### WHAT WE HAVE LEARNT FROM

### CHEMICAL FOOD INCIDENTS?

REGIONAL SYMPOSIUM:
"FROM FOOD INCIDENTS TO CRISIS MANAGEMENT"

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### Some initial personal views:

- 1) Most historical chemical food incidents by which Germany was affected did not immediately threaten consumer's health; possible effects of long-term exposure could not always be excluded, but the incidents were quickly managed and terminated;
- 2) Problems with feeding stuffs were sometimes the cause; occasionally criminal energy was at least partly involved;
- 3) Management of several incidents required enormous logistic efforts on the side of the regulatory authorities;
- 4) Some incidents disrupted [international] trade and caused large economic losses;
- 5) When third countries were involved, some of those countries did not yet have implemented an operational modern food safety system.

## SUPPORTING EXAMPLES OF HISTORICAL CHEMICAL FOOD INCIDENTS

Nitrofen in eggs and in turkey meat

Nitrofurans in poultry and in products of aquaculture

**Chloramphenicol** in shrimps and other aquaculture products and in honey

Medroxy progesterone acetate in [feeding stuffs and] glucose syrup

### Nitrofen in eggs and in turkey meat

Incident/ triggering event	Baby food producer finds (self-checks) illegal residues in organically produced turkey meat. Residues were later also found in eggs.
Cause	Grains destined for feed were stored in a heavily nitrofen- contaminated facility where historically the meanwhile banned pesticide had been stored.
Major risk	Teratogenicity; lowest tested effective dose in rats: 1.39 mg/kg of body weight.
Toxicological data base	Incomplete and not meeting contemporary standards
Historical assessments	JMPR and IARC 1983
Worst case exposure scenario	A person of 60 kg body weight consumes 300 g of turkey meat containing 0.8 mg/kg of nitrofen, resulting in a dose of 0.004 mg/kg of body weight
Margin of exposure	< 350 compared to the teratogenic LOAEL in rats

# Nitrofurans in poultry and in products of aquaculture

Incident/ triggering event	Residues of nitrofurans, primarily metabolites were found in poultry and aquaculture products imported to the EU from third countries
Cause	The ban on use in food producing animals established in the EU was apparently not implemented/not successfully enforced in the countries of origin.
Major risk	Carcinogenicity caused by furazolidone; furazolidone is considered a genotoxic carcinogen; Chronic LOAEL in rodents 25-50 mg/kg of body weight/day.
Toxicological data base	Incomplete and not meeting contemporary standards
Historical assessments	IARC 1983, JECFA (furazolidone) 1992, EM[E]A 1993, 1995
Worst case exposure scenario	Residue concentrations were in the range of < 1 $\mu$ g/kg to >300 $\mu$ g/kg food stuff. Occasional exposure to approximately 1 $\mu$ g/kg of body weight of consumers seemed to be possible.
Margin of exposure	Not meaningful; rapid management of the incident; no chronic exposure of consumers.

# Chloramphenicol in shrimps and other aquaculture products and in honey

Incident/ triggering event	Residues of chloramphenicol were found in a variety of commodities including aquaculture products imported to the EU from third countries
Cause	The ban on use in food producing animals established in the EU was apparently not implemented/not successfully enforced in the countries of origin.
Major risks (discussed)	Aplastic anemia, genotoxicity, carcinogenicity
Toxicological data base	Incomplete, mainly lack of adequate studies on carcinogenicity, reproductive toxicity, foetotoxicity
Historical assessments	IARC 1990, JECFA 1987, 1994, 2004, EM[E]A 1995
Exposure scenario	Comparison with ocular bioavailability from eye drops approved for human uses: intake from seafood contaminated in the incident is << systemic bioavailability from typical eye drop treatment (see extra slides!)

# CHORAMPHENICOL: DIETARY INTAKE CONSIDERATIONS (I)

#### **HOW MUCH SEAFOOD DO PEOPLE EAT?**

- Seafood consumption rates of 202 first- and secondgeneration Asian American and Pacific Islanders from 10 ethnic groups (Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Mien, Samoan, and Vietnamese) in King County, Washington in 1997 were found in the literature.
- The 90<sup>th</sup> percentile of all consumption rates for "all seafood" consumption was 3.928 g/kg of body weight/day.

Sechena R, Liao S, Lorenzana R, Nakano C, Polissar N, and Fenske R (2003). Asian American and Pacific Islander seafood consumption – a community-based study in King County, Washington. J Expo Anal Environ Epidemiol. 13, 256–266.

# CHORAMPHENICOL: DIETARY INTAKE CONSIDERATIONS (II)

What would be the intake resulting from eating contaminated shrimps imported during the incident?

Using the estimate of seafood intake from previous slide and multiplying it with the median concentration of chloramphenicol found in the published alert information on this incident of the Food Standards Agency of Ireland (0.5 µg/kg) would result in an estimated daily intake of chloramphenicol of approximately 2 x 10 <sup>-9</sup> g chloramphenicol per kg of body weight or 0.12 ug for a person with a body weight of 60 kg. This estimate of intake could be slightly too low for a total intake estimate since other products of animal origin could also occasionally contain traces of chloramphenicol.

## OCULAR BIOAVAILABILITY OF CHLORAMPHENICOL FROM EYE DROPS I

-BASIC FACTS-

- Beasley et al. (1975) applied chloramphenicol 0.5% ophthalmic solution topically (1 drop) to patients at various times before cataract surgery. Aqueous humor obtained at the time of surgery contained 3.5 µg/mL to 6.7 µg/mL of intact chloramphenicol one to two hours following topical administration.
- [Aqueous humor is the watery fluid produced by the ciliary body that fills the space between the lens and cornea of the eye, serves as a nutrient delivery system for the avascular cells in the cornea and eventually drains into a vein or lymphatic vessel.]
- [The normal human aqueous humor production during daytime is 2.75  $\pm$  0.65  $\mu$ l/min (mean  $\pm$  s.d.), while at night production is approximately half of that amount.]
- [The volume of the anterior chamber is age-dependent. In 51 normal healthy subjects from two age groups (20 to 30 years, n = 51 and 60 years of age and older, n = 53) it was  $247\pm39~\mu$ L in the younger group and  $160\pm39~\mu$ L in the older group.]

## OCULAR BIOAVAILABILITY OF CHLORAMPHENICOL FROM EYE DROPS II

- Using these figures one can obtain a lower estimate of the fraction of the bioavailable dose absorbed through the cornea per application of one drop as 0.6 to 1.6 µg or 2.4 to 6.4 µg per day (assuming four daily doses) during a treatment period. This figure does not include the (probably higher) absorption occurring at the other possible sites\*.
- This lower estimate of systemic absorption of chloramphenicol from eye drops is up to 50 times higher than the intake estimate from seafood and is about in the same order of magnitude as the occasional intake corresponding to the highest contaminated seafood sample found in 2002.

\*the tear fluid is rapidly drained from the lower conjunctival sac through the puncta and the lachrymal duct into the lachrymal sac from where it passes through the nasolachrymal duct into the inferior nasal meatus. From there the fluid moves to the nasopharynx where it swallowed into the gastrointestinal tract.

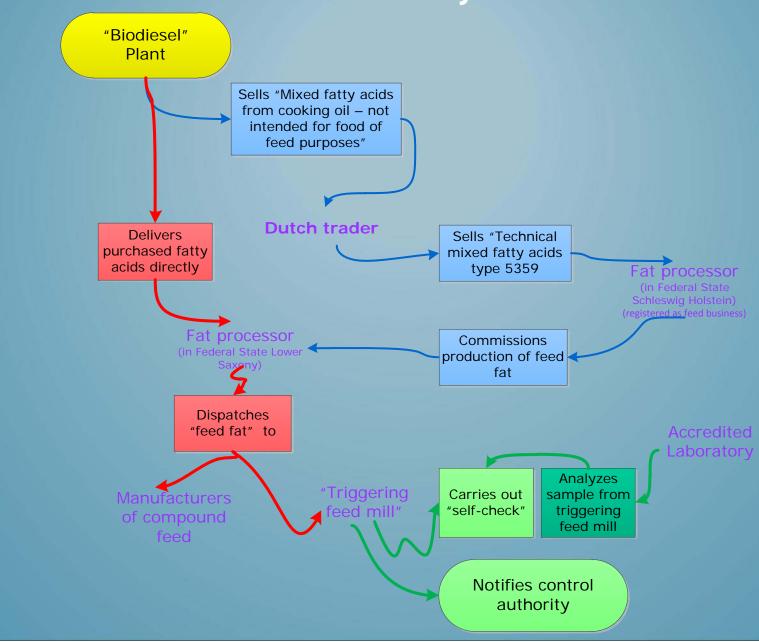
## Medroxy progesterone acetate in glucose syrup

Incident/ triggering event	Dutch authorities informed over the RASFF of the EU about fertility problems in sows fed on MPA contaminated feed; residues were later found in animals an meat imported to Germany
Cause	A glucose syrup containing 0.35 – 0.52 mg MPA/kg. The syrup was also used to a limited extent for the preparation of drinks.
Major risks	Hormonal actions
Data base	The no hormonal effect level in women is <b>not precisely known</b> . The NOEL derived from animal test systems (0.03 mg/kg/day] is in the order of the therapeutic dose (2.5 mg/person/day) used (at that time) in post-menopausal women.
Historical assessments	EM[E]A 1996
Exposure scenario	Intake from 300g muscle and 50g fat from contaminated animals would not exceed 0.65 to 2.8 µg/person/day; Consumption of 30g syrup in a soft drink would result in an intake of up to 0.016 mg/person and could range close to the unknown hormonal NEL in post-menopausal women.

## DETAILS OF A MOST RECENT CHEMICAL FOOD INCIDENT IN GERMANY

Dioxins in feed fat

# The 2010/2011 dioxin incident in feed fat in Germany



The Case was in fact even more complicated since some parties involved did not disclose in time the full information to the control authorities and even wrong farm distribution lists had been provided by a feed mill.

**Eight consignments** of technical mixed fatty acids were used in the manufacture of approximately 2,250 tons of vegetable feed fat. This was sent to 25 compound feed manufacturers in Germany. No deliveries of the contaminated feed fat were made to other Member States, or to third countries. ☐ The potentially contaminated fat of the 25 feed mills in Germany has been dispatched to nearly 5,000 farms; □ Nearly 44,000 deliveries of compound feed had to be examined in order to establish which farms had to be temporarily blocked by the authorities; ☐The analytical results of mixed fatty acids at the fat processor in Schleswig-Holstein showed a pattern of contamination which concerned, almost exclusively, dioxins, i.e. there was very little contamination with polychlorinated biphenyls (PCBs); □China and South Korea banned imports of German eggs and chicken and pork meat and products;

The *full description* of the incident can be found in <u>FVO report</u> DG(SANCO) 2011-6219 - MR FINAL: http://ec.europa.eu/food/food/chemicalsafety/contaminants/final report fvo mission en.pdf

#### **German Ten Points Action Plan**

developed in reaction to this incident (I)

- (1) Requirement for mandatory approval of feed producers [under Regulation 183/2005/EC].
- (2) Separation of production flows for feed and food fats and oils and for technical products [nationally and at EU level].
- (3) Expansion of legal feed control requirements [Stipulated analyses by business operators for contaminants and provision of the results to the control authorities].
- (4) Duty of private laboratories to report to the authorities of non-compliant samples [nationally and at EU level].
- (5) A binding positive list of feedstuffs. [Germany already has such an exclusive positive list of feed materials and is seeking to have a mandatory list also for the EU].
- (6) Coverage of the risk of liability [Study on costs of the incident and on feasibility is ongoing in Germany]

#### **German Ten Points Action Plan**

resulting from incident (II)

- (7) Revision of the system of penalties [draft currently in the legislative process in Germany]
- (8) Expansion of dioxin monitoring establishment of an early-warning system [Monitoring is to be performed by both the feed industry and enforcement/control offices. Draft currently in the legislative process in Germany].
- (9) Improvement of the quality of food and feed controls and inspections [working group of the federal states is working on a proposal for Germany].
- (10) Transparency for consumers [The German Government wants to provide more information to consumers on future feed and food incidents. This might involve names of companies and products concerned. Draft amendment to the Consumer Information Act under preparation for submission to the cabinet of ministers]

Source: A situation report of the federal government of 21 January 2011

### Some interim personal views:

- 1) In view of
- ✓ the significance of safe food for the quality of human lives,
- ✓ the possible hazards to human health caused by unsafe food,
- ✓ and the enormous economic losses generated if production and trade is temporarily blocked, countries need regulatory system minimizing the frequency of occurrence, the severity and duration of chemical food incidents;
- 2) All countries participating in international trade should implement equivalent legislation, controls, early warning and incident/crisis management systems;
- 3) Countries not doing so or being still on the way to reach such goals may be required to provide case by case specific guarantees.

### Selected Criteria for a Modern Basic Food Law (I)

- Food includes drinking water and feed includes water for animal nutrition;
   basic requirements for water quality and safety are laid down in the basic food law;
- 2) Basic food law takes into account that food of animal origin can only be obtained from **healthy animals** safe food and feed of plant origin can only be obtained from **intact environment**, **particularly from intact soil**;
- Basic food law includes basic provisions on feeding stuffs including production, manufacture, transport and distribution, as well as the requirement that specific legislation shall regulate animal nutrition and health, soil and water protection and use of fertilizers and pesticides.
- 4) The objectives of the basic food law are: Protection of human health and protection of consumers' interests and facilitating fair trade. It should not discriminate between imported, domestically produced and processed and consumed food and food destined for export. Domestically produced as well as imported or exported food and feed must all comply with the same requirements.

### Selected Criteria for a Modern Basic Food Law (II)

- 5) The basic food law obliges national authorities to preferably use internationally elaborated food/feed standards and to promote the development of international technical standards for food and feed;
- 6) The provisions of the basic food are based predominantly on **risk analysis paradigm** including **functional separation of risk assessment and risk management functions**; it may lay down conditions for the application of the **precautionary principle**.
- 7) Business operators at all stages of the food production/distribution chain must ensure that food and feed satisfies the requirements of food law. Food/feed business must be registered or under certain conditions be approved.
- 8) Operators are obliged to immediately undertake steps to eliminate or reduce the risks including withdrawal of unsafe and non-compliant products from the market. Operators and the competent authorities have to inform/warn consumers.
- 9) The **forward and backward traceability** of food and feed and all substances incorporated into food or feed must be established by operators at all stages of production, processing and distribution.
- **10)** The competent authority is empowered to suspend the marketing or the importation of food/feed constituting a serious risk to human or animal health and to impose the adoption of appropriate interim measures.

### Selected Criteria for a Modern Basic Food Law (III)

- 11) The basic food law should lay down that all food/feed business is to be adequately inspected an should foresee appropriate measures and penalties for infringements. All parts of the food production chain and their products must be subject to official controls.
- 12) A rapid alert network covering all food and feed is established enabling exchange of information on food or feed related risks and on any measures aimed at restricting marketing or forcing withdrawal or recall of unsafe food or feed, any rejection of batches or consignments at a border post.
- Basic food law obliges the Authority to draw up a general plan for crisis management setting out the practical procedures necessary for managing a crisis including setting up a crisis unit or team, which is responsible for collecting and evaluating all relevant information and identifying the available options for preventing, eliminating or reducing the risk to human health.
- 14) Basic food law obliges the Authority to search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields of food and feed with a view to counteract to emerging risks.
- 15) A **Regulatory Committee** is established to deal with and provide the Authority with advice on all the relevant matters related to the food law, safety of food from primary production along the whole chain to the consumers table, and on controls and import conditions.

### What means "[from] farm to table approach"?

It is a holistic approach to covering **coherently** all sectors of the food chain, including feed production, primary production, food processing, handling storage, transport and distribution in the regulatory system.

Its fundament is ensuring a high level of protection of human health and, taking into account as well animal health and welfare, plant health and the environment.

Its consequence for legislation is to create a coherent systems of basic food law and implementing laws and regulations covering all aspects of the highly complex food chains and eliminate the historical fragmentation/segmentation and sectoral approach.

It has also consequences for the organization of institutions. Food safety needs to be organized preferably in a minimum number of integrated and powerful authorities – with appropriate separation of certain functions according to the risk analysis paradigm - which are effectively co-ordinated.

# The Rapid Alert System for Food and Feed (RASFF) of the European Union

- ✓ The RASFF is a tool to exchange structured information between food and feed control authorities about measures taken in response to the detection of serious hazards in food or feed;
- ✓ It consists of a *network of contact points* in the European Commission (manager of the system), the European Food Safety Authority, the EU Member States, Iceland, Liechtenstein, and Norway;
- ✓ The legal basis for its operation is the Article 50 of the Regulation (EC) N° 178/2002 (the "basic food law" of the EU);
- ✓ Members report to the Commission which *assesses/evaluates*, *classifies and transmits* the information to the network;
- ✓ RASFF cooperates with the International Food Safety Authorities Network (INFOSAN).
- ✓ Nearly 60% of all notifications of the last decade were contributed by Italy, Germany, the UK, and Spain.

### Types of notifications in the RASFF of the EU

Several types of notifications have evolved over the years and are sent under the following conditions:

#### **Alert notifications**

A food or a feed presenting a serious risk is on the market and/or rapid action is required.

## Information notifications n identified risk does not requi

An identified risk does not require rapid action (e.g., because all necessary measures have been taken by the notifying member).

## Border rejection notifications

A food or a feed that was refused entry into the Community for reason of a risk to human or animal health.

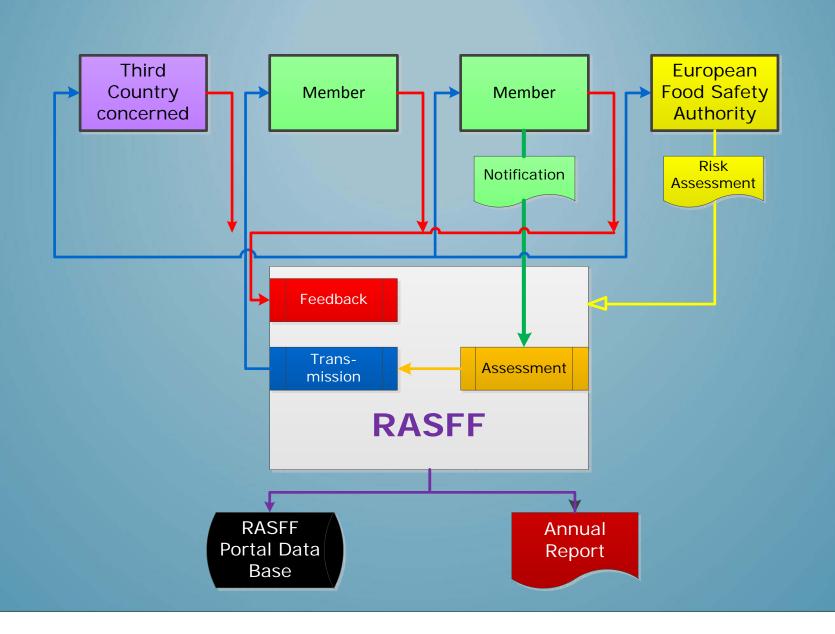
#### News notifications

Food/feed safety information not related to the three other categories is judged interesting for the control authorities in the Member States.

Notifications may be "original" (not previously notified) or "follow up" to an original notification. Most notifications result from border rejection followed by market control.

### Typical flow of information

in the Rapid Alert System for Food and Feed (RASFF)



#### A few selected results from annual reports 2002-2009

- Numbers in the tables in the annual reports cannot be directly quantitatively compared because they are not representative
- Certain illegal residues of veterinary drugs and pesticides, mycotoxins, polycyclic aromatic hydrocarbons, heavy metals, dioxins and marine biotoxins were notified in 2002, 2003 and 2004.
- For example, in 2003, the RASFF received notifications on:

Aflatoxins in pistachios, peanuts and hazelnuts;

**Dioxins** originating from feeding stuffs;

Polycyclic aromatic hydrocarbons and benzo(a)pyrene in smoked fish;

3-monoclor-1,2-propanediol in soy sauce;

Cadmium and mercury in swordfish and cephalopods;

Antimicrobial substances in honey and milk,

**Chloramphenical** in shrimps and in casings;

Nitrofurans [metabolites] in fishery products, poultry meat and meat products;

Coccidiostats in eggs and egg products;

Malachite green in salmon;

**Sudan 1** in hot chilli powder, spice mixes, sauces and products containing spices and sauces;

Dioxins and PCBs and chloramphenical in feeding stuffs.

### Selected results from annual reports 2002-2009 II

- The occurrence of *illegal Sudan dyes* was thoroughly investigated in 2004. Such dyes were found in chilli or curry powder and sauces or processed products containing chilli or curry, in sumac and curcuma (mainly Sudan I and with lower frequency Sudan IV) and in red palm oil (primarily Sudan IV).
- A serious dioxin contamination incident occurred in the autumn of 2004. The ultimate source was a kaolinitic clay used for increasing the water density for the separation of potatoes of different quality by flotation. The dioxins in these clays were formed through a natural process over a period of millions of years.
- In 2005 notifications on mycotoxins now also included ochratoxin A in dried fruits and vegetables, herbs and spices, and in coffee, Patulin in fruit juices and baby foods, and fumonisins in cereal products.
- Notifications on illegal dyes continued. In addition to the Sudan dyes other dyes, primarily Para Red were found.
- Most of the topics of earlier years recurred in 2006 and later.
- The notifications on FAH in fishery products (smoked sprats in vegetable oil) rose in 2006. Also notifications on mercury in fishery products (swordfish, shark and tuna) increased.
- Mycotoxins other than aflatoxins now also included deoxynivalenol and zearalenone in cereals.
- A lot of reports were made about **melamine** in pet food.

### Selected results from annual reports 2002-2009 III

- A specific incident was the finding of very high levels dioxins and pentachlorphenol
  in guar gum from India processed in Switzerland. The causes could not be
  identified.
- In 2008, as in the previous years, mycotoxins were the hazard category with the highest notification rate. There were increases in the groups of nuts, nut products and seeds, as well as fruits and vegetables and cereals and (on a lower scale) for feed for food producing animals.
- Notifications about pesticide residues which had almost doubled the year before remained at high levels.
- In 2009, the number of notifications on aflatoxin has decreased, except for animal feed.
- Cadmium and mercury were predominantly reported in fish and fishery products. The trends seemed to be increasing.

# Consequences of RASFF notifications and reports of the FVO

Increased levels of control in cases of known or emerging risks of food and feed of non-animal origin imported from third countries through designated points of entry.

- Minimum requirements for designated points of entry;
- Common Entry Document in the official language of the state of the point of entry;
- Prior notification of consignments;
- Increased frequency of checks;
- Documentary, identity and physical checks including laboratory analysis;
- **Release** only after favorable results.

COMMISSION REGULATION (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC – consolidated text of 01 April 2011 with all amendments. URL: <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2009R0669:20110401:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2009R0669:20110401:EN:PDF</a>

## Example (detailed)

Feed and Food (intended use)	CN code	Country of origin	Hazard	Frequency of physical and identity checks (%)
<ul> <li>Groundnuts</li> <li>(peanuts), in shell</li> <li>Groundnuts</li> <li>(peanuts), shelled</li> <li>Peanut butter</li> <li>Groundnuts</li> <li>(peanuts), otherwise</li> <li>prepared or preserved</li> </ul>	— 2008 11 10 — 1202 10 90 — 1202 20 00 — 2008 11 91; 2008 11 96; 2008 11 98	Argentina	Aflatoxins	10

## More examples (simplified)

Food/feed	Country of origin	Hazard	Frequency of checks
Groundnuts	Brazil	Aflatoxins	10
Dried noodles	China	Aluminum	10
Yardlong beans Bitter melon Lauki Peppers Aubergines	Dominican Republic	Pesticide residues analysed with multi-residue methods based on	50
Oranges, fresh or dried Peaches Pomegranates Strawberries Green beans	Egypt	GC-MS and LC- MS or with single residue methods	10
Groundnuts	Ghana	Aflatoxins	50
Curry leaves	India	Pesticide residues analysed with multi-residue methods based on GC-MS and LC- MS or with single residue methods	10
Chilli	India	Aflatoxins	50

#### What is a food incident?

The Food Standards Agency of the United Kingdom uses the following definition of an incident:

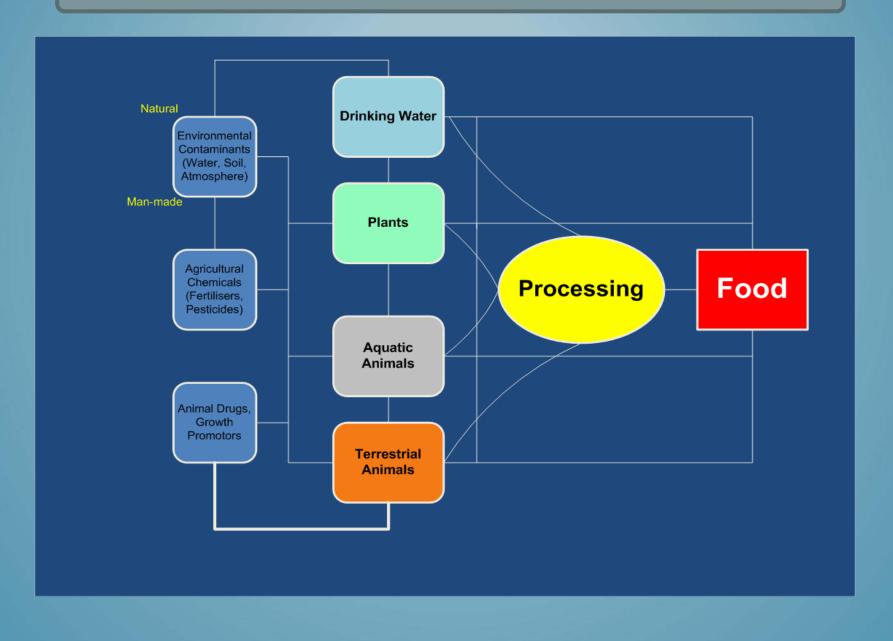
'Any event where, based on the information available, there are concerns about actual or suspected threats to the safety or quality of food that could require intervention to protect consumers' interests.'

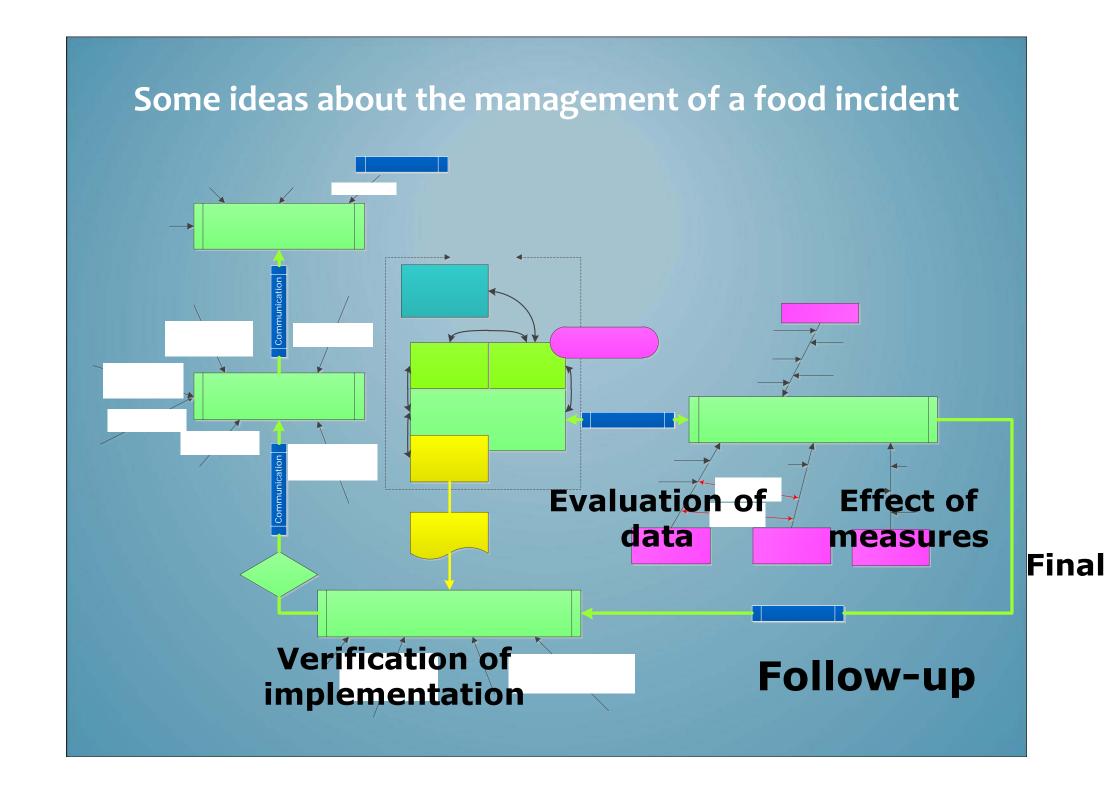
Incidents fall broadly into two categories:

olncidents involving contamination of food or animal feed in processing, distribution, retail and catering. These incidents may result in action to withdraw the food from sale and, in certain circumstances, to recall it, alerting the public not to consume potentially contaminated food. oEnvironmental pollution incidents such as fires, chemical/oil spills and radiation leaks, which may involve voluntary or statutory action ...

Source: Food Standards Agency (UK): <a href="http://www.food.gov.uk/foodindustry/incidents/">http://www.food.gov.uk/foodindustry/incidents/</a>

#### **Chemical Hazards in Food**





# EU Reference Laboratories (RLs) dealing with chemical hazards in Food and Feed

#### EU reference laboratory for ...

- 3. ... the monitoring of **marine biotoxins**;
- 12. ... residues of veterinary medicines and contaminants in food of animal origin;
- 14. ... additives for use in animal nutrition;
- 16. ... material intended to come into **contact** with foodstuffs;
- 17. ... residues of pesticides;
- 18. ... heavy metals in feed and food;
- 19. ... **mycotoxins**;
- 20. ... polycyclic aromatic hydrocarbons (PAH);
- 21. ... dioxins and PCBs in feed and food

Existing EU-RLs are listed in Annex VII to Regulation (EC) No 882/2004 (numbering as in the Annex VII, the other RLs are dealing with biological hazards)

# Responsibilities of EU Reference Laboratories for Food and Feed

- (a) **Providing** national reference laboratories with details of **analytical methods**, including reference methods;
- (b) **Coordinating application** by the national reference laboratories of the methods referred to in (a), in particular by **organizing comparative testing** and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;
- (c) Coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;
- (d) **Conducting** initial and further **training courses** for the benefit of staff from national reference laboratories and of experts from developing countries;
- (e) **Providing scientific and technical assistance** to the Commission, especially in cases where Member States contest the results of analyses;
- (f) Collaborating with laboratories responsible for analyzing feed and food in third countries.

Source: Article 32 (1) of REGULATION (EC) No 882/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (Last amendment: Commission Regulation (EU) No 208/2011 of 2 March 2011

## SPECIFIC WEAKNESSES OF CERTAIN TYPES OF SYSTEMS

Federal Systems and division of powers between federation and federal states, Example Germany;

Centralized systems with fragmented powers, Example Kuwait

## DIVISION OF AUTHORITY BETWEEN THE FEDERATION AND THE "LÄNDER" IN GERMANY

#### From the constitution:

#### Article 30:

Except as otherwise provided ..., the exercise of state powers and the discharge of state functions is a matter for the Länder.

#### Article 83:

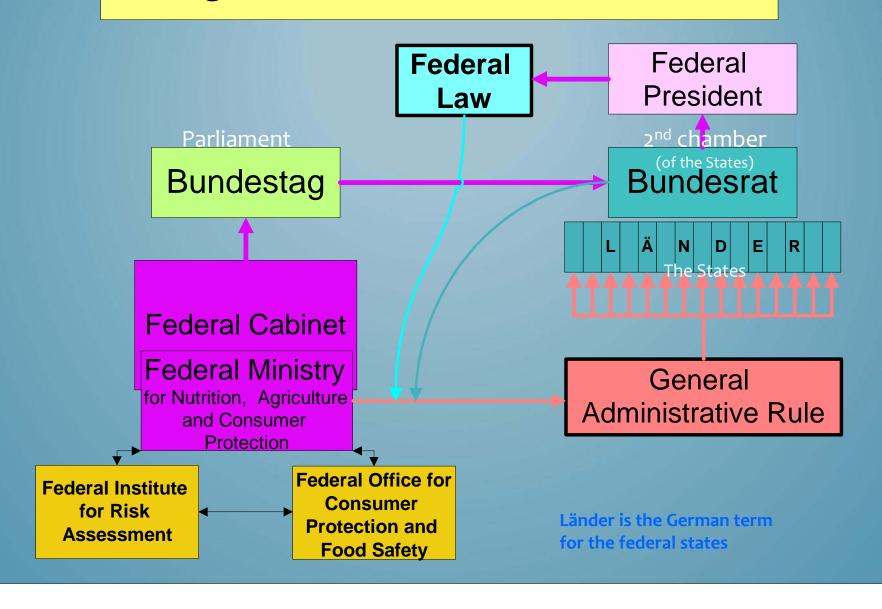
The Länder shall execute federal laws in their own right insofar as this Basic Law does not otherwise provide or permit.

#### From Article 84:

- (2) The Federal Government, with the consent of the Bundesrat, may issue general administrative rules.
- (3) The Federal Government shall exercise oversight to ensure that the Länder execute federal laws in accordance with the law...

#### **LEGISLATION AND CONTROL IN GERMANY**

#### **Legislation and Uniform Execution**



### FEDERAL INSTITUTE FOR RISK ASSESSMENT

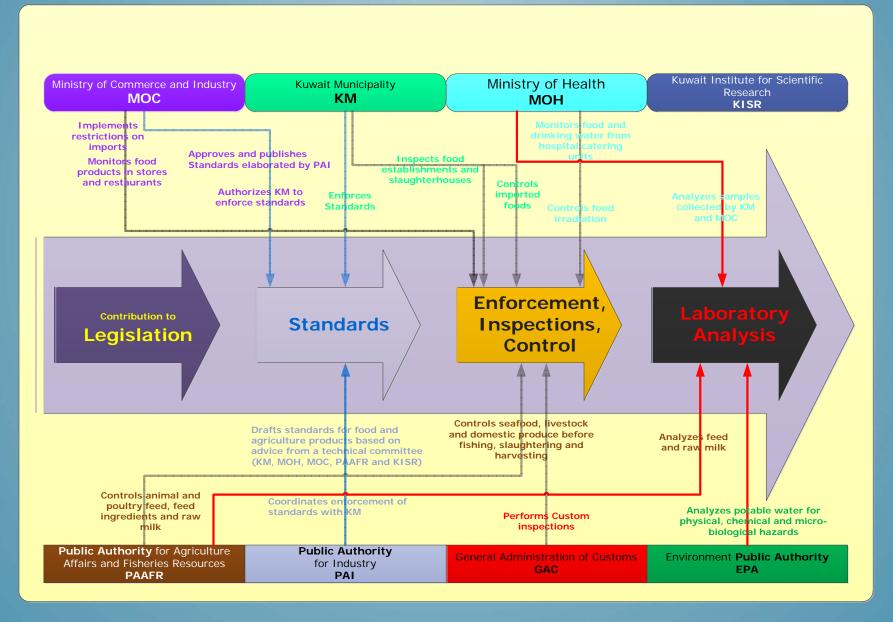
- It is the scientific risk assessment body of the Federal Republic of Germany.
- It provides scientific opinions and expert reports on questions directly or indirectly related to food safety and consumer health protection using internationally recognized methodologies.
- It particularly advices the competent Federal Ministries and the Federal Office for Consumer Protection and Food Safety.

# FEDERAL OFFICE OF CONSUMER PROTECTION AND FOOD SAFETY

#### The Office has and/or supports risk management functions, such as:

- Operation of the early warning system of hazardous foods and feeding stuffs;
- Crisis management;
- Co-ordination of national food contamination monitoring and residue control;
- Co-operation with the Food and Veterinary Office of the European Commission;
- Support to the "Länder" in their surveillance activities of foods, feeding stuffs, cosmetics, tobacco products, and other consumer products.
- Marketing authorization of pesticides;
- Marketing authorization and pharmaco-vigilance of veterinary drugs.
- Etc.

#### Kuwait: An example of segmentation in a small state



Information used for the preparation of this chart: Alomirah et al., Assessment of the Food Control System in Kuwait, Food Control 21 (2010), 496-504.

#### Blocks of Functions of a "Generic" Food Safety Authority

**Providing Scientific Advice**  Head of the **Authority** 

> Quality Manager

**Providing Advice** on Regulatory **Matters** 

Forum for discussions with NGO's

Administration and Communication

Risk assessment and Scientific Support

Coordinating scientific disciplines and research functions Risk Management (Legislation and Control)

Managing all risks related to food and

Planning and performing risk based inspections and controls

**Providing Testing** Laboratory **Services** 

Laboratory Services

Providina administrative services

Planning and

auditing

Legal affairs

Providing communication, promoting awareness

Concepts for education and creation of awareness

Drafting

Developing

training concepts

and programmes

IT services

responses to enquiries and complaints Human resources

Finances and budget

Organisation

Facility management

Hosting the fundamental disciplines of risk assessment

Supporting experimental research

Biological hazards

Nutrition

Pharmacology/ toxicology

Molecular Biology

Epidemiology and statistics

Exposure assessments

Scientific data bases

Supporting quality assurance

Applying physical/ chemical methods to research

biological

questions

Providing/

improving laboratory

support

Experimental solutions to

Developing and implementing

risk based

registration

systems

Developing and implementing standards and specifications

SPS, TBT

Legal limits

feed uses

Contact/enquiry Food and feed points for Codex including addtives and food contact material

Food and feed business

Fertilizers, pesticides, nnimal drugs

Planning and evaluating inspections and controls

Controlling products and inspecting business

Primary

Monitoring and control programs

Inspections and

Product specifications

Methods of sampling

Methods of Analysis

Providing control laboratory functions

Providina reference functions for control laboratories

production

Processing and enforcement distribution

Special and ad Imports and hoc programs exports

Data bases

