WHAT WE HAVE LEARNT FROM CHEMICAL FOOD INCIDENTS?

REGIONAL SYMPOSIUM: “FROM FOOD INCIDENTS TO CRISIS MANAGEMENT”

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Hong Kong, 1-2 June, 2011
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

<table>
<thead>
<tr>
<th>Incident/triggering event</th>
<th>Baby food producer finds (self-checks) illegal residues in organically produced turkey meat. Residues were later also found in eggs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cause</td>
<td>Grains destined for feed were stored in a heavily nitrofen-contaminated facility where historically the meanwhile banned pesticide had been stored.</td>
</tr>
<tr>
<td>Major risk</td>
<td>Teratogenicity; lowest tested effective dose in rats: 1.39 mg/kg of body weight.</td>
</tr>
<tr>
<td>Toxicological data base</td>
<td>Incomplete and not meeting contemporary standards</td>
</tr>
<tr>
<td>Historical assessments</td>
<td>JMPR and IARC 1983</td>
</tr>
<tr>
<td>Worst case exposure scenario</td>
<td>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</td>
</tr>
<tr>
<td>Margin of exposure</td>
<td>&lt; 350 compared to the teratogenic LOAEL in rats</td>
</tr>
</tbody>
</table>
Nitrofurans in poultry and in products of aquaculture

<table>
<thead>
<tr>
<th>Incident/triggering event</th>
<th>Residues of nitrofurans, primarily metabolites were found in poultry and aquaculture products imported to the EU from third countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cause</td>
<td>The ban on use in food producing animals established in the EU was apparently not implemented/not successfully enforced in the countries of origin.</td>
</tr>
<tr>
<td>Major risk</td>
<td>Carcinogenicity caused by furazolidone; furazolidone is considered a genotoxic carcinogen; Chronic LOAEL in rodents 25-50 mg/kg of body weight/day.</td>
</tr>
<tr>
<td>Toxicological data base</td>
<td>Incomplete and not meeting contemporary standards</td>
</tr>
<tr>
<td>Worst case exposure scenario</td>
<td>Residue concentrations were in the range of &lt; 1 μg/kg to &gt;300 μg/kg food stuff. Occasional exposure to approximately 1 μg/kg of body weight of consumers seemed to be possible.</td>
</tr>
<tr>
<td>Margin of exposure</td>
<td>Not meaningful; rapid management of the incident; no chronic exposure of consumers.</td>
</tr>
</tbody>
</table>
### Chloramphenicol in shrimps and other aquaculture products and in honey

<table>
<thead>
<tr>
<th>Incident/triggering event</th>
<th>Residues of chloramphenicol were found in a variety of commodities including aquaculture products imported to the EU from third countries</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cause</strong></td>
<td>The ban on use in food producing animals established in the EU was apparently not implemented/not successfully enforced in the countries of origin.</td>
</tr>
<tr>
<td><strong>Major risks (discussed)</strong></td>
<td>Aplastic anemia, genotoxicity, carcinogenicity</td>
</tr>
<tr>
<td><strong>Toxicological data base</strong></td>
<td>Incomplete, mainly lack of adequate studies on carcinogenicity, reproductive toxicity, foetotoxicity</td>
</tr>
<tr>
<td><strong>Exposure scenario</strong></td>
<td>Comparison with ocular bioavailability from eye drops approved for human uses: intake from seafood contaminated in the incident is &lt;&lt; systemic bioavailability from typical eye drop treatment (see extra slides!)</td>
</tr>
</tbody>
</table>
HOW MUCH SEAFOOD DO PEOPLE EAT?

- Seafood consumption rates of 202 first- and second-generation 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 90th percentile of all consumption rates for “all seafood” consumption was 3.928 g/kg of body weight/day.

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 $2 \times 10^{-9}$ g chloramphenicol per kg of body weight or **0.12 µg 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 ± 0.65 µl/min (mean ± 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±39 µL in the younger group and 160±39 µL in the older group.]
• 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.

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*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

<table>
<thead>
<tr>
<th>Incident/triggering event</th>
<th>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 and meat imported to Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cause</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Major risks</strong></td>
<td>Hormonal actions</td>
</tr>
<tr>
<td><strong>Data base</strong></td>
<td>The no hormonal effect level in women is <em>not precisely known</em>. 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.</td>
</tr>
<tr>
<td><strong>Historical assessments</strong></td>
<td>EM[E]A 1996</td>
</tr>
<tr>
<td><strong>Exposure scenario</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
DETAILS OF A MOST RECENT CHEMICAL FOOD INCIDENT IN GERMANY

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

"Biodiesel" Plant

Sells "Mixed fatty acids from cooking oil – not intended for food of feed purposes"

Dutch trader

Fat processor (in Federal State Lower Saxony)

Sells "Technical mixed fatty acids type 5359"

Commissions production of feed fat

Manufacturers of compound feed

Dispatches "feed fat" to

"Triggering feed mill"

Carries out "self-check"

Analyzes sample from triggering feed mill

Accredited Laboratory

Notifies control authority

Fat processor (in Federal State Schleswig Holstein) (registered as feed business)

Delivers purchased fatty acids directly

Sells "Technical mixed fatty acids type 5359"
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 poly-chlorinated biphenyls (PCBs)**;
- China and South Korea banned imports of German eggs and chicken and pork meat and products;

German Ten Points Action Plan
developed in reaction to this incident (1)

(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)

1) 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*;

3) 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.
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* and 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.

13) *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**
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-monochlor-1,2-propanediol** in soy sauce;
  - **Cadmium and mercury** in swordfish and cephalopods;
  - **Antimicrobial substances** in honey and milk,
  - **Chloramphenicol** 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 chloramphenicol** 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 *PAH* 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 of **dioxins and pentachlorophenol 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.

Example (detailed)

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

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

- Incidents 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.
- Environmental pollution incidents such as fires, chemical/oil spills and radiation leaks, which may involve voluntary or statutory action ...
Chemical Hazards in Food

Natural
- Environmental Contaminants (Water, Soil, Atmosphere)

Man-made
- Agricultural Chemicals (Fertilisers, Pesticides)
- Animal Drugs, Growth Promoters

Processing
- Drinking Water
- Plants
- Aquatic Animals
- Terrestrial Animals

Food
Some ideas about the management of a food incident
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*.

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 President**
- **Federal Cabinet**
- **Bundestag**
- **Federal Ministry for Nutrition, Agriculture and Consumer Protection**
- **Federal Institute for Risk Assessment**
- **Federal Office for Consumer Protection and Food Safety**

**Parliament**

**Bundesrat**

**General Administrative Rule**

Länder is the German term for the federal states.
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 advises the competent Federal Ministries and the Federal Office for 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

Ministry of Commerce and Industry (MOC)
- Implements restrictions on imports
- Monitors food products in stores and restaurants

Kuwait Municipality (KM)
- Approves and publishes Standards elaborated by PAI
- Authorizes KM to enforce standards
- Inspects food establishments and slaughterhouses
- Enforces Standards

Ministry of Health (MOH)
- Monitors food and drinking water from hospitals, catering units
- Controls imported foods
- Controls food irradiation

Kuwait Institute for Scientific Research (KISR)
- Analyzes samples collected by KM and MOC

Public Authority for Agriculture Affairs and Fisheries Resources (PAAFR)
- Controls animal and poultry feed, feed ingredients and raw milk

Public Authority for Industry (PAI)
- Coordinates enforcement of standards with KM

Environment Public Authority (EPA)
- Analyzes potable water for physical, chemical and microbiological hazards

General Administration of Customs (GAC)
- Performs Custom inspections

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

**Administartion and Communication**
- Providing administrative services
- Planning and auditing
- Legal affairs
- IT services
- Human resources
- Finances and budget
- Organisation
- Facility management

**Risk Assessment and Scientific Support**
- Providing scientific advice
- Head of the Authority
- Quality Manager
- Forum for discussions with NGO’s

**Risk Management (Legislation and Control)**
- Providing advice on regulatory matters
- Managing all risks related to food and feed uses
- Planning and performing risk based inspections and controls

**Laboratory Services**
- Providing testing laboratory services

**Coordinating scientific disciplines and research functions**
- Hosting the fundamental disciplines of risk assessment
- Supporting experimental research
- Developing and implementing risk based registration systems
- Food and feed including additives and food contact material
- Food and feed business
- Experimental solutions to biological questions
- Fertilizers, pesticides, minimal drugs
- Providing, pesticides, minimal drugs

**Supporting support**
- Nutrition
- Supporting quality assurance
- Applying physical/chemical methods to research
- Food and feed including additives and food contact material
- Contact/enquiry points for Codex SPS, TBT
- Legal limits
- Product specifications
- Methods of sampling
- Methods of Analysis

**Planning and performing risk based inspections and controls**
- Planning and evaluating inspections and controls
- Controlling products and inspecting business
- Primary production
- Inspections and enforcement
- Special and ad hoc programs
- Imports and exports
- Data bases