METALS AND ALLOYS IN CONTACT WITH FOOD
Overview of the activities of the EDQM and benefits for public health

François-Xavier LERY
Head of Section for Pharmaceutical Care, Consumer Health Protection and Anti-Counterfeiting - EDQM, Council of Europe

The Council of Europe

• Founded in 1949
• Development of European common and democratic principles
• 47 member countries
• Headquarters in Strasbourg
• Core values:
  - protection of human rights
  - pluralist democracy
  - the rule of law

François-Xavier LERY, Strasbourg 2014. Copyright EDQM, Council of Europe. All rights reserved
European Directorate for the Quality of Medicines & HealthCare (EDQM)

• A Council of Europe Directorate, based on the Convention on the Elaboration of a European Pharmacopoeia (PA, 1964)

• Mission: to contribute to a basic human right: access to good quality medicines and healthcare

Activities of the EDQM

➢ Quality of medicines and substances for pharmaceutical use (European Pharmacopoeia and Certification);
➢ Programmes for the market surveillance of medicinal products (OMCL network);
➢ Fighting the counterfeiting/falsifying of medical products;
➢ Pharmaceutical practices & pharmaceutical care;
➢ Activities in the field of blood transfusion and organ transplantation;
➢ Consumer health protection.
→ A single secretariat for all these activities: the EDQM.
European Pharmacopoeia

- Compilation of common standards for the quality of medicines and their ingredients
- Essential basis for the free movement of medicines within a legal/political entity
- After 50 years of activity:
  - from 120 to about 2600 common, mandatory quality standards
  - from 8 founder states to 37 member states today, with the EU as its 38th member
- Its influence extends far beyond Europe.

Influence of the European Pharmacopoeia

640 million Europeans citizens
- 28 EU member states and European Commission
- 9 non-EU member states
- 27 observers: 8 European countries, 17 non-European countries, as well as WHO and Taiwan FDA
Certification Procedure

- Centralised Procedure used to demonstrate that:
  - active substances used are in compliance with the Ph. Eur monograph(s)
  - The Ph. Eur. monograph is able to control the quality of this active substances (impurity profile)
- Direct collaboration of European Authorities
- Scope: Worldwide
  - # 3800 valid certificates
    - > 800 substances concerned
  - > 1000 manufacturers from 50 countries

Need for Quality Control of Medicines: OMCLs

- Reasons:
  - Quality defects (e.g. contaminations)
  - Counterfeit and Illegal products (e.g. “traditional” Chinese medicines)
- Official Medicines Control Laboratories (OMCLs):
  - Independent re-testing of key parameters for medicines
  - Pre-marketing: for vaccines and blood-derived products
  - Post-marketing: market surveillance
European OMCL Network: Concerted Effort in Medicines Control

- 75 OMCLs from all Ph. Eur. signatory states
- Sharing of work, equipment, competences
- Mutual recognition of results
- Saving of costs
- Financial support from EU

Pharmaceuticals and pharmaceutical care

This activity began because of a study which revealed that:

- worldwide, 50% of all medicines are inappropriately prescribed or dispensed;
- 50% of all patients fail to take their medicines properly.
Definition of Pharmaceutical Care*

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life:

1. curing a disease
2. elimination or reduction of a patient’s symptomatology
3. arresting or slowing down a disease process
4. preventing a disease or symptomatology

Achieved through co-operation pharmacist / patient / other healthcare professionals and therapeutic plan for good and safe use of medicines


CoE/EDQM anti-counterfeiting strategy

- Multisectorial training
- Medicrime
- Inspection Testing
- Mass serialisation
Activities in the areas of blood transfusion and transplantation

Productive international collaboration
Promotion of strong principles such as non-commercialisation of donations
Worldwide scientific recognition
60 years of CoE activities in the area of blood transfusion
Expertise used to alert states to new risks and help them respond

Consumer Health Protection

The aim: to establish common policies concerning:

- the quality and safety of cosmetics and packaging for food.
- A network of official cosmetics control laboratories (OCCL) was set up in 2010; it is open to European Pharmacopoeia member states and observers.
Impact of activities of the EDQM

The EDQM contributes to:

- protecting public health,
- promoting animal welfare,
- optimising the use of its member states’ resources,

......... its activities have an impact that extends well beyond Europe.

Thank you for your attention.
1) Focus of the symposium
2) Council of Europe (CoE) Resolution on metals and alloys for food contact
3) Cooperation in Europe
4) Technical Guide on metals and alloys
5) Follow-up activities
6) Access to information
Metals and alloys for food contact

1) Focus of the symposium:

Understanding

European regulations
Consumer health protection
Safety assessment
Specific release limits
Best practices for release testing


- supplements EU Regulation 1935/2004, Art 3: no transfer of constituents to food that endanger human health
- Adopted on 11 June 2013 by the Committee of Ministers, representatives of the 37 member states (incl. 28 EU member states):

  Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, “the former Yugoslav Republic of Macedonia”, Turkey, Ukraine and the United Kingdom.
3) Cooperation in Europe

MoU between CoE and EU signed in 2007, in particular aimed at:

- Intensifying co-operation and implementing common strategies and programmes, acknowledging expertise and standard-setting work of the Council of Europe and the European Union and ensuring legal coherence
- Searching for added value and making better use of existing resources, avoiding duplication and fostering synergy
- Seeking to achieve greater unity between the states of Europe through respect for the shared values of pluralist democracy, the rule of law and human rights and fundamental freedoms.

3) Cooperation in Europe (cont’d)

CD-P-SC (CoE): Consumer Health Protection Committee (open to 37 countries + EU incl. EFSA, JRC, + observers)
=> reports to Committee of Ministers

P-SC-EMB (CoE): Committee of Experts on packaging and working groups (open to 37 countries + EU incl. EFSA, JRC, + observers)

European Commission, FCM group
European Food Safety Authority (EFSA)
European industry and trade associations
3) Cooperation in Europe (cont’d)

Mr Carl Berthot (Belgium), Chair of the P-SC-EMB 2009-2013, Chair of Consumer Health Protection Committee (CD-P-SC, Steering Committee) since 2013

Ms Martine Jequier (Switzerland), Chair of the P-SC-EMB since 2013

Dr Fabien Bolle, Vice-Chair of the P-SC-EMB since 2014

Ms Christine Grasmick, Chair of the Cosmetics Committee P-SC-COS 2010-2014

Terms of reference of the Committee of Experts on packaging materials (P-SC-EMB)

Terms of reference of the Committee of Experts on packaging materials (P-SC-EMB)

- implement the decisions of the CD-P-SC
- examine questions related to quality and safety of food packaging materials
- set standards and define policies and practices
- collect and evaluate quality and safety data, while avoiding duplication of the work of other international bodies
P-SC-EMB activity areas

- Paper and board/printing inks
- Metals and alloys
- Cork
- Resins
- Rubber coatings

4) Technical Guide on metals, alloys

Intended to:
- protect consumers
- guide manufacturers
- guide legislators (national, EU)
- support enforcement activities

Health risk: release into food or drinks from packaging and utensils expose the consumer to small amounts of various metals

General provisions (chapter 1) for food packaging and utensils such as aluminium foil, knives, forks and spoons, cans, oven grids, sieves, food processing machines
4) Technical Guide on metals, alloys (cont’d)

RASFF: alerts for high levels of chromium, manganese and nickel!

⇒ **Specific Release Limits** (SRLs) = maximum permitted amount of metal ion when released from a material or article (defined surface area)

Harmonised SRL for silver, aluminium, cobalt, chromium, copper, iron, manganese, molybdenum, nickel, tin, vanadium, zinc and contaminants antimony, arsenic, barium, beryllium, cadmium, mercury, lithium, lead and thallium.

**Examples:**

**Cr:** SRL set at **0.250 mg/kg**
RASFF: stainless steel BBQ tool 7.7, kitchen sieve 105.7, BBQ grid 169.4

**Mn:** SRL set at **1.8 mg/kg**
RASFF: stainless steel BBQ tool 0.3, kitchen sieve 160.3, BBQ grid 852.0

**Ni:** SRL set at **0.14 mg/kg**
Kitchen sieve 0.3, BBQ grid 4.2, frying pan 5.9
5) Follow-up activities
- Transitional measures (nat. authorities)
- Transposition of Resolution (nat. authorities)
- Working group on Implementation and Best Practices with participation of manufacturers, industry associations, testing laboratories, competent authorities
- Special attention: test conditions for silverware, stainless steel knives, forks
- Labelling requirements

6) Access to information
Consumer Health Protection website:


Cosmetics & Packaging guides
paper copies and restricted website, EPUB
www.chp.edqm.eu
References: **CoE Partial agreements**

- **Social and Public Health Field, 18 member states**
  
  => dissolved by the Committee of Ministers as of 1 January 2009 (see Decision 1031/6.1).

  => transfer of packaging and cosmetics to PA European Pharmacopoeia


- **European Pharmacopoeia, 37 member states + EU**

  Basic text: Council of Europe Treaty Series No. 50

  **Accessions or other Participations** - Website

---

**Special thanks**

Ms Viviana Golja and Ms Marta Ciraj, Slovenian health authorities

Dr Fabien Bolle, rapporteur metals, supported by Mr Carl Berthot in his capacity as Chair P-SC-EMB and CD-P-SC

Distinguished speakers at this symposium

DGCCRF and ANSES (France), editorial+technical support for the French version of the Technical Guide

Experts from 35 European countries: ministries (health, food, consumer protection), national competent authorities, official control laboratories, private testing laboratories, food industry (manufacturer associations, companies)
Contact us: consumer.health@edqm.eu

Thank you for your attention!
Council of Europe

Practical Guide on metals and alloys used in food contact materials and articles

General provisions, objectives, elaboration procedure and legal status of the Practical Guide on Metals and Alloys used in FCM

C.Berthot, M.Ciraj, V.Golja

Overview

• Metal and Alloys history
• Objectives, general provisions, elaboration procedure, legal status of Practice guide
• Conclusions
Metals and alloys history

• First text on metals and alloys in 2001. A Danish initiative.
• No SRL, only labelling for 1 or 2 metals.
• Text interesting, but not sufficient to ensure safety of consumers.

Metals and alloys history

• Resolution on Metals and Alloys: Belgian initiative based on analytical results from release testing of utensils made from metal.
• Question of consumer safety.
• Work started in 2008.
  – Discussion with member states
  – Discussion with stakeholders
  – Realisation of studies like METAFOOD
Resolution on Metals and Alloys

- Adopted by the Committee of Ministers on 11 June 2013
- Text:
  - [https://wcd.coe.int/ViewDoc.jsp?id=2075683&Site=CM#](https://wcd.coe.int/ViewDoc.jsp?id=2075683&Site=CM#)
  - in Practical Guide

In absence of specific requirements - Practical Guide: produced by the P-SC-EMB, approved by the CD-P-SC, published by EDQM (to be regularly updated)

Benefits for MS - harmonisation of provisions at European level

Recommendation to the governments of MS to adopt legislative and other measures to reduce health risks according to the principles set out in Technical Guide (or stricter rules)
Practical Guide

• Objectives:
  – To help reducing exposure to certain metals
  – To assist national regulations and enforcement activities
  – To help harmonising regulations

• General provisions:
  – definitions,
  – scope,
  – general requirements (quality and safety requirements, DoC and documentation, labelling),
  – SRLs,
  – compliance with SRLs and release testing: new approach
  – DoC

• Legal status:
  – Not legally binding, but reference for implementation of Art.3 paragraph 1 of Regulation 1935/2004
Practical Guide

• Elaboration procedure:
  – CD-P-SC approved
  – Committee of Ministers adopted the resolution
  – Ad hoc group on release testing assisted P-SC-EMB
  – Consultations with professional associations and industry representatives during elaboration of Practical Guide

Practical Guide

• SRLs for 23 metals and alloy components:
• collaboration between national bodies (ANSES, BfR,FSA...)
  – Collection of data
  – When setting SRL, application of only one approach was not possible
    • every metal - a suitable approach
    • Justification
### Practical Guide

#### Table 1 - SRLs for metals and alloy components

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Name</th>
<th>SRL (mg/kg food)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al</td>
<td>Aluminium</td>
<td>5</td>
</tr>
<tr>
<td>Sb</td>
<td>Antimony</td>
<td>0.04</td>
</tr>
<tr>
<td>Cr</td>
<td>Chromium</td>
<td>0.250</td>
</tr>
<tr>
<td>Co</td>
<td>Cobalt</td>
<td>0.03</td>
</tr>
<tr>
<td>Cu</td>
<td>Copper</td>
<td>4</td>
</tr>
<tr>
<td>Fe</td>
<td>Iron</td>
<td>40</td>
</tr>
<tr>
<td>Mg</td>
<td>Magnesium</td>
<td>-</td>
</tr>
<tr>
<td>Mn</td>
<td>Manganese</td>
<td>1.8</td>
</tr>
<tr>
<td>Mo</td>
<td>Molybdenum</td>
<td>0.13</td>
</tr>
<tr>
<td>Ni</td>
<td>Nickel</td>
<td>0.14</td>
</tr>
<tr>
<td>Ag</td>
<td>Silver</td>
<td>0.08</td>
</tr>
<tr>
<td>Sb*</td>
<td>Tin</td>
<td>0.00</td>
</tr>
<tr>
<td>Ti</td>
<td>Titanium</td>
<td>-</td>
</tr>
<tr>
<td>V</td>
<td>Vanadium</td>
<td>0.01</td>
</tr>
<tr>
<td>Zn</td>
<td>Zinc</td>
<td>0.05</td>
</tr>
</tbody>
</table>

*except in field of application under Regulation (EC) No. 1881/2006*

#### Transitional SRLs
- 0.2
- 1
- 0.1
- 0.6
- 0.7
- 0.05

#### Table 2 - SRLs for metals as contaminants and impurities

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Name</th>
<th>SRL (mg/kg food)</th>
</tr>
</thead>
<tbody>
<tr>
<td>As</td>
<td>Arsenic</td>
<td>0.002</td>
</tr>
<tr>
<td>Ba</td>
<td>Barium</td>
<td>0.2</td>
</tr>
<tr>
<td>Be</td>
<td>Beryllium</td>
<td>0.001</td>
</tr>
<tr>
<td>Cd</td>
<td>Cadmium</td>
<td>0.005</td>
</tr>
<tr>
<td>Pb</td>
<td>Lead</td>
<td>0.009</td>
</tr>
<tr>
<td>Li</td>
<td>Lithium</td>
<td>0.004</td>
</tr>
<tr>
<td>Hg</td>
<td>Mercury</td>
<td>0.003</td>
</tr>
<tr>
<td>Tl</td>
<td>Thallium</td>
<td>0.00001</td>
</tr>
</tbody>
</table>

#### Transitional SRLs
- 0.01
- 0.05
- 0.02
- 0.04
- 0.015
- 0.0005

---

24
Practical Guide

• Establishing SRLs:
  • toxicological information (e.g. JECFA, EFSA, national risk assessment bodies)
  • ALARA principle or relevant legislation
  • specific approach for each metal (only one approach was not possible)
  • Avoiding over-conservative SRLs or limits where compliance would not be possible

• collaboration between national bodies (ANSES, BFR, ...)

Practical Guide

New approach

Release testing:
  • new simulants
  • envelope volume

Declaration of compliance (DoC)
Practical Guide

Publication in 2013, but work is not finished; there are specific applications such as silver plates, Japanese knives etc.
  – Creation of ad hoc groups for specific applications
  – Risk assessment to be adapted for these types of specific applications or new approach to be found

Practical Guide

• Need for continuous work
  – More tests with the collaboration of industry
  – Improvement of test conditions
  – To monitor new scientific data
  – To address metals used for recycling
Conclusions

• Specific rules for producers
• Harmonised rules for producers
• Text approved by Committee of Ministers of 37 countries (incl. 28 EU members)
• Text used by national authorities for the interpretation of the article 3 of regulation 1935/2004
• Contribution to harmonisation
Situation of harmonization in Europe in the field of food contact

Framework regulation applies to all types of food contact materials and articles (excluding antique objects, cheese crusts and water supply systems)

Article 3: Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:
(a) endanger human health;
(b) bring about an unacceptable change in the composition of the food;
(c) bring about a deterioration in the organoleptic characteristics thereof.

Article 5: For the groups of materials and articles listed in Annex I (Active and intelligent materials and articles, Adhesives, Ceramics, Cork, Rubbers, Glass, Ion-exchange resins, Metals and alloys, Paper and board, Plastics, Printing inks, Regenerated cellulose, Silicones, Textiles, Varnishes and coatings, Waxes, Wood) and, where appropriate, combinations of those materials and articles or recycled materials and articles used in the manufacture of those materials and articles, specific measures may be adopted or amended in accordance with the procedure referred to in Article 23(2).

Article 6: In the absence of specific measures referred to in Article 5, this Regulation shall not prevent Member States from maintaining or adopting national provisions provided they comply with the rules of the Treaty.
### Specific harmonized measure(s):

**Regulation 1935/2004/EC (Brussels)**

**Article 3**

Interpretation of Article 3 for matters not covered by specific EU legislation

"Complementarity of the four international bodies"

**Transposition in national texts**

**Resolutions and guidelines of CoE (Strasbourg)**

EC specific texts:
- 84/500 ceramics
- 10/2011 plastics...

**EFSA**

**JRC**

### Interest in the work of the CoE

Many materials are **not subject to specific texts** in the European Union

These materials are **often covered by a Resolution of the Council of Europe**

There are more and more national initiatives following the many crises in the "non-plastics" (inks: Swiss Ordinance, varnish: Belgian Decree, revision in the Netherlands, BfR revision of recommendations...)

Lack of up-to-date texts is detrimental for:

- Consumer ➔ mutual recognition ➔ the lower standard is favoured
- Industry: very difficult to implement different standards in different countries
Use of the texts of the Council of Europe

These documents may require a total or partial transposition in the national law to become binding.

However,…

In the absence of EU Regulation, the documents of the Council of Europe can be used as harmonized reference documents to show the harmlessness and the inertia of a FCM (art. 3 of the EU Regulation)

In any case, a resolution is useful because it constitutes harmonized guidance that has received political approval by the governments of all the member states.

Facts faced by the Member states

Approaches differ from one state to another for problems related to non-plastics

But mutual recognition

CoE inventory lists with many substances that are not assessed, but used!

Crises on non plastics : ITX, BzP,…

Issues of concern: metals, …

Increasing public concern : BPA, ITX,…

Increase of product imports : Nylon, melamine,…
CoE: Elaboration of international standards for food contact materials started in the early 1960’s. It was in the late 1960’s that the Partial Agreement started to work on these issues and a Committee of experts on materials coming into contact with food was set up.

EC: 1976 first EC directive

CoE: In the late 1980’s the Committee of experts revised and updated its activity programme and working methods. The work involves toxicological assessment and the definition of technological standards and limits as well as possible inventory lists of chemical substances used for the manufacture of these substance groups.

EC: 1982 Basic rules for testing plastics

EC: 1984: Ceramics (but only Pb and Cd)

CoE: 1996: Coatings → inventory lists of non evaluated substances
CoE: 1999: Silicones → inventory lists of non evaluated substances
CoE: 2002: Paper and boards → inventory lists of non evaluated substances
CoE: 2004: Rubber → inventory lists of non evaluated substances


CoE: 2005: Inks → evaluation system but difficult to apply

2010 - 2011: ESCO WG on non-plastics (EFSA)

EC: 2011: Plasctics regulation
The inventory list of ESCO WG on non-plastics was an essential step to put an end to the problem of lists of substances which are not assessed for more than thirty years.

But thousands of substances are not evaluated and are used!

Development of a single approach needed to continue to implement this work → Database of CoE substances.

However now:

1. No EC specific measures for non plastics
2. Lists of unevaluated substances of CoE are still very... very ... long

But Roadmap of EC...
Market share of food packaging materials (by market value)
### Packaging: distribution by type of material

<table>
<thead>
<tr>
<th>Packaging formats Frequency</th>
<th>(n)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-contact layer formats</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal and alloys</td>
<td>261</td>
<td>7,1</td>
</tr>
<tr>
<td>Paper and board</td>
<td>270</td>
<td>7,4</td>
</tr>
<tr>
<td>Plastic</td>
<td>1787</td>
<td>55,9</td>
</tr>
<tr>
<td>Wax</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Subtotal</td>
<td>3319</td>
<td></td>
</tr>
<tr>
<td>Combination of contact layer formats</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glass and metal and alloys</td>
<td>165</td>
<td>4,4</td>
</tr>
<tr>
<td>Glass and plastic</td>
<td>40</td>
<td>1,1</td>
</tr>
<tr>
<td>Metal and alloys and plastic</td>
<td>8</td>
<td>0,2</td>
</tr>
<tr>
<td>Metal and alloys and paper and board</td>
<td>100</td>
<td>2,7</td>
</tr>
<tr>
<td>Paper and board and plastic</td>
<td>39</td>
<td>1,1</td>
</tr>
<tr>
<td>Subtotal</td>
<td>350</td>
<td></td>
</tr>
<tr>
<td>Missing information</td>
<td>3</td>
<td>0,1</td>
</tr>
<tr>
<td>Total</td>
<td>3672</td>
<td></td>
</tr>
</tbody>
</table>

Source: Food additives and contaminants: Estimation of exposure to food packaging materials. 1: Development of a food-packaging database. E. Duffy; A. P. Hearty; M. B. Gilsenan; M. J. Gibney

But FCM is not only Packaging: see utensils (example of RASFF)

### Looking at alerts (RASFF) and crises

<table>
<thead>
<tr>
<th>RASFF (2006 to 2010)</th>
<th>(n)</th>
<th>Utensil (%)</th>
<th>Packaging (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL</td>
<td>884</td>
<td>86</td>
<td>14</td>
</tr>
</tbody>
</table>

From 2006 to now (n=1915)

<table>
<thead>
<tr>
<th>Material</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rubber</td>
<td>0,1</td>
</tr>
<tr>
<td>Silicon</td>
<td>1,5</td>
</tr>
<tr>
<td>Plastic</td>
<td>39,7</td>
</tr>
<tr>
<td>Inks</td>
<td>6,7</td>
</tr>
<tr>
<td>Coatings</td>
<td>0,4</td>
</tr>
<tr>
<td>Metals&amp;Alloys</td>
<td>35,9</td>
</tr>
<tr>
<td>Glass</td>
<td>7,8</td>
</tr>
<tr>
<td>Wood</td>
<td>0,5</td>
</tr>
<tr>
<td>Ceramic</td>
<td>7,8</td>
</tr>
<tr>
<td>UE</td>
<td>47,6</td>
</tr>
<tr>
<td>CoE</td>
<td>52,4</td>
</tr>
</tbody>
</table>

Inks was only 6,7 % but 2 crises occurred

Less than 50% of alerts are in fields of EU rules
Controls are made:
1. on basis of EU rules, esp. 10/2011 and 84/500
2. preferably on utensils that are not yet in contact with food
3. mainly on known substances with SML

Gaps in general knowledge and rules in non-plastics: all actors are concerned (Collaboration JRC, CoE, EC and EFSA is needed)

- EU/CoE: harmonized texts for guidance for respect of Article 3 (the renewed interest of MS for CoE WG's is hopeful)
- JRC/CoE: harmonized guidance for analysis in non plastics
- EFSA/CoE: harmonized view on substances
  → As much as possible single reference for a substance information = harmonization MS lists)
  → toxicological guidance for evaluation of substances in inventory lists

In any case, CoE may be an actor!
Important CoE results in recent years

1. Resolution metals and alloys (adopted June 2013): complete document with limits, new practical concepts, harmonized view of assessment agencies, new methods (simulants, SRL,...)

2. Establishment of a database of substances known by member states of CoE and used in FCM with toxicological evaluation by software (more than 10,000 substances): free access for member states and subscription for companies (see next slide) → a Belgian initiative

3. Participation of EU authorities: JRC, EFSA,... invitation of CoE at EU experts committees... (initiatives to increase the participation of member states of the EU at meetings of CoE)

But not only task for CoE: methods and guidance are missing for some materials or articles → we need support from JRC, EC WG, EFSA,...

Conclusion

Harmonized texts for determination of conformity of non plastics with art 3.
→ Revised technical standards of CoE

Identity and toxicity of substances to be of concern for authorities
→ Database of Coe substances

Solid administrative procedures (CoE and EC) for control: sampling, methods,...
→ Guidelines or technical standards of CoE
Thank you for your attention…
Role of consumer organisation in food safety

marjana.peterman@zps.si

Ljubljana, 6-7-November 2014

Slovene Consumers’ Association

- ZPS is non-profit,
- Independed and internationally recognised NGO
- Established in 1990
- Founder of consumer magazine VIP in 1991
Slovene Consumers’ Association

• Our mission are informed consumers who are aware of their rights and know how to assert them.
• We are active in creating consumer friendly society.

Consumer policy – EU, SLO

• main objectives
  – A high common level of consumer protection
  – Effective enforcement of consumer protection rules
  – Involvement of consumer organisations in EU policies
What is BEUC? www.beuc.org

- The European Consumers’ Organisation (BEUC)
- 45 members, independent consumer NGO’s from 31 countries

What does it do?

- Represents rights and interests of european consumers in the process of policy making decisions in the EU

Its legitimacy and legality is recognized by EU policy and strategies
### Main activities

<table>
<thead>
<tr>
<th>INFORMATION DESEMINATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>INDEPENDEND CONSUMER ADVICE, LEGAL AID</td>
</tr>
<tr>
<td>CONSUMER PRODUCT TESTING</td>
</tr>
<tr>
<td>EDUCATION</td>
</tr>
<tr>
<td>CONSUMER REPRESENTATION AND ADVOCACY</td>
</tr>
<tr>
<td>NATIONAL AND INTERNATIONAL CO-OPERATION</td>
</tr>
</tbody>
</table>

- monthly magazine, known by 50% of people in SLO, (reach: 50,000 people)
- content: tests, information, advises, consumer legal cases
- circulation: 8500 copies
www.zps.si

• daily updated news, tests, advises,
• monthly over 40.000 visits
• brochures
• voice clips
• Forum

We are active also on social networking websites

Who is the consumer?

• Child, elderly
• Worker, engineer,
• Citizen

Nobody is just a consumer and consumers are not a separate group of people within society.
Consumers by definition buy products for own use.

Consumer – at the end of the food chain

- What ends up on my plate?
  Food and Chemicals

- From food
- From the environment
- From chemical migration
Consumer exposure to risk (chemical/metals) – at the end of food chain

**Aggregate:**
Consumers are exposed to a large number of chemicals from products they use every day (aggregate)

**Cumulate:**
Cumulative exposure from multiple sources throughout the lifespan

---

**Conclusion on risk assessment**

- Account for aggregate and cumulative exposure
- Product, process, and usage consideration of representative group of consumers
- Vulnerable groups of consumers are limited to exposure
- If no scientific agreement – precautionary principle applied
J.F.Kennedy, 1967

- Consumers by definition, include us all. They are largest economic group, affecting and affected by almost every public and private economic decision. Yet they are the only important group...whose views are often not heard

March 15. is a world consumer day, J.F.Kennedy, 15.3.1962:

- Right to safety,
- Right to information
- Right to choice
- Right to representation.

Consumers International added four more:
- Right to satisfaction of basic needs,
- Right to redress,
- Right to education
- Right to healthy environment.
Role of consumer organisation in food safety

• Thank you for listening

• ??

Marjana Peterman
marjana.peterman@zps.si
Metals and alloys in food contact applications

Viviana Golja, Tina Grča
Overview

- Use of metals and alloys
- Legislation & official control in SI
- Possible issues
- RASFF notifications
- Conclusions

Use of metals and alloys

- Kitchenware
- Cookware
- Packaging
- Food production
- Food processing machinery
Kitchenware
Cookware
Cookware

Packaging
Food production

Food processing equipment
Legislation & official control in SI

General legislation:
- Framework Regulation 1935/2004
- GMP Regulation 2023/2006
- No specific legislation for metals: Practical Guide is much appreciated
- Slovenia (after 2012) no national legislation

- Official control: Health Inspectorate: inspections and sampling on the border and on the market
- National reference laboratory for FCM: testing
Regulation 1935/2004

Article 3
General requirements

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:
   (a) endanger human health;
   or
   (b) bring about an unacceptable change in the composition of the food;
   or
   (c) bring about a deterioration in the organoleptic characteristics thereof.

2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.

Issues

- Release of metals in quantities that can endanger human health: chromium, nickel, lead, cadmium, aluminium, arsenic, mercury, thallium...
- Organoleptics
- Recycling - scraps
- Harmonisation of testing procedures – utensils!
Issues

- Use of inappropriate materials: e.g. lead parts of appliances, lids for pots, traditional brass tea pots…

- Organoleptics

- Innappropriate use: aluminium (SRL= 5 mg/kg): contact with acidic or alkaline or salty foods

Stainless steel:
Specific release of chromium, nickel, manganese (Cr SRL= 0.250 (1) mg/kg, Ni SRL= 0.14 (0.7) mg/kg, Mn SRL= 1.8 mg/kg)
Overall migration (It – limit)
Nickel- plated items (e.g. heating coils in electric kettles): nickel
Chromium- plated items: chromium, copper, nickel
Issues

- Tin-plated items (e.g. tin cans): possible release of Sn, As into acidic foodstuffs
- Zinc-plated items: release of Zn, Cd and Pb (impurities)
- Brass: possible release of Sn, Al, Mn, Ni, Fe, Si, As, Pb

- Plumbing, boilermaking, piping
- Food contact materials containing nanoparticles: need to be evaluated separately on a case-by-case basis

RASFF notifications on FCMs

Health risk detected in one or more consignments of a food contact materials

Alerts, border rejections, information for follow up, information for attention
RASFF notifications on FCMs

287 notifications in 2012

- Plastics: 44.6%
- Metals and alloys: 32.7%
- Coatings: 7.3%
- Glass: 6.9%
- Ceramics: 3.8%
- Silicone: 2.8%
- Rubber: 0.7%
- Material not defined: 0.7%
- Wood: 0.4%

RASFF notifications on FCMs

218 notifications in 2013

- Metals and alloys: 53.6%
- Plastics: 27.1%
- Glass: 5.5%
- Ceramics: 3.7%
- Material not defined: 3.2%
- Coatings: 3.2%
- Paper: 1.8%
- Silicone: 0.9%
- Wood: 0.5%
RASFF notifications on FCMs

112 notifications until July 2014

Subject of notification

- Metals and alloys: 50.9%
- Plastics: 33.9%
- Glass: 6.3%
- Ceramics: 2.7%
- Coatings: 2.7%
- Inks: 1.8%
- Wood: 0.9%
- Paper: 0.0%

RASFF notifications on FCMs

Subject of notification

- 2012: 54%
- 2013: 54%
- July 2014: 54%
RASFF notifications on FCMs

- All issues reported?
- Different national legislations
- Different SRLs
- Nonharmonised testing procedures
- Metals: „easier“ analysis?

Conclusions

- Complex and important subject
- Significant exposure
- Need for harmonisation – Practical Guide!
- Future: different testing procedures, enamels, coatings, nanomaterials?