How Industry Complies with the Framework Regulation (EC) No 1935/2004

Presentation of the Cross Sector Group to the Commission and Member States

24th September 2018

What is the Cross Sector Group?

- Grouping of some 30 Trade Associations involved in the Food Contact supply chain
- All stages of production with manufacturers of:
  - Substances and additives
  - Raw materials
  - Intermediates
  - Final food contact materials and articles
  - Packed foodstuffs
- Most types of materials covered
- Not just packaging – it includes manufacturers of food contact articles such as kitchen ware and domestic appliances

Cross Sector Group Activity

- Formed in autumn 2016
- Plenary group has met 3 or 4 times each year
  - Sub-groups working on individual issues, e.g.:
    - Risk Assessment
    - Communication
    - Trust & Transparency
- Aims to:
  - Identify advantages and disadvantages of the current system.
  - Identify principles which could form the basis of future harmonised legislation for all food contact materials and articles (FCM&A).

How do We Comply Today

- Basis of all compliance
  - Framework Regulation (EC) No 1935/2004
  - GMP Regulation 2023/2006
- These regulations state WHAT is required for manufacture, supply and use of safe FCM&A.

Benefits of Framework and GMP

- EU wide rules applicable to all FCM&As, whether harmonised or not.
- Universally accepted by authorities and industry.
- Article 3 is the cornerstone of ensuring consumer safety and remains the best way of doing this:
  - Similar requirements in other jurisdictions, e.g. USA, China, Mercosur
- Allows for specific measures.
- GMP requirements have formed the basis of specific industry guidelines.

How do We Comply Today

- Basis of all compliance
  - Framework Regulation (EC) No 1935/2004
  - GMP Regulation 2023/2006
- These regulations state what is required for manufacture, supply and use of safe FCM&A.
- The Framework was designed to be complemented by specific measures.
- Harmonised measures.
  - *You have heard from the Plastics Coordination Group (PCG) who have explained their view*
- Non harmonised materials:

Approaches Used

- To demonstrate compliance with Framework
  - Use EU legislation wherever possible.
  - Use National legislation.
  - Use other recommendations and guidelines.
  - Do our own risk assessments “in accordance with internationally recognised scientific principles on risk assessment”.
- Matrix showing, for each sector
  - European and Member State Legislation used
  - Guidelines or other methods
  - Current way of working
  - Advantages of current way of working
  - Disadvantages of current way of working
- Very complex so hard copy has been made available

Sector	CEPE Can Coatings	
What European or Member State Legislation is in place for the sector?	Framework 1935/2004 GMP 2023/2006 Epoxy 1895/2005 BPA 2018/213	Dutch Warenwet (Coatings) Belgian (Coatings) Italian (Coatings) Spanish (Coatings)
Guidelines or other means of demonstrating safety/compliance	CoE Resolution on Coatings AP(2004)1 Can Sector Coatings Code of Practice COM & MS measures on other materials US FDA CFR (Coatings - 175.300)	
How does the current way of working function	SSA checked against , 10/2011, Warenwet (list of approved starting substances being updated) , EFSA opinions CoE database (Begian) or synoptic document. Any restrictions or limitations are respected. Migration testing using 10/2011 methods with modifications where needed due to differences between coated metal and plastics. For fully evaluated SSA use SML For non fully evaluated starting substances using either 0.01mg/kg SML or TTC approach with exposure	
Advantages of the current way of working	Provides science based consumer safety. In the absence of harmonised legislation, this is the most effective method of demonstrating compliance with 1935/2004 Widely used across sector	
Disadvantages of the current way of working	Lack of Mutual Recognition Lack of NGO understanding/acceptance Unilateral MS action. Different rules and limits/restrictions in different MS	

FPE Materials	Main Legislation Used by FPE Members	
General	Framework 1935/2004. GMP 2023/2006.	
Plastics	Plastics 10/2011. Recycled 282/2008.	
Colourants	Germany BfR Recommendation IX. France “Circulaire No 176 du 2 Décembre 1959” on pigments etc. France Draft Order notified to the Commission on the 6th August 2004 under reference 2004/328/F.	
Paper	Germany BfR Recommendation XXXVI.	
RCF	RCF Directive 2007/42.	
Coatings	Plastics 10/2011. Epoxy Derivatives 1895/2005. BPA 2018/213. Germany BfR Recommendation XIV.	Germany BfR Recommendation XXI. Netherlands Warenwet (Chapter 10). Belgium Royal Decree of 25th September 2016.
Adhesives	Plastics 10/2011. Germany BfR Recommendation XIV- Part A. Germany BfR Recommendation XXVIII. Germany BfR Recommendation XXV.	
Waxes	Plastics 10/2011.	
Active & Intelligent	Active & Intelligent 450/2009.	

Issues

- Sheer number of regulations require great expertise
- Different countries have different rules and different limits.
- National legislation not available in all EU languages
- All of the above are challenging, particularly for SMEs.
- Enforcement Authorities may have different interpretations and expectations, leading to supply chain difficulties.
- National measures can be a barrier to trade.
- Difficult for non EU producers to understand what is needed.

Issues

- Lack of EU wide accepted test methods for non plastics,
  - But exceptions eg JRC Guidance Doc on Kitchen Ware.
- For non-harmonised FCM&A application of 10/2011 rules can be unsuitable
- No EU wide legal requirement for DoC
  - No sector specific guidance on DoC content from authorities
- EFSA not permitted to evaluate non harmonised substances
- No official rules or guidelines for how industry demonstrates compliance with Art. 3
  - Different sectors have specific approaches using internationally recognised principles
  - Makes it difficult for those outside the industry to understand

Summary

- Non-harmonised measures does not mean that the use of FCM&A is unsafe.
- The process to demonstrate compliance and safety is complex and lacks legal certainty.
- Even though industry does all that is required to demonstrate compliance and safety, it is difficult to communicate this to the outside world.

List of member associations of the Cross-Sector Group FCM/As

Updated 11/9/2011

ACE - The Alliance for Beverage Cartons and the Environment **APEAL – Association of European Producers of Steel for Packaging** **APPLIA Europe – Domestic Equipment Manufacturers** **Cefic-FCA – food contact additives** **CES – Silicones Europe** **CEPE – Coatings** **CEPI –European Paper Industries (pulp and paper)** **CERAME-UNIE – European Ceramic Industries Association** **CONCAWE – Division of Oil Refiners Association** **CPME – PET industry** **EAFA – European Aluminium Foil Association** **EDANA – Non-Wovens** **ED/ESGA/Institut du Verre - Glass Alliance Europe** **EEA : European Enamel Association** **EUROPEAN ALUMINIUM (observer)** **EuPC – European Plastics Converters** **EUPIA – Printing Inks** **EUROFER** **European Wax Federation** **FEICA – Adhesives** **FINAT – Self-Adhesive Labelling**	**FoodDrinkEurope** **FEC – The European Federation of Cutlery, Flatware, Hollowware & Cookware Industries and Brands** **FEFCO - Corrugated Packaging** **Flexible Packaging Europe** **Intergraf - European Federation for Print & Digital Communication** **Metal Packaging Europe** **Nickel Institute** **PlasticsEurope** **WBT - World Association Bottle & Teats**

	Measures Used by Association Members		
Association	**Metal Packaging Europe**	**CEPE Can Coatings**	**CES - Silicones Europe**
What European or Member State Legislation is in place for the sector	Framework 1935/2004 GMP 2023/2006 Epoxy 1895/2005 BPA 2018/213 Plastics 10/2011 (Closure Gaskets & PCM) Dutch Warenwet (Coatings/Metal/Rubber) Belgian (Coatings) Italian (Coatings/Rubber) Spanish (Coatings/Rubber)	Framework 1935/2004 GMP 2023/2006 Epoxy 1895/2005 BPA 2018/213 Dutch Warenwet (Coatings) Belgian (Coatings) Italian (Coatings) Spanish (Coatings)	Framework 1935/2004 GMP 2023/2006 BfR recommendations XIV (polymer dispersions), XV (silicones), XXXVI (pulp & paper), XXXVI/2 (baking paper), LI (cookware) and LII (fillers) French Arrêté of 25 November 1992 on silicone elastomers Plastics EU 10/2011 + Amendments (plastic additives) Swiss Ordinance SR 817.021.23 (printing ink additives + silicones) Dutch Warenwet (coatings + rubbers) Belgian (Coatings), Italian (rubbers), Spanish (silicones)
What Guidelines or other means of demonstrating safety/compliance are in place	CoE Resolution on Coatings AP(2004)1 CoE Resolution on Metals and Alloys CoE Resolution on Rubbers and Elastomers Sector Coatings Code of Practice COM & MS measures on other materials US FDA CFR (Coatings/Rubber)	CoE Resolution on Coatings AP(2004)1 Can Sector Coatings Code of Practice COM & MS measures on other materials US FDA CFR (Coatings - 175.300)	CoE Resolution on silicones AP (2004)5 CoE Resolution on Coatings AP (2004)1 CoE Resolution on paper and board AP (2002)1 CES - Guidelines on Compliance Testing for Silicone Elastomers CES - Good Manufacturing Practices for Organosilicon materials intended to come into contact with food FCA - Guidelines on Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS)
How does the current way of working function	Starting Substances & additives (SSA) either from 10/2011 or AP (2004)1. Migration testing using 10/2011 methods with modifications where needed due to differences between coated metal and plastics. For fully evaluated SSA use SML For non-fully evaluated starting substances using either 0.01mg/kg SML or TTC approach with exposure	SSA checked against 10/2011, Warenwet (list of approved starting substances being updated) , EFSA opinions CoE database (Belgian) or synoptic document. Any restrictions or limitations are respected. Migration testing using 10/2011 methods with modifications where needed due to differences between coated metal and plastics. For fully evaluated SSA use SML For non-fully evaluated starting substances using either 0.01mg/kg SML or TTC approach with exposure	Silicone fluids, resins and elastomers are made according to GMP principles. Starting Substances and Additives (SSA) checked against positive lists referenced above. Any restrictions or limitations are respected or provided further down in the supply chain. For NIAS and NLS a risk assessment is done based on the FCA Guidelines under the requirements of Article 3 of the Framework Regulation (EC) 1935/2004, together usually with a Worst- Case Calculation (EU cube) as exposure part. The final exposure evaluation of the RA for a specific silicone application can only be done further down in the supply chain.
What are the advantages of the current way of working	Provides science-based consumer safety Widely used across sector	Provides science-based consumer safety. In the absence of harmonised legislation, this is the most effective method of demonstrating compliance with 1935/2004 Widely used across sector	In the absence of harmonised legislation, this is the most effective method of demonstrating compliance with 1935/2004. Makes best use of available toxicity data, and risk assessment in accordance with internationally recognised scientific principles. Practicable and provides science- based consumer safety
What are the disadvantages of the current way of working	Lack of Mutual Recognition Lack of NGO understanding/acceptance Unilateral MS action	Lack of Mutual Recognition Lack of NGO understanding/acceptance Unilateral MS action. Different rules and limits/restrictions in different member states	Lack of mutual recognition. Different rules and limits/restrictions in different Member States. Missing clear and agreed (enforcement authorities & test laboratories) guidelines for risk assessment of not officially evaluated substances (based on tox data - ECHA, TTC models). EU 10/2011 migration & analytical methods not always suitable.
Comments			

	Measures Used by Association Members		
Association	**EAFA (Aluminium Foil)**	**Wax federation**	**EuPIA - inks**
What European or Member State Legislation is in place for the sector		Framework 1935/2004 GMP 2023/2006 Dutch Warenwet (Chapter X Coatings) Germany: BfR Recommendation XXV Both contain positive lists of materials and additives as well as relevant purity criteria	Framework 1935/2004 GMP 2023/2006 Plastic 10/2011 + Amendments Swiss Ordinance SR 817.021.23 Epoxy 1895/2005 BPA 2018/213 Dutch Warenwet 2008/1333 and 2008/1334 (food additives & flavourings)
What Guidelines or other means of demonstrating safety/compliance are in place	Compositional compliance with one or more of the following standards: EN 573-3, EN 601, EN602, EN 14287, EN 14392. Council of Europe Resolution CM/Res(2013)9 on metals and alloys used in food contact materials. FDA 21 CFR 178.3910. Code for Good Manufacturing Practices for the European Aluminium Industry.	US FDA CFR Relevant Chapters include e.g. §172.886 and 172.888 for mineral and synthetic waxes in food uses, 178.3710 and 178.3720 for non-food articles in contact with food.	'BfR recommendations XXXVI.x (various paper applications) AP 89/1 - CoE Resolution on colourants used in plastic for food contact Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food EuPIA Exclusion Policy EuPIA GMP EuPIA Statement of Composition EuPIA NIAS and NLS Guideline EuPIA Migration Guideline EuPIA Photo initiator Suitability List various company specific positive/negative lists (for example: Nestle)
How does the current way of working function	The CoE Resolution provides limits for aluminium release which are increasingly being accepted. Commercial users are warned against using uncoated foil products with acidic or salty food. Consumer products are labelled with such warnings	The application of the EC 2023/2006 for food contact Directive is sufficient. Proper quality assurance systems and traceability are common practice in our industry. In situations where waxes are used as additives in Plastics, Printing Inks, Paper and Board, Adhesives etc, the requirements come from our customers and the customers of our customers down the supply chain.	Inks for p-FCMs are made according to GMP. EuPIA member are requesting from raw material suppliers' details about the composition of the raw material based on a list of standard questions (by far exceeding legal data for example in SDS). Substances used should be listed in the Swiss Inks Ordinance SR 817.021.23 Annex 10 Migration limits in official EU & national regulations need to be met in pFCM's. Limits for non-listed substances (NIAS, pigment additives etc) are self-derived based on publicly available tox data (ECHA) and/or TTC models. Information about potential migrating substances, solvents and reactive substances in the inks (identity, concentration, applicable limit/restriction & dual use), are provided from ink suppliers to the printers via Statement of Composition (SoC) (also includes information on known NIAS). For NIAS and NLS a risk assessment is done based on the EuPIA NIAS and NLS Guideline (ink manufacturer) together usually with a Worst- Case Calculation (EU cube) as exposure part. The final exposure evaluation of the RA for a specific p-FCM can only be done further down in the supply chain but the data provided in the SoC give the needed adequate information.
What are the advantages of the current way of working	A European level for aluminium release	Widely used across sector and in other regions. Mutual recognition typically not an issue for this sector	In the absence of harmonised legislation, this is the most effective method of demonstrating compliance with 1935/2004. Makes best use of available toxicity data, and risk assessment in accordance with internationally recognised scientific principles. Principles agreed within the printing ink value chain and written in the PIJITF position paper. Practicable and provides science-based consumer safety. Provides effective and pragmatic solution for assessing the large number of 'not-officially evaluated' substances used in inks.
What are the disadvantages of the current way of working	Testing methodology is not yet agreed. Inappropriate time/ temperature conditions taken from Plastics guidance can be used for accelerated testing.	Lack of NGO understanding/acceptance	Lack of mutual recognition. Missing clear and agreed (control authorities & test laboratories) guidelines for self-assessment of not officially evaluated substances (based on tox data - ECHA, TTC models). Migration & analytical methods not suitable and/or existing for many applications and substances to meet for example the 10 ppb non-detection limit.
Comments			

	Measures Used by Association Members		
Association	**EEA – Porcelain Enamel**	**APPLiA Home Appliance Europe**	**FoodDrinkEurope (provisional input)**
What European or Member State Legislation is in place for the sector	Framework 1935/2004 GMP 2023/2006 Dutch Warenwet. KEMA and TNO. Austria: GESG $8. OFI Technologie und Innovation, AGES, LVA Labor Germany: LFGB (version 30.06.18).TUV (SueD), Hygiene Institut Gelsenkirchen (Hyg). France : Norm 84/500 EEC and 2005/31/EC EU directives by IANESCO. Italy: Ministry of Health Note 20072 dated May 20th 2014.	Framework 1935/2004 Plastics 10/2011 Epoxy 1895/2005 BPA 2018/213 Ceramics 84/500/EEC Italian decree 21/03/1973 French BPA legislation (BPA ban)	As food and drink industry we should only use materials and articles that comply with all FCM&A legislation. In addition, our products should comply with the contaminants legislation (EEC) No 315/93 which includes contaminants originating from packaging and the general food law Regulation (EC) No 178/2002. These make us having shared responsibilities with the FCM&A manufacturers.
What Guidelines or other means of demonstrating safety/compliance are in place	Sector: EEA guideline 1001. ISO FDIS 4531. ISO: new edition of EN ISO4531 will soon be published	APPLiA manufacturers look at EU harmonized laws (when existing) + a set of national laws + a set of guidelines and recommendations (e.g. CoE recommendations and guidelines, BfR recommendations, JRC guidelines, etc.) that come from their risk assessment based on materials used, selling countries, appliances-use, market experience, among others.	Please consult the other matrices
How does the current way of working function	Migration is tested with different testing methods (time, temp, solution) and different limits are used (limits used for other materials and self- defined limits). Even in countries that have a national legislation, sometimes other test methods and limits are used.	- Manufacturers request a Food Contact Document of Compliance (FC DoC), when mandatory (e.g. at Plastic resins producers). - Test of compliance is made through selected EU Regulations/national laws/recommendations and guidelines that each company defines necessary and based on risk-assessment. - The testing-approach may be based on Food Contact Material (FCM) level or on appliances level depending on each company risk assessment.	Through transfer of information along the supply chain as we are not manufacturing the FCM&A (in most cases): Food Business Operators transfer info on foreseen application while FCM&A manufacturers issue DoC.
What are the advantages of the current way of working	None	- Provides science- based consumer safety: it proves that material and/or component and/or appliance is safe to consumers for a defined use because they are based on toxicological risk assessment made by competent Authorities, EU and/or Nationals. - May provide proof of compliance according to specific selling countries in case of national deviations from EU Regulations or not EU harmonized materials.	In the absence of other legislation this is the way to demonstrate compliance

What are the disadvantages of the current way of working	lack of conformity, lack of acceptance	- DoC's information on FCMs (list in Annex 1 Regulation (EC) 1935/2004) are not structured. The level of information transferred downstream is, therefore, highly variable depending on specific material and supplier disclosure choices. The fact of receiving a useful and structured information is very time consuming and include business negotiations. - Sustainability of maintenance of the compliance testing system in case of unilateral actions of Member States, restrictions modifications, conflicting restrictions or conflicting testing methods and lack of common toxicological risk assessments, these are also reasons why the mutual recognition cannot work properly.	In the absence of positive list for the other streams than plastic, the supply chain must endure a higher level of trust and transparency. We notice issues on the functioning of the information in the Supply Chain. The Declaration of Compliance needs to be followed by audits and surveillance plans are key elements in order to be effective. The quality of the DoC's available on the market is low. Alignment on the risk assessment is needed.
Comments		- APPLiA calls for a better definition of the content of the FC DoC (including relevant information for the manufacturing stage of a value chain) and of supporting materials, which bear information needed to show compliance to competent authorities. - APPLiA wants to make sure that FCMs do not contaminate food or endanger human health through a sustainable solution for all FCMs, promoting the EU harmonization for those which are not yet harmonised. This will generate an advantage for EU internal market of FCMs and will also encourage national competent authorities to ensure compliance and enforcement. - APPLiA manufacturers acknowledge their responsibility to guarantee the product safety on the market, and recognize to Competent Authority the toxicological risk assessment, the definition of safety limits and critical information to be transferred along supply chain. This is a crucial to transfer the useful information from up to down the supply chain. - The detection limit of substances shall be always reported in the law in case of a total ban of the substance. This to prevent different interpretations of the Regulation and to ensure a level playing field among laboratories regarding testing methods.	Where full harmonisation of a food contact material, as listed in Annex 1 of Regulation (EC) 1935/2004, has not yet taken place consistent application of the principle of mutual recognition by Member States would improve the functioning of the single market for FCM&A.

	Measures Used by Association Members		
Association	**Glass Alliance Europe**		
What European or Member State Legislation is in place for the sector	Framework Regulation 1935/2004 GMP-Regulation 2023/2006 National regulation in France and Italy		
What Guidelines or other means of demonstrating safety/compliance are in place	Quite often ceramic directive is also applied to glass ISO standard on methods and limits for glass and ceramic articles Documentation from GAE on GMP and DoC		
How does the current way of working function	Mostly, producers give a self-declaration on their packaging material according to the law relating to food and drugs. This declaration might be complemented by migration analysis for Pb and Cd mainly (as for ceramic)		
What are the advantages of the current way of working			
What are the disadvantages of the current way of working	Internal market fragmentation Difficult for customers/clients to understand the situation… requirements from plastics are sometimes required….		
Comments			

	Measures used by FEC Members (Page 1)		
Material Type	**FEC Plastics & thermoplastic elastomers including recycled plastics**	**FEC Rubbers including thermoset elastomers**	**FEC Metals- Stainless steels**
What European or Member State Legislation is in place for the sector	Framework 1935/2004 GMP 2023/2006 Regulation 10/2011 Regulation 284/2011 (imports from PRC) Regulation 282/2008 (recycled plastics) French BPA legislation Denmark, Sweden, Belgium: national BPA legislation Netherlands (Warenwet) Spain (1982, Plastics & rubbers	Framework 1935/2004 GMP 2023/2006 Directive 93/11 (N-nitrosamines and N-nitro-sable substances from rubber teats and soothers) France (1992) Italy (1973) The Dutch (Warenwet), Spain (1982, Plastics & rubbers), Czech Republic (2001) Romania (2006) Slovakia (2003) Slovenia (several)	Framework 1935/2004, GMP 2023/2006 France (Arrêté du 13 Janvier 1976 in combination with NF A 36-711/NF EN 10088-1) Dutch Warenwet, Italy art. 37 decreto 21/03/1973 mod DECRETO 11 November 2013, n. 140 and mod Decree 195 of 6 August 2015 Czech Republic, Slovakia, Greece, Croatia Belgium: draft Royal Decree, Nordic Council of Ministers
What Guidelines or other means of demonstrating safety/compliance are in place	EU Guidance for Plastics JRC Guidelines on testing conditions for articles in contact with foodstuffs (2009).	Res AP (2004)4 on rubber products Germany: BfR XXI JRC Guidelines on testing conditions for articles in contact with foodstuffs. (2009)	CoE/EDQM CM Res (2013)9 France (Fiche MCDA n°1 (V02 – 01/04/2017) sheet n°1) JRC Guidelines on testing conditions for articles in contact with foodstuffs. (2009) Suppliers declaration of conformity
How does the current way of working function	Starting Substances & additives (SSA) from 10/2011 Migration testing based on 10/2011	Variable: Depends upon national legislation (if any available)	Several grades of SS are very widely used for all types of food contact applications Conformity with composition rules is generally a prerequisite in combination with CoE Resolution Res (2013)9 as it is also requested by many customers
What are the advantages of the current way of working	Provides science-based consumer safety Widely used across sector	Provides science-based consumer safety Widely used across sector	Provides science-based consumer safety Widely used across sectors
What are the disadvantages of the current way of working	Most regulated category of FCMs, but still deviating national legislation (e.g. for non-regulated or based on safeguard clause). Frequent subsequent changes and new issues (like NIAS, oligomers, EDCs in plastics, Nano-plastics) difficult to follow for small companies. Most regulated FCM should mean confidence by NGOs and consumers, but all new issues create new lack of confidence.	Standardised EU test methods missing Lack of mutual recognition Lack of communication in supply chain Efforts are still needed to control imports Even more complex when combined with other FCMs	Italy accepts mutual recognition but does not apply CoE Res(2013)9 Unless CoE Res (2013)9 is incorporated in national legislation it is not legally enforceable, however CoE Res(2013)9 is widely accepted and requested by large customers Too many different national provisions: very challenging for SMEs
Comments	Standardised EU-wide test methods for certain substances still missing 10/2011 only applies to plastics, but often used outside plastics with adaptations	Standardised EU-wide test methods for certain substances still missing	FEC would like to have dedicated EEA-wide uniform legislation for all FCMs and FCAs that also equally applies to all imports (equal level playing field) Future REACH/CLP regulations will have strong impacts despite safety already being covered by food contact regulations or recommendations. Define tests conditions to realistically overestimate conditions of use.

	Measures used by FEC Members (Page 2)		
Material Type	**FEC Metals - Carbon steels**	**FEC Silicones**	**FEC Ceramics**
What European or Member State Legislation is in place for the sector	Framework 1935/2004 GMP 2023/2006 Dutch Warenwet, Italy, Czech Republic, Slovakia,, Greece Croatia, Belgium: draft Metals and Alloys Nordic Council of Ministers	Framework 1935/2004 GMP 2023/2006 France (silicones order 1992) Italy (silicones in rubbers order 1973) Spain (plastics including silicones) Czech Republic (silicones order) Slovak Republic (Similar as rubbers) Switzerland (EDI Regulation, Ch 9)	GMP 2023/2006, Directive 84/500/EC Directive 2005/31/EC, Draft Ceramics regulation (covering also enamels and glass under discussion) France (Fiche MCDA n°2 (V01 – 01/05/2016))
What Guidelines or other means of demonstrating safety/compliance are in place	CoE/EDQM CM Res (2013)9, France (Fiche MCDA n°1 (V02 – 01/04/2017) sheet n°4) JRC Guidelines on testing conditions for articles in contact with foodstuffs. (2009) Suppliers declaration of compliance	CoE/EDQM Res AP(2004)5 on silicones Germany: BfR XV Silicones France: French Arrêté 25 Nov 1992 CES: DO'S and DONT'S for silicone bakeware Suppliers declaration of conformity New draft CoE/EDQM General Resolution in preparation	Directive 84/500/EEC (ceramic articles) + Directive 2005/31/EC have set SMLs + analytical methods for Pb & Cd from glass, ceramics and porcelain/vitreous enamelled articles. France (Fiche MCDA n°2 (V01 – 01/05/2016)) covers migration of some additional metals Cr^{VI} Al As Co Suppliers declaration of conformity
How does the current way of working function	Carbon steels are used for specific food contact applications	Different approaches depending on country and national legislation and/or national guidelines. Use of French and German rules as a basis and locally adapt when necessary.	Current EU legislation covers only release of Pb and Cd from ceramic articles in their finished state [also when (ceramic) articles are glazed, enamelled and/or decorated]. French legislation covers migration of some additional metals (Cr^{VI} Al As Co). Test methods for Pb, Cd and other metals have been evaluated by JRC.
What are the advantages of the current way of working	Provides science-based consumer safety Widely used across sectors	Easy to process tests	Provides consumer safety for Pb and Cd, but in draft Regulation: lower limits for Pb and Cd are discussed.
What are the disadvantages of the current way of working	Most regulated category of FCMs, but still deviating national legislation (e.g. for non-regulated or based on safeguard clause). Frequent subsequent changes and new issues (like NIAS, oligomers, EDCs in plastics, Nano plastics, etc) difficult to follow for SMEs. Most regulated FCM should mean confidence by NGOs and consumers, but all new issues create new lack of confidence.	Standardised EU test methods often missing Many different national provisions Problems with mutual recognition Lack of communication in supply chain Efforts are still needed to control imports Even more complex when combined with other FCMs	Not the same rules everywhere: Additional national legislations (e.g. France) can regulate what is not regulated at EU level. Present Directives allow "more severe" national legislation during transposition How to comply for FCAs made of ceramics and other FCMs having different legally imposed SMLs and SRLs for same metal?
Comments	FEC would like to have EEA-wide uniform legislation for all FCMs and FCAs that also equally applies to all imports (level playing field). REACH/CLP regulations will have strong impacts although safety is already demonstrated via food contact regulations or recommendations. Adjust tests conditions to realistically overestimate conditions of use.	FEC would like to have EEA-wide uniform legislation for all FCMs and FCAs that also equally applies to all imports (level playing field) REACH SVHC candidate list may apply	FEC would like to have EEA-wide uniform legislation for all FCMs and FCAs that also equally applies to all imports (level playing field)

	Measures used by FEC Members (Page 3)		
Material Type	**FEC Enamels**	**FEC Non-stick PTFE coatings**	
What European or Member State Legislation is in place for the sector	Framework 1935/2004 (but enamels not mentioned in Annex 1) GMP 2023/2006 Partly covered by Directive 84/500/EEC (ceramic articles) + Directive 2005/31/EC Draft Ceramics regulation (covering also enamels and glass under discussion) Dutch Warenwet. KEMA and TNO. Austria: GESG $8. OFI Technologie und Innovation, AGES, LVA Labor Germany: LFGB (version 30.06.18). TUV (SueD), Hygiene Institut Gelsenkirchen (Hyg). Italy: Ministry of Health Note 20072 dated May 20th 2014	Framework 1935/2004 GMP 2023/2006 EU and national legislation regarding BPA and epoxides derivatives when relevant Dutch (Warenwet, PTFE) Belgium (RD Varnishes & coatings) France (Fiche MCDA n°1 (V02 – 01/04/2017) sheet 2a and 5b) covers organic coated metals	
What Guidelines or other means of demonstrating safety/compliance are in place	As far as covered by Directive 84/500/EEC (ceramic articles) + Directive 2005/31/EC which have set SMLs + analytical methods for Pb & Cd from glass, ceramics and porcelain/vitreous enamelled articles. Enamelled electric/electronic kitchenware: RoHS Directive 2002/95/EC applies Certain REACH restrictions apply Suppliers declaration of conformity	Regulation 10/2011 for SSA Recommendation AP(89) for inorganic pigments Germany: BfR LI US FDA CFR21 177.1550 JRC Guidelines on testing conditions for articles in contact with foodstuffs. (2009) Suppliers declaration of conformity or self- risk assessed substances	
How does the current way of working function	Migration is tested with different methods (time, temperature, simulant) and different limits are used (based on current usage and exposure of consumer).	In the absence of harmonised legislation, this is the most effective method of demonstrating compliance with 1935/2004.	
What are the advantages of the current way of working	Provides consumer safety for Pb and Cd, but in draft Regulation: lower limits for Pb and Cd are discussed.	Provides science-based consumer safety.	
What are the disadvantages of the current way of working	Standardised migration limits and test methods are missing at EU level. Use of acetic acid in hot conditions must be still confirmed (against citric acid) Introduction of different national legislations may lead to problems with mutual recognition. The above may lead to lack of confidence by customers, NGOs and consumers. Efforts are still needed to control imports of enamelled FCAs.	Standardised test methods missing at EU level; 10/2011 adapted differently by FCA manufacturers Even more complex when combined with other FCMs Efforts are still needed in improving communication through supply chain Efforts are still needed to control imports Need to follow closely the evolution of scientific knowledge of this product category: very challenging for SMEs	
Comments	FEC would like to have dedicated EEA-wide uniform legislation for all FCMs and FCAs that also equally applies to all imports (level playing field) Expected technical difficulties with formulation if list of restricted metals is extended requiring adaptation time for FCMs and FCAs manufacturers Define tests conditions to realistically overestimate conditions of use.	FEC would like to have dedicated EEA-wide uniform legislation for all FCMs and FCAs that also equally applies to all imports (level playing field). Continuous efforts to maintain consumers' confidence. REACH and POP Restrictions may apply. Revision of CoE/EDQM ongoing Work of FEC WG on "non-stick coating test methods" not yet finished but following recommendations by CoE/EDQM rapporteurs	

	Measures used by Members of Flexible Packaging Europe and of The Alliance for Beverage Cartons and the Environment (Page 1)				
Material Type	**General**	**Plastics**	**Colourants**	**Paper**	**Aluminium**
What European or Member State Legislation is in place for the sector	Framework 1935/2004. GMP 2023/2006.	Plastics 10/2011. Recycled 282/2008.	Germany BfR Recommendation IX. France "Circulaire No 176 du 2 Décembre 1959" on pigments and colorants. France Draft Order notified to the Commission on the 6th August 2004 under reference 2004/328/F.	Germany BfR Recommendation XXXVI.	
What Guidelines or other means of demonstrating safety/compliance are in place	FPE Code for Good Manufacturing Practices (GMP) for Flexible and Fibre-Based Packaging for Food. FCA Guidelines on "Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) …". ILSI "Guidance on best practices on the risk assessment of non-intentionally added substances (NIAS) in food contact materials and articles".	Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain. Draft "Technical Guidelines for Compliance Testing". Draft "Practical guidelines on the application of migration modelling for the estimation of specific migration".	Council of Europe Resolution AP (89) 2 on colourants in plastic materials. FDA 21 CFR 178.3297.	Council of Europe policy statement (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs (version 3 of 11 December 2007). CEPI Industry Guideline for the Compliance of Paper and Board Materials and Articles for food contact. CEPI "Good Manufacturing Practice for the Manufacture of Paper and Board for Food Contact". FDA 21 CFR 176.170 or 176.180.	Compositional compliance with one or more of the following standards: EN 573-3, EN 601, EN602, EN 14287, EN 14392. Council of Europe Resolution CM/Res(2013)9 on metals and alloys used in food contact materials. FDA 21 CFR 178.3910. Code for Good Manufacturing Practices for the European Aluminium Industry.
How does the current way of working function		Legal compliance supported by the guidelines etc listed above.	Ideally: 1. Well defined structure (specific material grades and sources) and knowledge of application (food type, S/V ratio, time & temperature of use). 2. Raw material suppliers declare that, under defined conditions of use, their materials are safe to use in FCM structures together with the identity of any migratable substances for which there are restrictions (e.g. migration limits). Such declarations will generally be based on, and will quote, EU or national legislation or other guidelines. 3. In some cases, it is possible for raw material suppliers to certify that their product meets all restrictions. 4. To demonstrate compliance with Art. 3 of the Framework, the finished FCM is shown to meet the restrictions applicable to each substance. This may be done by using supplier certification, "worst case calculation", migration modelling or migration testing using the appropriate conditions of use (food type, time, temperature). TTC and similar techniques may be used in the case of NIAS. 5. The conditions of safe use are defined to the food packer.		
Advantages of the current way of working	When done properly throughout the entire supply chain, it delivers a high level of confidence in FCM safety. It allows different material types to be combined so as to make a wide range of structures which can fulfil packaging requirements efficiently.				
Disadvantages of the current way of working	Wide range of regulations require a high level of expertise both for companies to operate and for enforcement authorities to understand. National measures can contradict each other and there are no harmonised test methods. Hence inappropriate test methods can be used with misleading results. Few legal obligations to provide the necessary information about substances, especially for unregulated material types, leading to varying degrees of information (SML substances, concentrations thereof, etc.) which are transmitted within "DoCs" for unregulated as well as regulated material types. This often has to be negotiated on a time-consuming business-to-business basis. It also means the same compliance work is done unnecessarily redundantly on different levels of the chain. Missing of official guidelines to assess NIAS leads to uncertainty in the chain (up to packer) how to assess substances.				
Comments					

	Measures used by Members of Flexible Packaging Europe and of The Alliance for Beverage Cartons and the Environment (Page 2)					
Material Type	**RCF**	**Printing Inks**	**Coatings**	**Adhesives**	**Waxes**	**Active & Intelligent**
What European or Member State Legislation is in place for the sector	RCF Directive 2007/42.		Plastics 10/2011. Epoxy Derivatives 1895/2005. BPA 2018/213. Germany BfR Recommendation XIV. Germany BfR Recommendation XXI. Dutch Warenwet (Chapter 10). Belgium Royal Decree of 25th September 2016.	Plastics 10/2011. Germany BfR Recommendation XIV- Part A. Germany BfR Recommendation XXVIII. Germany BfR Recommendation XXV.	Plastics 10/2011.	Active & Intelligent 450/2009.
What Guidelines or other means of demonstrating safety/compliance are in place		EuPIA" Exclusion Policy for Printing Inks and Related Products" (Compliance by supplier). EuPIA "Good Manufacturing Practice (GMP) Printing Inks for Food Contact Materials" (Compliance by supplier). EuPIA "Guideline on Printing Inks applied to the non-food contact surface of food packaging". Swiss Ordinance 817.023.21 (Listing in Annex 2 and/ or 10).	Council of Europe Resolution AP (2004)1 on coatings intended to come into contact with food – version 3 of 12 February 2009. Council of Europe Resolution AP (2004) 5 on silicones used for food contact applications. FDA 21 CFR 175.300. FDA 21 CFR 175.320.	FDA 21 CFR 175.105. FDA 21 CFR 177.1390. FEICA Guideline on Good Manufacturing Practices in the Production of Adhesives and Sealants Intended for Food Contact Materials.	European Wax Federation position paper of July 2009.	EU Guidance ... on active and intelligent materials and articles intended to come into contact with food.
How does the current way of working function	Ideally: 1. Well defined structure (specific material grades and sources) and knowledge of application (food type, S/V ratio, time & temperature of use). 2. Raw material suppliers declare that, under defined conditions of use, their materials are safe to use in FCM structures together with the identity of any migratable substances for which there are restrictions (e.g. migration limits). Such declarations will generally be based on, and will quote, EU or national legislation or other guidelines. 3. In some cases, it is possible for raw material suppliers to certify that their product meets all restrictions. 4. To demonstrate compliance with Art. 3 of the Framework, the finished FCM is shown to meet the restrictions applicable to each substance. This may be done by using supplier certification, "worst case calculation", migration modelling or migration testing using the appropriate conditions of use (food type, time, temperature). TTC and similar techniques may be used in the case of NIAS. 5. The conditions of safe use are defined to the food packer.					
What are the advantages of the current way of working	When done properly throughout the entire supply chain, it delivers a high level of confidence in FCM safety. It allows different material types to be combined so as to make a wide range of structures which can fulfil packaging requirements efficiently.					
What are the disadvantages of the current way of working	Wide range of regulations require a high level of expertise both for companies to operate and for enforcement authorities to understand. National measures can contradict each other and there are no harmonised test methods. Hence inappropriate test methods can be used with misleading results. Few legal obligations to provide the necessary information about substances, especially for unregulated material types, leading to varying degrees of information (SML substances, concentrations thereof, etc.) which are transmitted within "DoCs" for unregulated as well as regulated material types. This often has to be negotiated on a time-consuming business-to-business basis. It also means the same compliance work is done unnecessarily redundantly on different levels of the chain. Missing of official guidelines to assess NIAS leads to uncertainty in the chain (up to packer) how to assess substances.					
Comments						

<table>
<tr><td></td><td colspan="6">Measures Used by Association Members</td></tr>
<tr><td>Association</td><td colspan="6">Paper & Board industry (CEPI, ECMA, FEFCO)</td></tr>
<tr><td rowspan="2">What European or Member State Legislation is in place for the sector</td><td>EU general</td><td>Paper & Board</td><td>Inks</td><td>Varnishes</td><td>Adhesives</td><td>Window film</td></tr>
<tr><td>Framework 1935/2004.
GMP 2023/2006.</td><td>Germany : BfR Recommandation XXXVI
France : DGCCRF Fiche Matériaux organiques à base de fibres végétales
Italy: DM of 21.03.1973
Dutch Warenwet regeling verpakkingen en gebruiksartikelen, Chapter 1</td><td>Swiss Ordinance 817.023.21</td><td>Plastics Regulation No 10/2011
BfR Recommendations XIV (and XLI)
Swiss Ordinance 817.023.21
Spanish Royal Decree 847/2011
FDA 21 175.300</td><td>BfR Recommendation XXVIII
FDA 21 175.105</td><td>Plastics Regulation No 10/2011</td></tr>
<tr><td>What Guidelines or other means of demonstrating safety/compliance are in place</td><td colspan="6">Paper & Board:
“Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact”, 2010 (revised 2012), last update 2018 (to be published soon).
CEPI “Good Manufacturing Practice for the Manufacture of Paper and Board for Food Contact”, 2010.
ECMA Good Manufacturing Practice Guidance, 2011 (revised 2013).
FEFCO Good Manufacturing Practice Standard, 2003 (revised 2006).
Inks and varnishes: EUPIA Guidelines on printing inks applied to the non-food contact surface of food packaging.
Adhesives: FEICA Guidelines.</td></tr>
<tr><td>How does the current way of working function</td><td colspan="6">Two-ways and effective communication in the supply chain is key to ensure safety of the paper & board material/article. Downstream operators provide information on the intended food contact use, supply and storage conditions and time. Upstream operators inform about compliance of the material and possible restrictions to be followed during converting or use.
The paper producers perform risk assessment, considering the substances added, formed or present in the material and provide compliance information in the supply chain. The producers of the finished articles (i.e. paper converters) perform their own risk assessment using the information received from the paper producers and other material suppliers (e.g. inks, adhesives).
The BfR Recommendation XXXVI is the one mostly used by the paper & board sector.</td></tr>
<tr><td>What are the advantages of the current way of working</td><td colspan="6">Full commitment of the paper & board supply chain to ensure safety of the food contact materials and articles it places on the market. Ability to demonstrate compliance with the existing requirements. This is paramount in the absence of harmonised EU legislation for the sector.</td></tr>
<tr><td>What are the disadvantages of the current way of working</td><td colspan="6">Lack of specific EU legislation on paper & board.
Divergent national requirements and new initiatives.
Mutual recognition principles rarely applied.
Limited or no control over the imported goods in paper & board packaging.
Customers and retail are easily confused. Plastic rules often applied to paper & board by labs.
High economic burden resulting from the need to use additional resources (cost, time, etc.) to comply with many different non-harmonised national legislations; this is particularly significant for the SMEs.</td></tr>
<tr><td>Comments</td><td colspan="6"></td></tr>
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