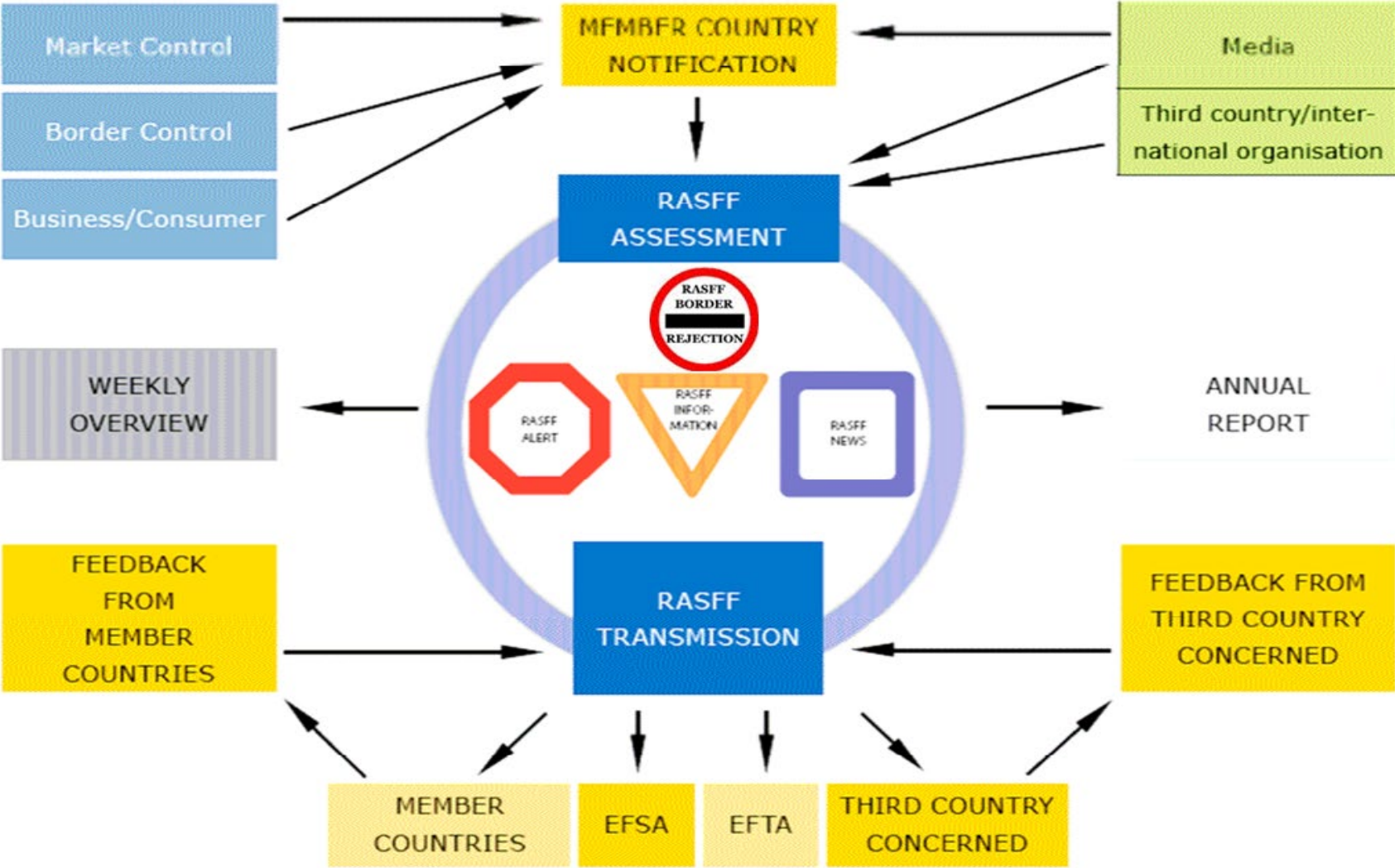
- **Rapid Alert System for Food and Feed (RASFF)**, plus **Food Contact Materials** (EC Reg. 178/02, Art. 50. EC Reg. 1935/04)

- **Alert procedure** includes the **Border Inspection Posts** network

- **Notifications** are weekly published **on the EC website**

- Non-food products alarms are circulated via the RAPEX system, provided by the *General Product Safety Directive*, 2001/95/CE

Rapid Alert System of Food & Feed (RASFF)



RASFF - *alert* notification, eg.

Date	Notified by:	Ref:	Reason for notifying:	Notification basis:	Status:
28/3/2008	Finland	2008.0363	ochratoxin A (9.7; 14; 25 µg/kg - ppb) in rye from Lithuania	border control – screening sample	distribution on the market / product returned to dispatcher
28/3/2008	Germany	2008.0369	Listeria monocytogenes in vacuum packed smoked trout fillets from Turkey, via the Netherlands	official control on the market	distribution on the market / public warning – press release
28/3/2008	Italy	2008.0370	Salmonella in kebab meat from Germany	official control on the market	distribution on the market / product detained

Council Regulation (EEC) 315/93

- Regulatory framework :

Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food

(this Regulation does not apply to contaminants which are the subject of more specific Community rules, such as pesticide residues, veterinary drug residues, ...)

Regulation (EEC) 315/93

Provisions

- General provision:
 - food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market
- Good practice:
 - contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)

Regulation (EEC) 315/93

Provisions

- When necessary for protecting public health maximum levels shall established for specific contaminants --> Procedure for setting maximum levels. This can also include a reference to the sampling and analysis methods to be used.
- Obligatory consultation of the European Food Safety Authority(EFSA) Panel on contaminants in the food chain before provisions having effect upon public health shall be adopted.

Contaminants regulated / to be regulated under 315/93 – Regulation (EC) 1881/2006

- **Nitrates**
- **Mycotoxins**: aflatoxins, ochratoxin A, patulin, Fusarium-toxins (zearalenone, fumonisins, trichothecenes: Deoxynivalenol, *T-2* and *HT-2* toxin), ergot alkaloids, ...
- **Heavy metals**: lead, cadmium, mercury, arsenic, methylmercury...
- **Other environmental contaminants**: dioxins, dioxin-like PCBs, PAH, non-dioxin-like PCBs, BFRs, PFOS, tributyltin (TBT), iodine,...
- **Processing/industrial contaminants**: 3-MCPD, inorganic tin, PAH, acrylamide, furan, ethylcarbamate
- **Inherent plant toxins**: pyrrolizidine alkaloids, hydrocyanic acid, solanine
...

Contaminants feed

Directive 2002/32/EC

- Regulatory framework for contaminants/undesirable substances in feed:
 - Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed

(this Directive does not apply to veterinary matters relating to public and animal health regulated by other Community rules)

Directive 2002/32/EC

Basic provision

- Products intended for animal feed may enter for use in the Community from third countries, be put into circulation and/or used in the Community **only if** they are sound, genuine and of merchantable quality and therefore when correctly used do not represent any danger to human health, animal health or to the environment or could adversely affect livestock production.
 - In particular products for animal feed not complying with the maximum levels established in Annex I are not “genuine, sound and of merchantable quality”

Directive 2002/32/EC Annex undesirable substances

- Ions and elements
 - arsenic, lead, fluorine, mercury, nitrites, cadmium
- mycotoxins
 - aflatoxin B1, rye ergot
- organic contaminants
 - dioxins, dioxin-like PCBs, organochlorine pesticides (aldrin, dieldrin, camphechlor, chlordane, DDT, endosulfan, endrin, heptachlor, HCB, HCH (alpha, beta and gamma isomers))

Directive 2002/32/EC Annex undesirable substances

- inherent plant toxins
 - hydrocyanic acid, free gossypol, theobromine, volatile mustard oil, vinyloxazolidine thione, ...
- botanical impurities
 - (*Lolium temulentum*, *Lolium remotum*) Datura stramonium, Castor oil plant, *Crotalaria* spp, (*apricots*, *bitter almond*,) unhusked beech mast, (*camelina*), mustard (Indian, Sareptian, Chinese, black, Ethiopian), (*Mowrah*, *Bassia*, *Madhuca*), purghera, croton

Risk management contaminants – food

- Scientific risk assessment:
 - assessment of the risks related to the presence of a contaminant in foodstuffs for human health / establishment of a tolerable intake / health based guidance value
 - exposure assessment: human exposure (average and 95 percentile)
Particular attention to vulnerable groups of population, high level consumers, ...
 - Risk characterisation: human exposure assessed in relation to the health based guidance value

--> is the basis for the measures to be taken

Risk management contaminants – food

- Determination of foods/food groups significantly contributing to the exposure
- Occurrence data of the contaminant in the various food/food groups
- Setting a maximum level following the ALARA principle (As Low As Reasonably Achievable - see before prevention versus regulation). The degree of severity of the application of this principle depends on the relation exposure - tolerable intake
- Other appropriate management tools

Risk management tools used for contaminants food

- **Maximum levels:** aflatoxins, ochratoxin A, lead, cadmium, 3-MCPD, nitrates, inorganic tin
- **Maximum levels with regional derogations:** dioxins and dioxin-like PCBs
- **Maximum levels combined with code of practice for prevention and reduction:** patulin, Fusarium-toxins
- **Comprehensive strategy (feed and food) comprising of a combination of maximum levels, action levels, target levels and source-directed measures:** dioxins and dioxin-like PCBs

Risk management tools used for contaminants food

- **Maximum levels with data collection:** PAH, dioxins
- **Maximum levels combined with dietary advice:** mercury
- **Code of practice:** ethylcarbamate
- **Dietary advice**
- **Data collection:** acrylamide, furan
- **Tools for reduction of presence:** acrylamide combined with monitoring to monitor effective implementation of tools

REGULATING CONTAMINANTS IN FEED: ISSUES TO BE CONSIDERED

- Contaminant: effect on public health, animal health, environment → determining the nature of the measure
- Sensitivity /tolerance towards a contaminant (animal health): species specific
- Carry over of contaminants of feed into food of animal origin: species specific
- Feed materials: non species specific
- Compound feed: species specific

REGULATING CONTAMINANTS IN FEED: ISSUES TO BE CONSIDERED

- Bio-availability of contaminant in a certain feed material or additive
- Achievability of certain levels under normal good practice production conditions
- Feed materials: can be by-products of food production, other production processes such as bio-energy...
- Proportion of use of a certain product for feed in comparison with the total production
- Feasibility to decontaminate at a reasonable cost

Recommendation

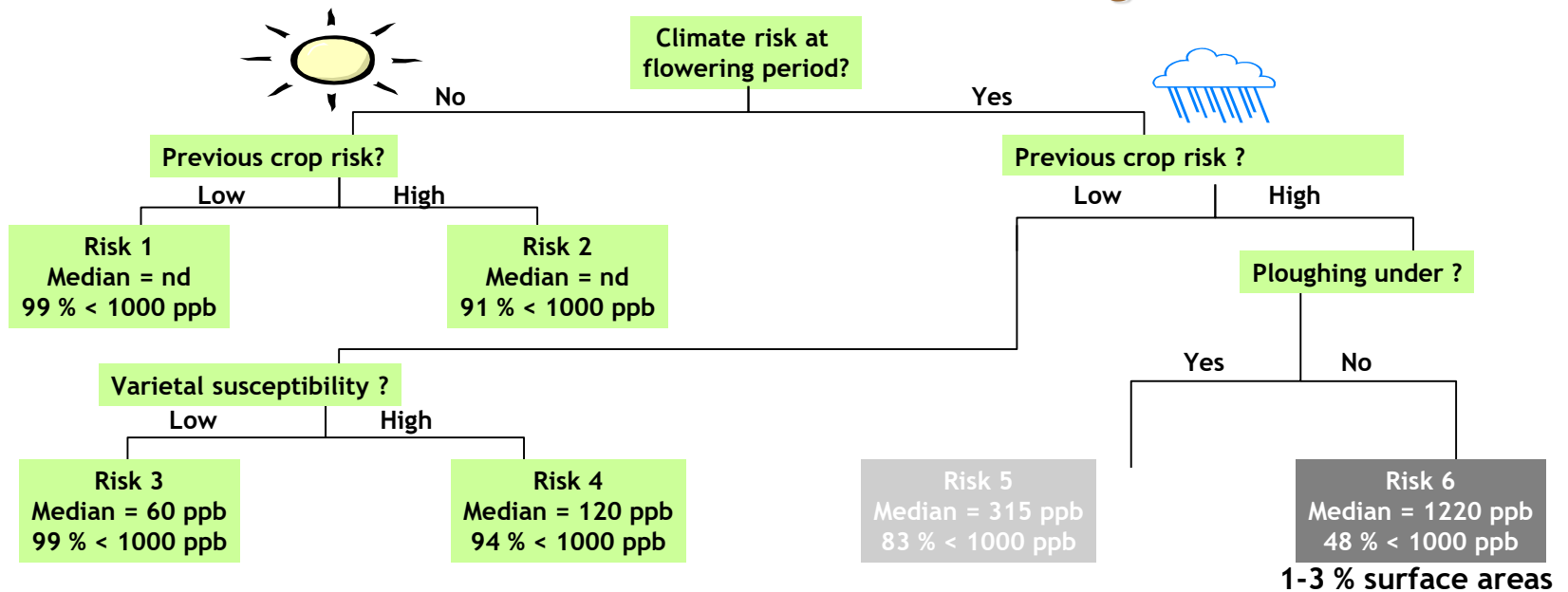
Prevention *Fusarium*-toxins

- Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of *Fusarium* – toxins in cereals and cereal products
 - Risk factors to be considered for inclusion in Good Agricultural Practices (GAP)
 - Contamination by *Fusarium*-toxins of cereals can be imputed to multiple factors
 - integrated approach addressing in a reasoned way all possible risk factors taking into account the local situation

MYCOTOXINS IN CEREALS

FEASIBILITY

Example of agro-climatic model to predict risk of DON contamination in soft wheat grain



MYCOTOXINS IN CEREALS

FEASIBILITY

- Presence of Fusarium-toxins
 - Large year to year variation
 - Management measures a relative (limited) impact on presence
- Presence of ochratoxin A and aflatoxins
 - Management measures (storage conditions) major impact on presence

REGULATING MYCOTOXINS IN FEED: considerations

- European Food Safety Authority (EFSA) opinions on deoxynivalenol (2 June 2004), zearalenone (28 July 2004), fumonisins (22 June 2005), ochratoxin A (22 September 2004)
- Scientific risk assessment concludes that the presence of deoxynivalenol, zearalenone fumonisins and ochratoxin A in animal feed can **endanger animal health and livestock performance** but is of **limited** (ochratoxin A) or **no** (deoxynivalenol, zearalenone and fumonisins) **significance for public health**

Mycotoxins – Feed

Recommendation 2006/576/EC

- Animal health effects critical effects – impact public health minor as carry-over from feed to food is limited
- **Two-step approach: Recommendation on increased monitoring combined with guidance/orientation values as first step – evaluation on achievement of objectives in 2 years time (2009) to consider possible further legal measures in the frame of Directive 2002/32/EC**

Mycotoxins – Feed Recommendation 2006/576/EC

- Cereals and cereal products include also cereal forages and roughages
- Guidance values to be applied to judge acceptability of compound feed and cereal and cereal products for animal feeding
- Guidance values to be used by feed business operators as guidance for the determination of critical limits in their HACCP system – attention for cereals and cereal products for the production of feed for sensitive animal species - guidance values for cereals and cereal products have been determined for the most tolerant animal species – “upper guidance values”

Driving forces for initiating new EC-legislation on contaminants

- **Contamination incidents with “new” (not yet regulated) contaminants:** melamine, mineral oil, ...
- **New (at EU level) risk assessments:** non-dioxin like PCBs, arsenic, ...
- **Updated risk assessments:** cadmium, PAH, mercury, ochratoxin A, lead, ...
- **Developments in risk assessment approaches**
 - **Risk-benefit assessment:** nitrates in vegetables
 - **Margin of Exposure (MOE):** genotoxic carcinogens such as aflatoxins, PAH

Driving forces for initiating new EC-legislation on contaminants

- **Emerging contaminants:** Brominated flame retardants (BFR), PFOS/PFOA, Alternaria toxins, 3-MCPD esters, enniatins, ...
- **Changing production conditions/ climate change:**
Fusarium toxins
- **International developments within the Codex Alimentarius :** lead in fish, aflatoxins, melamine (?), ...
- **Identified problems with current legislation:**
Fusarium toxins ...

T-2 and HT-2 Toxin

- Occurs in particular in oats but also in other cereals
- Correlation of the presence of T-2 and HT-2 toxin with the presence of other Fusarium-toxins
- Factors involved in the development of *Fusarium langsetii* and the formation of T-2 and HT-2 toxin
- Causes for the observed regional differences as regards the occurrence of T-2 and HT-2 toxin (not only climatic conditions)
- Current possibilities to mitigate the risk for presence of T-2 and HT-2 toxin in cereals // management measures to reduce/avoid presence of T-2 and HT-2 toxin

T-2 and HT-2 Toxin

- Fate of T-2 and HT-2 toxin during processing
- Levels of T-2 and HT-2 toxin in different cereal products (for human consumption and for feed)
- Analytical methods (screening)
- **EFSA opinion**
 - **Update toxicology**
 - **Updated exposure assessment // Call for data**
 - **Feed**

Standards and Conformity Assessment Bodies - EU

- **Health and Consumer Protection DG**
 - http://europa.eu.int/comm/dgs/health_consumer/index_en.htm
 - Takes care of public health, food safety, and consumer affairs issues
 - Contact point of European Commission to Codex and WTO/SPS

- **EFSA (European Food Safety Authority)**
 - www.efsa.eu.int
 - Provides scientific advice on food and feed safety - including animal health and welfare and plant protection - and provides scientific advice on nutrition in relation to Community legislation.

- **Environment DG**
 - www.eu.int/comm/environment/index_en.htm
 - Controls technical policy and regulations relating to environment, such as MEA's and Eco labeling.

- **Agriculture DG**
 - www.eu.int/comm/agriculture/index_en.htm
 - Controls food quality.

Standards and Conformity Assessment Bodies - EU

- **EA (European Cooperation for Accreditation)**
 - www.european-accreditation.org
 - The Members of EA are the nationally recognized accreditation bodies of the member countries or the candidate countries, of the European Union and EFTA.
- **EOTC (European Organization for Conformity Assessment)**
 - www.eotc.be
 - Established by the European Commission, the European Free Trade Association (EFTA) and the European Standards Bodies.
- **EUROLAB (European Federation of National Associations of Measurement, Testing and Analytical Laboratories)**
 - <http://141.63.4.16/>
 - Created on the basis of a memorandum of understanding, signed by delegations representing the private and public laboratories of 17 out of the 19 countries of the EEC and EFTA.
- **CEOC (European Confederation of Organizations for Testing, Inspection, Certification and Prevention)**
 - www.ceoc.com
 - Voluntary group of independent private, semi-private or governmental third party organizations, or associations of such organizations, for testing, technical inspection, certification of products and Quality Management Systems and risk prevention.

Standards and Conformity Assessment Bodies - EU

- **EurepGAP (Euro-Retailer Producer Working Group - Good Agricultural Practices)**
 - www.eurep.org
 - EurepGAP is a set of normative documents suitable to be accredited to internationally recognized certification criteria such as ISO Guide 65
- **ANEC (The European Consumer Voice in Standardization)**
 - www.anec.org
 - Contributes directly to the work of more than 60 technical committees, working groups and new deliverables of the European Standards Organizations (ESOs).
- **ECOS (European Environmental Citizens Organization for Standardization)**
 - www.ecostandard.org
 - A consortium of NGOs active in the field of environmental protection, created to enhance the voice of environment within the European standardization system.
 - Influences the content of the European standards established by CEN (European Committee for Standardization) and CENELEC
- **NORMAPME (The European Office of Crafts, Trades and SMEs for Standardization)**
 - www.normapme.com
 - To defend the interests of all European SMEs within the standardization system

CIAA Good Manufacturing Practices

- CIAA PRP-GMP - based on company experience and *Codex Alimentarius* - are **standardized** as **PAS 220** (Publicly Available Specification 220) from BSI (British Standards Institute) -> ISO recognition in progress

Example of single certification and audits related to food safety:

ISO 22000 System **certificate**



Confédération des industries agro-alimentaires de l'UE
Confederation of the food and drink industries of the EU

**iMP (Product/process
certificate for good practices)**