Method Requirements for Official Food Control in the European Union

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European Commission – Joint Research Centre

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Stimulating innovation
Supporting legislation
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- 7 institutes in 5 countries: Italy, Belgium, Germany, The Netherlands, Spain
- 2,845 permanent and temporary staff in 2010
- 1,398 scientific publications in 2010
- 125 instances of support to the EU policy-maker annually
- Budget: €356 million annually, plus €62 million earned income

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  Institute for Reference Materials and Measurements
- **ITU** – Karlsruhe, Germany and Ispra, Italy
  Institute for Transuranium Elements
- **IE** – Petten, The Netherlands and Ispra, Italy
  Institute for Energy
- **IPSC** – Ispra, Italy
  Institute for the Protection and Security of the Citizen
- **IES** – Ispra, Italy
  Institute for Environment and Sustainability
- **IHCP** – Ispra, Italy
  Institute for Health and Consumer Protection
- **IPTS** – Seville, Spain
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• Clean transport
• Environment & Climate change
• Agriculture & Food security
• Health & Consumer protection
• Safety and security, including nuclear
• Information and communication technology
JRC-IRMM mission

To promote a common and reliable European measurement system in support of EU policies

Confidence in Measurements®
Food scandals

China reports big rise in food-poisoning deaths

A survey released yesterday said food safety is more worrying to the majority of people believing social and economic development has given China an advantage in the past 10 years. The survey showed that Chinese milk with melamine sickness affects 1,253 babies who have fallen ill after they were fed milk powder. Two babies died, and many more were affected. The government ordered the producers to recall the products and investigate the cause of the contamination.

Growing defensive as melamine contamination continues, Chinese milk producers have been hit by a series of food safety issues. A recent survey found that 42% of respondents are concerned about food safety.

Koreans Name Food Safety as Biggest Headache

A survey released last week by the National Statistical Office (NSO) found that 50% of respondents are concerned about food safety, with the government reportedly stepping up efforts to combat food fraud. The NSO reported that a survey of 1,200 respondents found that 42% are worried about food safety, while 20% are concerned about health issues.

Improvements in food safety urged

Salmonella Outbreak Exposes Food-Safety Flaws

Salmonella outbreaks have been reported in Mexico, Portugal, and Italy. The outbreak in Mexico is believed to be linked to a distribution center that supplied contaminated tomatoes to supermarkets. The outbreak in Portugal is linked to a restaurant that used contaminated seafood. The outbreak in Italy is linked to a supermarket chain that used contaminated meat.

Vietnam to intensify food safety

Improvements in food safety urged

Salmonella-Tainted Tomatoes Linked to Markets, Restaurants

Consumer Group Seeks Ban on Some Food Dyes

U.S. company recalls about 286,000 pounds of meat

The U.S. Department of Agriculture (USDA) has recalled about 286,000 pounds of meat products that were potentially contaminated with Salmonella. The recall was announced after the USDA received a report of Salmonella outbreak linked to the products.

Mums-to-be warned of fish danger

Health group overhaul of US food safety system

EU: Could Ban Mozzarella Unless Gets Contamination Info

The European Commission has warned Italy and South Korea that it could ban mozzarella if they don’t provide sufficient information on the origin of the cheese. The Commission said that it wants to ensure that the cheese is safe and healthy.

Japan scare over China dumplings

A recent scare over contaminated dumplings in China has prompted Tokyo officials to launch an inquiry. Dozens of Japanese people say they have fallen ill after eating dumplings known as gyoza, prompting Tiantan to recall the products. Interviews with dumpling makers have revealed that the dumplings were made by Tiantan, a company that has had previous food safety issues.

Food Safety and Olympic challenge for Beijing Games

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Legal background

Food crises and scares
BSE
Dioxins
Nitrofuran
BADGE
Acrylamide
...

- **White Paper on Food Safety (COM/99/719):** assuring the highest standards of food safety is a key priority for the Commission; identifies the need to establish a Community-wide framework for official controls

- **Regulation EC/178/2002 (general food law):** to protect public health and consumers’ interests in relation to food, while promoting free movement of food within the EU

- **Regulation EC/882/2004 (official feed and food control):** sets out the approach that competent authorities of Member States must adopt for official controls
EU food and feed legislation

To protect the well-being of consumers, to allow them to make informed choices and to ensure free movement of goods

Safety:
- limit amount of hazardous substances in food supply chain
- ensure that legal limits are implemented and respected

Quality:
- ensure compliance with label declaration (content of valued ingredients, origin, manufacturing process)
EU legislation requiring chemical measurements in foodstuffs

- Residues of veterinary medicinal products (growth promoters, antibiotics, etc)
- Food contact materials
- Pesticide and veterinary drug residues (EU-wide monitoring programmes)
- Food contaminants and residues (mycotoxins, heavy metals, PAHs, PCBs, dioxins, etc)
- Food labelling (nutritional properties, allergens)
- GM food and feed labelling
- Common Agricultural Policy (support and intervention schemes)
Measurements and legislation

- millions of measurements are performed every year to implement European legislation
- important decisions are taken based on those measurements
- need for harmonized implementation of policies in EU27+
Compliance and measurement uncertainty

- Result plus MU below limit
- Result below limit but limit within MU
- Result above limit but limit within MU
- Result minus MU above limit
CC(alpha), CC(beta)

- Decision limit (CC α) means the limit at and above which it can be concluded with an error probability of α that a sample is non-compliant.
- Detection capability (CCβ) means the smallest content of the substance that may be detected, identified and/or quantified in a sample with an error probability of β.
EU food and feed legislation relating to method validation

Regulation (EC) No 882/2004

• Recital (17): Laboratories involved in the analysis of official samples should ... use methods of analysis that have, as far as possible, been validated.

• Article 11 (Methods of sampling and analysis):
  Para 1: Sampling and analysis methods used ... shall comply
  ▪ with relevant Community rules
  ▪ with internationally recognised rules or protocols, for example those CEN has accepted
  ▪ with other methods fit for the intended purpose

• Where para 1 does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol
Community methods


Examples:

- Commission Directive 1999/76/EC establishing a Community method of analysis for the determination of lasalocid sodium in feedingstuffs
- Commission Directive 1999/27/EC establishing Community methods of analysis for the determination of amprolium, diclazuril and carbadox in feedingstuffs
Criteria approach

Mandating a certain analytical method in regulations

• denies the analyst to choose the most appropriate method for a given task
• discourages development of alternative approaches and the use of automation
• complicates administrative procedures if the prescribed method needs to be replaced by a more suitable one
C.3.3. Specific requirements

C.3.3.1. Performance criteria

Where no specific methods for the determination of contaminants in foodstuffs are prescribed at Community level, laboratories may select any validated method of analysis (where possible, the validation shall include a certified reference material) provided the selected method meets the specific performance criteria set out in Tables 5 to 7.

Performance criteria for methods of analysis for benzo(a)pyrene

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value/Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOD</td>
<td>Less than 0.3 µg/kg</td>
</tr>
<tr>
<td>LOQ</td>
<td>Less than 0.9 µg/kg</td>
</tr>
<tr>
<td>Precision</td>
<td>HORRATₚ or HORRATₚ values of less than 2</td>
</tr>
<tr>
<td>Recovery</td>
<td>50 to 120 %</td>
</tr>
<tr>
<td>Specificity</td>
<td>Free from matrix or spectral interferences, verification of positive detection</td>
</tr>
</tbody>
</table>
Standard

A document established
• by consensus, and
• approved by a recognized body, that provides, for common and repeated use,
• guidelines or characteristics for activities or their results, aimed at the
• achievement of the optimum degree of order in a given context.

Standards as knowledge resource

- Easily available
- Complete documentation
- Proven performance
- Acceptance
- Consensus
- Market driven
**Examples of international standards for food & feed analysis**

<table>
<thead>
<tr>
<th>Substance and Product</th>
<th>Standard(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semduramicin in animal feeding stuffs</td>
<td>EN 16158:2012</td>
</tr>
<tr>
<td>Zearalenone and aflatoxin B1 in cereal products</td>
<td>EN 15850:2010 &amp; EN 15851:2010</td>
</tr>
<tr>
<td>For infants and young children</td>
<td></td>
</tr>
<tr>
<td>Patulin in fruit juice and fruit purée</td>
<td>EN 15890:2010</td>
</tr>
<tr>
<td>Nine sweeteners in soft drinks and canned and</td>
<td>EN 15911:2010</td>
</tr>
<tr>
<td>Bottled fruits</td>
<td></td>
</tr>
<tr>
<td>Foreign fats in dark chocolate</td>
<td>ISO 11053:2009</td>
</tr>
</tbody>
</table>
Method validation

- applicability (matrix and concentration range)
- calibration, linearity, working range, sensitivity
- limit of detection
- limit of quantification
- precision (repeatability, reproducibility)
- trueness (recovery)
- selectivity / specificity
- ruggedness
- (measurement uncertainty)
Life cycle of analytical method

Proficiency test

Validated method

Control charts

Verify implementation
Mandated by Regulation (EC) No 882/2004
Amended by Regulation (EC) No 776/2006

• support to the **authorisation** of products used in human and animal nutrition

• support to the efficient **control** of the compliance of food and feed with European legislation carried out by Member States’ official control laboratories

*Note: The actual control aspect is the duty of national reference laboratories and competent authorities in the Member States – not the EU-RL.*
Tasks of EU Reference Laboratories (EU-RLs)

EU reference laboratories should contribute to a high quality and uniformity of test results, in areas where a need for precise analytical results exists (regulatory limits)

- providing national reference laboratories with details of analytical methods, including reference methods;

- coordinating application by the national reference laboratories of the methods, in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols
The EU-RL/NRL network

- A common language for measurements
- Improvement of measurement capabilities
- Contribution to standardisation
- Requirements for accreditation
- Reference materials
- Interlaboratory comparisons

Control laboratories in the Member States

EU-RL

NRL
Forty one EU-RLs in EU

27 EU-RLs for feed and food

14 EU-RLs for animal health and live animals
# EU-RLs for food and feed

<table>
<thead>
<tr>
<th><strong>Milk and milk products</strong></th>
<th><strong>Marine biotoxins</strong></th>
<th><strong>Dioxins and PCBs</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>ANSES, FR</td>
<td>AESA, SP</td>
<td>CVUA-Freiburg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Salmonella</strong></th>
<th><strong>Bivalve molluscs</strong></th>
<th><strong>GMOs</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>RIVM, NL</td>
<td>CEFAS, UK</td>
<td>JRC (Ispra)</td>
</tr>
</tbody>
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<thead>
<tr>
<th><strong>Campylobacter</strong></th>
<th><strong>Parasites</strong></th>
<th><strong>Food contact materials</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>SVA, SW</td>
<td>ISS, IT</td>
<td>JRC (Ispra)</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th><strong>Listeria monocytogenes</strong></th>
<th><strong>Veterinary drug residues</strong></th>
<th><strong>PAHs</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>ANSES, FR</td>
<td>RIVM, NL; AFSSA, FR; BVL, DE; ISS, IT</td>
<td>JRC (Geel)</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th><strong>Coagulase+Staphylococci</strong></th>
<th><strong>Pesticides</strong></th>
<th><strong>Feed Additives</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>ANSES, FR</td>
<td>DFVF, DK; CVUA-Freiburg, DE; LAGV, SP; CVUA-Stuttgart, DE</td>
<td>JRC (Geel)</td>
</tr>
</tbody>
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<thead>
<tr>
<th><strong>Escherichia coli</strong></th>
<th><strong>TSEs</strong></th>
<th><strong>Heavy metals</strong></th>
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</thead>
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<td>ISS, IT</td>
<td>VLA, UK</td>
<td>JRC (Geel)</td>
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<tr>
<th><strong>Antimicrobial resistance</strong></th>
<th><strong>Animal proteins in feed</strong></th>
<th><strong>Mycotoxins</strong></th>
</tr>
</thead>
<tbody>
<tr>
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<td>CRA-W,</td>
<td>JRC (Geel)</td>
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</tbody>
</table>
Participants in IMEP-107
As in rice

103 laboratories from 35 countries

98 reported results for total As
30 for inorganic As

Europe = 76%
Asia Pacific = 24%

29 NRLs took part in the PT
8 reported values for inorganic As
Total As in rice

98 laboratories

(X_{\text{ref}}, u_{\text{ref}}) cf. certification

\sigma-hat = 15 \%.
Inorganic arsenic in rice

- it is possible to measure inorganic As in rice
- results agree within a range of ± 15 %.
- results are not method-dependent
Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products

Joint Research Centre (JRC)

Robust science for policy making

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