FCM Working Group

9-10 November 2020

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agenda

9 November

- 16th Amendment
- State of play (15h00)
  - FCM Inception Impact Assessment
  - Chemicals strategy
  - Ceramics
- Controls Regulation (15h30)
- Monitoring Recommendation (15h45)
- Styrene
  - Introduction (16h30) / Industry (16h45)

10 November

- Styrene discussion (**09h00**)
- Future amendments R 10/2011 (09h45)
  - Biocides
  - Other matters shortly
    - Substances
    - Risk Management Policy / Other Matters
- Discussion DoC template (10h30)
- AoB (11h10)
  - Personal data protection / Bamboo / AIM
  - EDQM (11h40)
  - Industry cross sector group (12h15)

European Commission

16th amendment

to Regulation (EU) No 10/2011

European Commission

Procedure

- Thank you for your comments – to a large extent these have been taken into account
- 16th amendment nevertheless slightly delayed
  - not to be voted during PAFF next week
  - we will consider FCM PAFF late December / Early January
- Split in 3 texts
  - remaining part of 16th amendment
  - phthalate limit in rubber
  - styrene
- 2021
  - **substances**: only amendment foreseen for PAFF in February
  - **template:** possibly also in February – depends on recycling + outcome discussion
  - **other matters:** later – need additional time for discussions – overview tomorrow
  - however, **recycling amendment has high priority**

Present draft text

- Main text
  - Microbial fermentation
    (also change to Annex)
  - Off-cuts and scraps (Article 10(1))
  - Labelling of restrictions (Article 10(3))
    - related to column 10 of table 1 of Annex I
- Transition
  - separated into two Articles – editorial changes
  - check legal service
- Rubber and Styrene
  - no longer part of 16th amendment
- Annex
  - Wood flour, salicylic acid and lauric acid, vinyl ester to be deleted
  - German language BPA
  - Phthalates
    (but no limits for Rubber FCMs)
  - Update to PHBH (1059)
  - new substances 1078, 1080 (793, 822)
  - Cheese assignments
  - **NEW** (discussion NRL DK – EURL):
    - OM0 in coverage OM8 and OM9 (clarification)
    - OM6 also worst case for D1 (correction)
- We will provide you with updated text – legal check launched next week

State of Play

- FCM Inception Impact Assessment
- Commission policy: Farm to Fork, Circular Economy Action Plan, Chemicals Strategy
- Ceramics

European Commission

FCM Evaluation

Evaluation still ongoing but indicates several issues with functioning of the current EU legislation and absence of EU specific measures

Title	Document
JRC "baseline report" on non-harmonised food contact materials in the EU: regulatory and market situation	Baseline report
Ecorys study supporting the Evaluation of Food Contact Materials (FCM) legislation - (Regulation (EC) No 1935/2004)	Final report
Executive summary to the study supporting the Evaluation of Food Contact Materials (FCM) legislation - (Regulation (EC) No 1935/2004)	Executive summary (EN); Sommaire et résumé (FR) Zusammenfassung (DE)
Annexes to the study supporting the Evaluation of Food Contact Materials (FCM) legislation - (Regulation (EC) No 1935/2004)	Annex 1 State of Play; Annex 2 Case Studies Annex 3 Methodological Annex and Quantification of costs Annex 4 Methodological Annexes - Composite Index
BTSF Workshop report on strengthening Member States' response to Union audits on FCM	Report
Study on the use of compliance documentation in official controls and in the supply chain	Pending

European Commission

New FCM initiative

Quarter 4 2020: Inception Impact Assessment (roadmap) setting out problem definition and broad options. 4 week feedback period. Under internal validation

Quarter 1 2021: Public Consultation on Impact Assessment setting out proposal in more detail.

Quarter 4 2022: Planned Commission adoption.

Related EU initiatives: Farm to Fork

Food packaging plays a key role in the sustainability of food systems. **The Commission will revise the food contact materials legislation** to improve food safety and public health (in particular in reducing the use of hazardous chemicals), support the use of innovative and sustainable packaging solutions using environmentally-friendly, re-usable and recyclable materials, and contribute to food waste reduction. In addition, under the sustainable products initiative announced in the CEAP, it will work on a legislative initiative on re-use in food services to substitute single-use food packaging and cutlery by re-usable products.

Q4 2022: Proposal for a revision of EU legislation on Food Contact Materials to improve food safety, ensure citizens' health and reduce the environmental footprint of the sector

Related EU initiatives: Circular Economy Action Plan

Packaging

- Reducing (over)packaging and packaging waste, including by setting targets and other waste prevention measures;
- Driving design for re-use and recyclability of packaging
- Considering reducing the complexity of packaging materials, including the number of materials and polymers used.

Plastics

- Use of biodegradable or compostable plastics
- New Directive on Single Use Plastic Products

Related EU initiatives: Chemicals Strategy for sustainability

Materials

- “Safe and sustainable” by design;
- Non-toxic material cycles and clean recycling

Substances

- Banning the most harmful chemicals in consumer products - allowing their use only where essential
- Criteria for EDs applicable to FCMs
- Account for combination effects of chemicals

Assessment

- Coordination and agreement on hazard identification and risk assessment

Ceramics

- Stakeholder consultation strategy
- Study to support the IA – Evaluation finished
- Next steps

Official Control Regulation

Accreditation and designation

European Commission

Is accreditation an issue?

- Article 37(5) requires that OCLs (and NRLs) **are accredited for methods** they actually use in official controls

BUT

- N° of substances, matrices and testing conditions in FCM
- Accreditation varies across MS

SO

- Is accreditation an issue?
- Is a derogation needed?

Approach proposed

- List of designated official control laboratories across MS and which accredited methods
- Harmonisation of flexible scope accreditation – per group of substances
- Network of specialised OCLs and NRLs.

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Monitoring Recommendation

- Recommendation (EU) 2019/794
- Overview of results from the coordinated control plan establishing the prevalence of certain substances migrating from FCMs

Summary

- Purpose to coordinate controls on FCM
- 21 Member States participated + NO/ EFTA
- Most results relate to PAAs, formaldehyde and melamine, bisphenols, fluorinated compounds, phthalates and metals
- Total of around 3800 samples
- Issues with reporting of data

PAAs – Overview of sampling

- Data submitted by 15 countries
- 578 samples, total of 4656 analytical data points
- Total PAA plus many different individual substances e.g. 4,4´-oxydianiline, aniline, 2,4-diaminotoluene, benzidine, 4-chloroaniline, phenylenediamine
- FCMs tested predominantly repeat use plastics (nylon kitchen and table-ware) or paper and board packaging (e.g. paper straws, serviettes)
- Substances most commonly reported on were:
  - 4,4 methylenedianiline (202)
  - Aniline (184)
  - 2,4 toluendiamine (168)

PAAs – Analysis of results

- Samples
  - 556 samples out of 578 determined or assumed to be compliant* (96,2%)
  - 22 samples from which at least one data point (e.g. analyte) was non-compliant (3,8%)
- Analytical data points
  - 3281 of the 4656 analytical data points were reported as compliant
  - 158 of the 4656 analytical data points were reported non-compliant. Most frequently: 4,4 methylenedianiline (18), aniline (11), 4-chloroaniline (10), 4,4-oxydianiline (10)
  - 1217 analytical data points did not indicate whether compliant or not (e.g. cell was not completed)
  - 2187 analytical data points did not include any values for migration (or quantity) measured (< LOD or <LOQ?)

* Compliance assumed if not reported non-compliant (i.e. “No” or “U”)

Formaldehyde and Melamine – Overview of sampling

- Data submitted by 20 countries
- 744 samples, total of 1944 analytical data points
- In addition to formaldehyde (FCM 98) and melamine (FCM 239), migration of hexamethylenetetramine (FCM 196) was tested (group SML with formaldehyde) in 7 samples
- Vast majority of FCMs tested were plastic bowls, cups, plates including melamine-bamboo

Formaldehyde and melamine – Analysis of results

- Samples
  - 646 samples out of 744 determined or assumed to be compliant* (86,8%)
  - 98 samples from which at least one data point (e.g. analyte) was non-compliant (13,2%)
- Analytical data points
  - 1442 of the 1944 analytical data points were reported as compliant
  - 377 of the 1944 analytical data points were reported non-compliant.
    Melamine (196) and formaldehyde (181)
  - 125 analytical data points did not indicate whether compliant or not
    (e.g. cell was not completed)
  - 29 analytical data points did not include any values for migration (or quantity) measured

* Compliance assumed if not reported non-compliant (i.e. “No” or “U”)

Phenol - Overview of sampling and analysis of results

- 22 samples submitted by 3 countries
- Most FCMs either coated/ printed packaging or plastic/ bamboo tableware
- 17 of the samples determined to be compliant (77,3%)
- 5 samples of plastic/ bamboo tableware determined to be non-compliant based on 3rd extraction test (initial(?) migration < LOQ/ LOD)

Bisphenols – Overview of sampling

- Data submitted by 11 countries
- 446 samples, total of 1673 analytical data points
- 20 different substances, including BPA, BPS and BADGE/ BPA derivatives
- FCMs tested were mostly packaging but also some food samples
  - Examples include paper bags, plastic bottles, jars, metals lids, beer cans.
  - Foods tested included tomato sauce, tinned fish, cheese, and olives.

Bisphenols – Analysis of results

- 438 samples out of 446 determined or assumed to be compliant* (98,2%)
- 8 samples from which at least one data point (e.g. analyte) (1,8%)
  - 2 samples concerning suspected migration into food from coated cans (Commission Regulation 2018/213)
  - 2 samples concerning migration from laminated paper/ cardboard (Article 3 Regulation 1935/2004 + risk assessment)
  - 3 samples concerning cake boxes, bisphenols and derivatives tested in material with ink in direct contact with food
  - 1 sample concerning content in colander/ sieve (national law)
- 725 of the 1673 analytical data points were reported as compliant
- 948 analytical data points did not indicate whether compliant or not (e.g. cell was not completed)
- 896 analytical data points did not include any values for migration (or quantity) measured

* Compliance assumed if not reported non-compliant (i.e. “No” or “U”)

PFAS – Overview of sampling

- Data submitted by 3 countries
- 224 samples, total of 2147 analytical data points
- 36 individual substances reported including PFOA and PFOS
- FCMs were packaging, paper and board or multi-layer materials
  - Examples: paper bags, fast food cartons (big mac box, pizza box, popcorn bucket), bakeware (baking tin, muffin moulds, baking paper)
  - Food tested included fish sticks, pastries

PFAS - Analysis of results

- All 224 samples determined or assumed to be compliant*
- However, 10 samples where PFAS was detected in the material (paper and board packaging) (4,5%)
  - Analytical data points (individual or PFAS sum) quantified in ~ 50 out of a total 404 analytical data points covering these 10 samples
  - Unclear if these findings rendered them non-compliant (not indicated)

* Compliance assumed if not reported non-compliant (i.e. “No” or “U”)

Metals – Overview of sampling

- Data submitted by 18 countries
- 1127 samples, total of 5640 analytical data points
- 33 different substances were recorded, including Lead, Cadmium, Nickel, Aluminium, Iron, Copper, Zinc, Tin
- FCMs mainly metal-alloy and ceramic articles for re-use, some packaging

Metals – Analysis of results

- Samples
  - 1089 samples out of 1127 determined or assumed to be compliant* (96,6%)
  - 38 samples from which at least one data point (e.g. analyte) was non-compliant (3,4%)
- Analytical data points
  - 4198 of the 5640 analytical data points were reported as compliant
  - 276 of the 5640 analytical data points were reported non-compliant
    Cr (29), Al (26), Ni (23), Pb (18), Cd (17)
  - 1166 analytical data points did not indicate whether compliant or not
    (e.g. cell was not completed)
  - 1854 analytical data points did not include any values for migration (or quantity) measured

* Compliance assumed if not reported non-compliant (i.e. “No” or “U”)

Overall Migration – overview of sampling and analysis of results

- Data submitted by 15 countries: 658 samples and results
- Samples split relatively evenly between
  - kitchenware/ tableware (majority plastic or silicone) e.g. flexible moulds, cups, plates, bowls
  - packaging (plastic and multi-layer plastic) e.g. tubs, heat-shrink bags, films, trays, disposable cups
- 630 of the 658 samples determined or assumed to be compliant (95,7%)
  - 21 samples did not indicate whether compliant or not (no follow-up action recorded)
- 28 of the 658 samples determined to be non-compliant (4,3%)
  - Most bamboo-based tableware

Other substances

- 1 Member States submitted results for 12 samples of silicone FCMs (baking moulds or cooking items) for Free Volatile Organic Compounds
- 5 samples were determined to be non-compliant with national legislation (41,6%)

Reporting issues

- Blank cells
  - Migration or QM/ QMA not indicated
  - No indication of compliance
- Absence of sample numbers (unique identifiers)
- Cell restrictions not respected
- Absence of FCM or CAS numbers
- Consistency of terminology
- Language issues

Reporting spreadsheet circulated October

Member State/ country	Sample no.	Type of FCM	Basic material description	Detailed sample description	Point of sampling	Date of sampling	Country of origin	Substances to be tested	Specific substance name	Short name or abbreviation	
CAS number	Method of analysis	Test type	Migration result or QM/ QMA result	Units (mg/kg or mg/dm²/ mg/6dm²)	Date result generated	Relevant SML, OML or QML	Relevant SML(T)	EU or national legislation or other	Compliant	Description of any follow up action including RASFF ref if relevant	Additional relevant information

- Notes accompanying reporting template on CIRCABC FCM Group

Questions and priorities in 2020

- Phthalates and other plasticisers in rubber, machinery and food processing equipment
- Styrene
- Fluorinated compounds

Styrene

- Introduction of issue
- Overview of results from the coordinated control plan establishing the prevalence of certain substances migrating from FCMs

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Overview

- Introduction of the issue
- Position Industry (PlasticsEurope)
- Discussion (Tomorrow)

European Commission

Possible limit for styrene

- assign 'ND'
  - i.e. styrene shall not be detectable with a method with a limit of detection of 10 ppb
  - Inter-laboratory Comparison being prepared
- In addition: testing at real S/V ratio will always be required
  - derogations in article 17(2) shall not apply
  - to account for small containers

"193	24610	0000100-42-5	Styrene	no	yes	no	ND		The derogations provided for in Article 17(2)(a) and 17(2)(d) shall not apply and migration testing shall be done using a surface to volume ratio representative of the real surface to volume ratio	"

Key EFSA conclusions

The Panel concluded that, based on the data provided in the IARC Monograph and by the industry, a concern for genotoxicity associated with oral exposure to styrene cannot be excluded.

- **For the majority of the foods packed in styrenic plastics, migration is below 10 µg/kg,** but in some cases, it ranged up to 230 µg/kg: migration is high when the contact is with fatty foods and/or with high S/V ratios of the FCM.
- **In standard testing using food simulants, migration of styrene may reach several thousand µg/kg.** Such testing refers to foreseeable worst-case uses and does not reflect typical exposure.
- Dietary exposure of the consumers to styrene migrating from styrenic plastics was estimated in the order of 0.1 µg/kg bw per day. It is in the same range as exposure from styrene present in foods as such.
- The dietary exposure (food component plus migration from styrenic plastics) for children is slightly higher than that for adults.
- In the general population, the total dietary exposure is similar or lower than that by inhalation.
- Presently, the only limitation of the styrene migration is linked with the sensory properties of styrene (it must not bring about a deterioration in the organoleptic characteristics; Article 3, Regulation (EC) 1935/2004). Reported odour and taste thresholds ranged from 4 to 6,000 µg/kg, depending on the type of the food.
- Free styrene content in the plastic can vary by more than two orders of magnitude, which in turn strongly influences migration levels.
- No classification of polystyrenes and styrene copolymers by styrene migration was possible due to the variability in the levels of styrene within a given type of styrene (co)polymer.
- **The IARC conclusion, which is based on studies on high-dose occupational exposures by inhalation and animal studies, also mainly by inhalation, pertains to hazard identification.Therefore, the Panel considered that the IARC evaluation cannot be directly applied to the evaluation of risks for consumers from the oral exposure to styrene associated with FCM.**
- The implications of styrene oral exposure via FCM on the health of consumers should be evaluated based on a comprehensive analysis of the reliability and relevance of all available experimental and human findings on styrene genotoxicity, with consideration of toxicokinetic aspects, ultimately enabling a qualitative and quantitative genotoxic risk estimate associated with the oral exposure to styrene.

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Reasoning

- EFSA cannot exclude genotoxicity from oral consumption
  - Based on limited data set – IARC monographs + industry exposure data
  - needs to study toxicology comprehensively, expected to take > 2 years.
- → precautionary measure needed
  - No health based guidance value (such as TDI) → exposure reduction
- Overall exposure ~ 24 µg/day
  - FCM 6 µg but with outliers exceeding 200 µg, not linked to specific styrenics
  - 20% allocation factor → SML 5 µg/kg food
  - controls at that level cannot presently be achieved → 10 µg/kg LoD
  - most styrene based plastics below 10 µg/kg → burden mostly limited to quality control

State of Play

- Sufficient indication regarding toxicity of styrene for regulatory action – but, no health based guidance value
  - Genotoxicity cannot be excluded
  - In addition suspected to be Toxic to Reproduction (REACH)
- Strong reaction from industry → major impact expected

  'it would be unjustified and create a precedent to assume genotoxicity and apply corresponding risk management measures'
- will become stand alone initiative;
  - Initially to be included under 16th amendement, but in view of possible impact it will require its own time-line and additional consultation

Follow-up

- Main issue may be migration testing
  - use of styrene not subject to a limit →testing may not have taken due account of specific use → too severe testing
  - however some materials may remain problematic, also if tested appropriately
- Presently foreseen course
  - take pre-cautionary measure limiting FCM exposure to 20% of overall exposure; no identified basis for different approach so-far
  - consider FRF – fatty foods are the most problematic, but are less consumed
  - consult industry on styrene use and testing methods →in order to set transition time
  - mandate to EFSA to re-evaluate styrene and to establish a health base guidance value (if possible)
- consider regulating use for other materials as well; wide use in rubber, coatings and adhesives

Some data from a MS

Description	Testing conditions	Styrene [mg/kg]
Glass PS	2h@70°C in oil	0.066
Plate PS	2h@70°C in oil	0.15
Glass for champagne PS	2h@70°C EtOH 20%	0.026
Glass for wine PS	2h@70°C EtOH 20%	0.012
Glass for beer PS	2h@70°C EtOH 50%	0.041
Glass for wine PS	2h@70°C EtOH 20%	0.041
Glass for liquor PS	2h@70°C EtOH 50%	0.025
Glass for wine PS	2h@70°C EtOH 20%	0.079
Glass for champagne PS	2h@70°C EtOH 20%	0.015

- None of these items would be compliant (ND=0.01 mg/kg)
- However,
  - In most cases, 40°C could be sufficient, if labelled for cold drinks only
  - FRF would help further
- Note SUPD
  - dis-allows single use plastic plates
  - affects expanded PS food containers (but not packaging)

Styrene discussion

- Is precautionary action justified now?
- If yes, what action?
  - the 10 ppb ND limit?
  - another limit?
  - another approach?
- What lessons did we learn about testing conditions?
  - Do the alleged large differences between testing and real exposure really occur?
  - Is the Regulation not clear regarding testing conditions?
  - Or, do they approximate, albeit conservatively, the true exposure

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Future matters R 10/2011

- Biocides
- Other matters

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Time-line

- As soon as possible
  - Styrene amendment
  - DoC Template – next main agenda point
- February
  - Text concerning only Substances
- Later in 2021
  - biocides
  - SML setting
  - risk assessment policy

Biocides

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Possible occurrence of biocides in FCMs

PT 4 (food and feed area)

- Substances e.g. Ag in chopping boards, food preparation and storage surfaces (e.g. fridge) in domestic and professional manufacturing

PT 6 (preservatives for products during storage)**, 7** (film preservatives) and **12** (slimicides)

- Polymer dispersion agents (processing aids excluded?)
- Slimicides in paper manufacturing

EU FCM legislation – specific measures on biocides

Regulation 10/2011 concerning authorisation of biocidal substances

- Authorised list of substances (monomers, other starting substances and **additives** inc biocides intended to function in the final FCM i.e. PT 4). Assessment by EFSA
- Currently listed on a provisional list for which a derogation applies for the need to authorise these substances and subject to national legislation
- Triclosan + 10 silver-based substances, for which EFSA has published positive opinions ~ 2004 – 2005
- Other national rules may apply for other types of materials (e.g. paper and board) and for biocides which remain unintentionally in the final FCM i.e. NIAS

Regulation 528/2012

Article 19 Conditions for granting an authorisation [of a biocidal product]

1(e) where appropriate [….] specific migration limits or limits for the residual content in food contact materials have been established with respect to such active substances in accordance with Regulation (EC) No 1935/2004 of the European Parliament and of the Council

7 Where appropriate, the prospective authorisation holder or its representative shall apply for the establishment of [….] specific migration limits or limits for the residual content in food contact materials with respect to such substances in accordance with Regulation (EC) No 1935/2004.

Regulation 528/2012

ANNEX II INFORMATION REQUIREMENTS FOR ACTIVE SUBSTANCES

8.16.7. Any other available information that is relevant

- It may be appropriate to include information on migration into food, especially in the case of treatment of food contact materials

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Current situation

- 11 substances remain subject to national legislation for plastic FCM under Regulation 1935/2004. these substances are also subject to Reg 528/2012
- For anything new, business operators should apply twice:
  - for authorisation of new substances under Regulation 1935/2004 (e.g. for plastics)
  - for approval and authorisation (including treated articles) under Reg 528/2012
- There is **no format or procedure for application** set out in either Regulations
  - to allow prospective applicants to request the setting of an SML
  - in accordance with Regulation 1935/2004, the derivation of an SML would logically come from a comprehensive assessment of the substance in FCM by EFSA

Transparency Regulation (Regulation (EU) 2019/1381)

- Four Pillars
  - Quality & Reliability of studies
  - Transparency of EU risk assessment
  - Sustainability and governance of EFSA
  - Improved risk communication
- **Consequence:** studies/data supporting any request for a scientific output, including applications for authorisations, are:
  - to be made public proactively and automatically, in an easily accessible format through EFSA's website,
  - early on in the risk assessment process (i.e. when an application is found valid or admissible)
  - except for duly justified confidential information

Three possible options for integration

1. Assessment by EFSA and basis for SML **prior** to the biocidal product authorisation procedure i.e. after the approval of PT4
2. Assessment by EFSA and basis for SML **during** the assessment of the biocidal product for authorisation
3. Assessment by EFSA and basis for SML **after** to the biocidal product authorisation procedure (RMS has already concluded)

- Comments so far from only 3 MSs

Challenges

- Legal basis
- Exchange of information between rapporteur MS/ ECHA and EFSA
- Time constraints (12 months)

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Other On-going work on Regluation (EU) No 10/2011

Risk Management Policy

Re-evaluations to determine a possible SML

Other matters

Risk Assessment Policy

- Presently unclear mandate for risk assessment
- Discussion with EFSA whether to define a RM Policy
- Basis is Codex Manual
- Will be integrated in Article 5.

'…RISK ASSESSMENT POLICY

13. Determination of risk assessment policy should be included as a specific component of risk management.

14. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.

15. ***The mandate given by risk managers to risk assessors should be as clear as possible.***

16. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

RISK ASSESSMENT

17. ***The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy****. The output form and possible alternative outputs of the risk assessment should be defined…'*

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Re-evaluations to determine a possible SML

- EFSA was asked to set priorities for the re-evaluation of substances in Annex I to Regulation (EU) No 10/2011
- Priority groups for substances for which EFSA considered that re-evaluation is needed
  - High priority: Two substances addressed under 16th amendment + styrene
  - Medium priority: 102 substances
  - Low priority: 179 substances
- Further prioritisation of medium and low priority substances; based on risk management:
  - on-going activities / new data under REACH indicating higher priority
  - volatility (not covered by the OML test)
  - usage – as far as we can assess
  - expected workload EFSA
- Same approach as for the two high-priority substances: delete and re-apply

Other future activities on R 10/2011

- No further plans for now – wait for evaluation
- Regular substances updates continues
- Any views? Let us know

- (DoC Template is next agenda point)

DoC template

In support of Regulation (EU) No 10/2011

- Relevant also for Regulation (EC) No 282/2008
- Posibly other legislation

European Commission

DoC template

- The template should provide:
  - A uniform basis for enforcement and exchange of information in the supply chain
  - A first step towards a digital DoC
- We consulted you to prepare short discussion today
- Main questions:
  - Is this – in general – the good way forward in your view?
  - Is the structure good for its purpose – missing/superfluous elements?
  - Does this version adequately support R 10/2011?
  - Views on mechanism for proprietary information
- More detailed consultation to follow, also with Industry

European Commission

Structure: 5 sections

- Pre-amble, general and specific rules
- Sections:
  1. Identification
  2. Compliance information
  3. Information for the users of the product (including end-users)
  4. Signature
  5. Annexes
- Maximum field lengths
  - to ensure DoC stays relevant, concise and clear
  - to facilitate digital DoC

Pre-Amble

- Rules on the use of the DoC
  - number of characters
  - possibly further administrative rules needed;
- registration number – to contact competent authority
- use of sections 2.3 and 2.4 – how to use, which substances
- Non-Disclosure Agreements
- Signing
- Digital documents

Section 1

(2) *the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;*

DECLARATION of COMPLIANCE with REGULATION (EU) 10/2011					
I, the undersigned in section 4 declare in name of [ADD NAME OF Manufacturer] as identified in section 1.1, that the plastic material identified in section 1.2 was produced in accordance with Regulation (EU) No 10/2011. The product to which this declaration applies is suitable for use in contact with food, provided it is used in accordance with the restrictions set out section 3 of this declaration, to which purpose I provided adequate instructions in this declaration, and labelling on the product. Hereby I declare the contents of this declaration is correct to the best of my knowledge and in compliance with Regulation (EU) No 10/2011.					
Section 1 Identification					
1.1 **Manufacturer**		1.2 **Plastic product**		1.3 **competent authority**	
1.1.1 name	50	1.2.1 tradename / designation	50	1.3.1 name	50
1.1.2 address	100	1.2.2 Production stage	☐ Intermediate ☐ final* (check one)	1.3.2 address	100
1.1.3 country	50	1.2.3 other info identifying the product (add image or other additional information to annex in section 5)	100	1.3.3 country or region	50
				1.3.4 reg. number	50
(note – section 2 of Annex IV is omitted – is there really a need for this – can this be done differently?)					

Section 2

Section 2: Compliance information			
2.1 general			
2.1.1	☐ yes	the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004;	
2.1.2	☐ yes ☐ N/A	when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.	
2.2 Specifications on the use of the material or article:			
2.2.1	type or types of food with which it is intended to be put in contact		100
2.2.2	time and temperature of treatment and storage in contact with the food;		100
2.2.3	the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information		100
2.2.4	Limitations on use in final products		100
2.2.5	Other relevant specifications		100

Section 2.3/2.4

2.3 Substances (presence) – only list substances subject to specific restrictions, including NIAS if so

Number	FCM No (if any)	CAS Nr (if any)	Name / other identification / **NDA code**	amount	Unit 1: mg/kg f 2:mg/dm² 3: mg/kg p 4: % w/w	Basis art. 5 or art. 6 **	Dual use	Nano	Table 1 Annex II/ genotoxic
1			50				☐	☐	☐
2							☐	☐	☐
3							☐	☐	☐
4							☐	☐	☐
…			Add additional substances as appropriate				☐	☐	☐

2.4 Substances (compliance) – substance numbers shall be the same as in section 2.3

Number	Aplicable SML	Aplicable SML (T)	Compliant with applicable SMLs	NDA information available	S/V test	Applicable or internal purity specifications	compliant	Other restrictions in table 1 of Annex I	Compliant
1			☐ yes ☐ N/A	☐ yes ☐ N/A		100	☐ yes ☐ N/A	100	☐ yes ☐ N/A
2			☐ yes ☐ N/A	☐ yes ☐ N/A			☐ yes ☐ N/A		☐ yes ☐ N/A
3			☐ yes ☐ N/A	☐ yes ☐ N/A			☐ yes ☐ N/A		☐ yes ☐ N/A
4			☐ yes ☐ N/A	☐ yes ☐ N/A			☐ yes ☐ N/A		☐ yes ☐ N/A
…			☐ yes ☐ N/A	☐ yes ☐ N/A			☐ yes ☐ N/A		☐ yes ☐ N/A

Section 2.5

2. 5 adequate information not specified in section 2.2, 2.3 or 2.4		
2.5.1	Other adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to this Regulation to allow the downstream business operators to ensure compliance with those restrictions;	1000
2.5.2	Other adequate information relative to the substances which are subject to a restriction in food, marked as 'Dual Use' in section 2.3, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;	1000
2.5.3	Any other information relevant for achieving compliance	1000
2.5.4	Instructions for receiving information under NDA, including address of third party that holds this data, if any – note this information shall always be provided to competent authorities on their request without delay	1000

Section 3

Section 3: instructions and information to users of the product			
3.1	**Instructions to converters** – leave fields empty or indicate N/A if none		
3.1.1	Maximum use (%)	%	(% recycled material in final/intermediate material, if any maximum)
3.1.2	Restrictions of use**	500	
3.1.3	Other instructions	500	
3.2	**Instructions to users** further down the supply chain, including end users – leave fields empty or indicate N/A if none		
3.2.1	Restrictions of use**	500	
3.2.2	Summary of labelling	500	
3.2.3	Other instructions	500	

Section 4 and 5

Section 4: Signature	
4.1 Signature (Add Signature, place, company stamp)	
4.2 Name of person signing	50
4.3 Date of the declaration	
5 Annexes – in case the maximum field length is too short add additional information, please add that to the annex fields below – add a line for every field.	
Field	Information
x.y.z	(unlimited field length, however, per field not more than two pages should be used, images/graphs/tables may be added as required)

Short discussion

- Main questions:
  - Is this – in general – the good way forward in your view?
  - Is the structure good for its purpose – missing/superfluous elements?
  - Does this version adequately support R 10/2011?
- Views on Mechanism for confidential proprietary information
  - substitute substance name with number; substance name in supporting documentation
- Views on register number in National enforcement registries
  - Article 10(2) OCR: *'the competent authorities shall draw up and keep up-to-date a list of operators'*

Short discussion

- How to deal with other materials / multi-material materials and articles
  - section 1, 4 and 5 are generic, section 2 and 3 are material specific
  - this template is for R 10/2011;
  - similar template foreseen for R 282/2008; allows combining sections 2
  - other materials?
  - National legislation?
- Way forward
  - detailed consultation with Member States and Industry
  - appropriate measure

AoB

Personal data protection / Bamboo / AIM guidance

EDQM presentation

Cross sector group