FCM Working Group

11-12 February 2021

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  - no 'hand raising' as we might not see

agenda

11 February – whole day

- present amendments Regulation 10/2011
  - 15th amendment – transition
  - 16th amendment – biocides, transition
- future amendments Regulation 10/2011
  - Styrene
  - Authorisation of substances
  - DoC Template
  - Risk assessment policy
- Recycling amendment (afternoon)
- AoB

12 February

- Ceramics and vitreous materials
  - presentation by contractor
  - next steps
- Revision of FCM rules, update
- AoB
  - SML formaldehyde
  - Bamboo
  - Recommendation
  - EDs (FR)

European Commission

15th + 16th amendment

to Regulation (EU) No 10/2011

European Commission

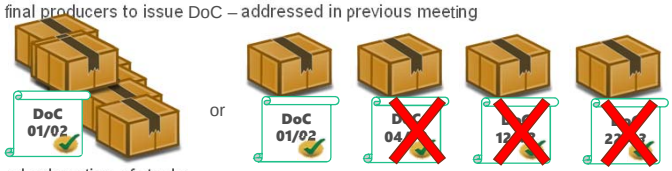
15th amendment

(b) 'placing on the market': the holding of materials and articles for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

- Transition period is raising questions:

  'Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation, and which were first placed on the market before 23 March 2021 may continue to be placed on the market until 23 September 2022 and remain on the market until the exhaustion of stocks.'

  - **First issue:** Intermediate producers may issue DoC too late for final producers to issue DoC – addressed in previous meeting
  - **Second issue:** Issuing – only one time, or for every product?



  - **Third issue:** first placed, continue to be placed on the market, and exhaustion of stocks
    – first placed means it has never been placed before, exhaustion of stocks happens at customers
  - **Fourth issue:** when do you need to update the DoC?
    Article 15(3) – changes in production or composition – but also when product is no longer compliant – see fifth issue
  - **Fifth issue:** Does product compliance includes the DoC?
    Yes, Article 15 and Annex IV apply to product. So if change to Annex IV requires update to DoC, product is no longer compliant.
  - **Sixth issue:** import FCM after 23/03 if the products were produced and already on the market in a third country?
    to consider: placing on the market refers to the EU – can a product not placed on EU market fully comply?

European Commission

16th amendment transition new wording

- It clarifies 'first placed on the market'
- It gives more time for final materials
  - Intermediate materials shorter period
- However,
  - It only solves issues 1 and 2 for 16th amendment
  - It does not apply to the 15th amendment
  - (but, other issues may not need 'solving')
- NOTE: 16th amendment text and approach subject to development and perhaps change – not final!

Article 3
Transitional measures

1. For the purpose of this Article, plastic materials and articles, and products from intermediate stages of their manufacturing shall be considered to be first placed on the market on the date of the declaration of compliance issued in accordance with Article 15 of Regulation (EU) No 10/2011.

(40) In some cases it is not clear to which materials and articles transitional rules apply, and in particular which materials and articles where placed on the market before a transition date and of which the placing on the market may continue for a specified period. Therefore it should be clarified when materials and articles are first placed on the market for the purpose of the Regulation. A convenient date is the date when the declaration of compliance is first issued. Thereafter, business operators should be able to continue placing more materials and articles on the market based on that declaration of compliance. Only when there is a need to re-issue the declaration of compliance, including when the formulation of an material or article has changed, or other information present in the declaration of compliance, for the purpose of the Regulation and the transitional provisions the product should be regarded as a new product, that was placed on the market from the date the updated declaration of compliance was issued. It should however be possible for operators receiving materials or articles legally placed on the market to continue using those until exhaustion of stocks. Therefore it is appropriate to lay down such provisions in this Regulation accordingly.

European Commission

16th amendment specific transitional provision

- The 16th amendment would remove substances from the list
- **special transition approach considered**

1. substance is removed after 1 year (article 3(2))
2. user may apply for authorisation before
3. substance added to register
4. as long as substance on register substance can continued to be used for specific use, for 4 years
5. substance is removed from register when one of five conditions is met – transition applies

16th amendment - biocides

- polymer production aids and additives with a biocidal function will be allowed without authorisation subject to the BPR (Regulation 528/2012)
- Article 6(1)(ii) and Article 6(5) in draft text
- Article 7 + provisional list removed
  - use of present substances cannot continue – not (yet) authorised under BPR

Other Issues

Upcoming Amendments

- Styrene
- Authorisation of substances
- Template based declaration of compliance
- Introduction of risk assessment policy

European Commission

Styrene – the issue

- 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

Styrene state-of-play + approach

- limit more difficult than first considered
  - compliance tests would significantly overestimate migration
  - migration in (non-fatty) foods OK (?)
- we are now planning to regulate styrene separately
- consultation being prepared with business operators

- Consultation Questions:
  - FCMs in which they use styrene + function of styrene therein
  - migration into simulants + testing conditions
  - migration into foods + real conditions
  - market volume (to assess priority materials and exposure)
  - alternatives
- Consultation Approach
  - On-line survey, individual business operators
  - significant time, testing may be required
  - All materials (not only plastics), but focus on styrene users not styrene producers
  - estimated launch in March

Styrene Measure (+ phthalates in Rubber)

- General application – not (necessarily) limited to plastic FCM
- Will be based on outcome survey
  - which materials?
  - which limits?
  - which compliance testing rules?
- Will also include limits for phthalates in rubber
  - as in early version of 16th amendment
  - to save time in the procedures

authorisation of new substances

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Authorisation of substances

- Four substances could not be authorised under 16th amendment
  - need to prepare decisions on confidential information in the dossiers
- Substances:
  - N,N-bis(2-hydroxyethlyl) - C16C18 fatty acids
  - Bis(2-ethylhexyl)-cyclohexane-1,4-dicarboxylate
  - benezophenone,3,3,4,4- tetracarboxylic dianhydride
  - phosphoric acid, mixed wtih 2-hydroxyethyl methacrylate
- Preparation of decisions underway
  - If EFSA would publish new opinions without confidential information before finalisation, those substances will be added if before final consultation

DoC template

Considerations of a possible harmonised 'DoC' Regulation

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DoC Template

- Purpose of discussion is to decide course
- A: limit template to apply to recycled plastics and plastic
  - i.e. establish it under Regulations 282/2008 (being done) and 10/2011
  - immediate need is to combine primary (virgin) with secondary (recycled) plastic
- B: harmonise template for all FCM
  - also applicable to National legislation
  - also applicable to FCMs not subject to specific rules
  - rationale: many advantages related to compliance, straightforward, requested
  - option A could be problematic when combining materials (no more flexibility)

DoC template – state of play

- In the autumn we consulted you on the Annexes
  - editorial changes, but essentially unchanged
- Internal preliminary draft regulatory text being developed
  - no Annexes added
- Following this meeting we will decide how to take it forward

Objectives

- To ensure coherent approach between R 10/2011 and R 282/2008
  - needed for combining primary with secondary plastic
- To greatly increase the quality of information in DoCs
  - no more ‘disclaimers’
  - imports
- To ensure business operators adequately verify compliance
- To increase enforceability
- To start towards digital DoCs – including digital exchange

Sketch of a potential new Regulation

- On the following slides – for the purpose of discussion on a general course – we outline what a DoC Regulation could address
- Based on internal preliminary text – no completed document yet
  - drafted to understand main concepts
- No decision or commitment from our side on a course
  - We could decide just to implement under Regulation (EU) 10/2011

Basic Structure: 5 sections

- Sections:
  1. Identification
  2. Compliance information – specific to material + pre-amble with rules
  3. Information for the users of the product (including end-users) – specific to material
  4. Signature
  5. Annexes
- Section 1, 4 and 5 the same for all FCM
- Section 2 and 3 set out under specific measures, whether Union or National
  - if not provided in Union or National rules the DoC Regulation will provide a default
  - (to declare compliance with Articles 3, 11(5) and 15 of R 1935/2004 + R 2023/2006 (GMP))
- Multiple instances of section 2 can be present in one Declaration of Compliance

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 – Specific to material, here plastic multiple sections 2 possible in one DoC

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 3– Specific to material, here plastic single section 3 in one DoC

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)

A possible Regulation

- Drafting in progress
- Articles – logic similar to GMP Regulation
  1. subject matter
  2. scope (all FCMs)
  3. definitions
  4. general rules for issuing a declaration of compliance
  5. general rules on the formatting and contents of a declaration of compliance
  6. *specific rules on the formatting and contents of a declaration of compliance*
  7. rules on the combination of information
  8. Non-Disclosure Agreements
  9. amendment of EU acts
  10. transitional provisions

Article 1
subject matter

This Regulation lays down the rules on declarations of compliances for the groups of materials and articles intended to come into contact with food (hereafter referred to as materials and articles) listed in Annex I to Regulation (EC) No 1935/2004 and combinations of those materials and articles or recycled materials and articles used in those materials and articles.

Article 2
scope

This Regulation shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles.

Article 3
Definitions

For the purpose of this Regulation, the following definitions shall apply:

(1) 'Declaration of compliance ('DoC')' means a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

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Article 4: general rules for issuing DoCs

- All marketing stages, easy identification
- How to provide it
- Derogations to FBOs (no issuing), importers and distributers (may forward)
- Link to Article 5-8
- Time of issue
- Link to supporting documentation + obligation to provide that quickly

Article 5: general formatting and contents rules

- Defines section 1-5 + link to annexes
- Obligation for commission to provide the templates
- Allows automated exchange via information systems
  - provided paper versions can be made available

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Article 6: specific formatting and contents rules

- Requires that section 2 and 3 follow rules set out in specific measures
- If no specific Union measure, National legislation shall be followed
  - this means that templates should be set out under National legislation
- If no template either under Union or National rules the default shall be used

Article 7: combination of section 2

- In case of multiple materials in single article, single DoC is required
- Two cases:
  - Union measure requires combination of section 2 (recycling Regulation)
  - Multi materials materials and articles
- Requires to but different instances of section 2 applicable for each material
- Requires additional table that lists these materials

Article 8: Non-Disclosure Agreements

- New DoCs will require to exchange more information
  - reduces flexibility to business operators
  - some information will be commercially sensitive, e.g. composition of preparations
- Therefore Regulation could allown non-disclosure agreements
- Two types:
  - full NDA: no disclosure to customer, but to neutral 3rd party consultant/laboratory
  - limited NDA: substance identies and amounts disclosed to customer, customer cannot identify supply and composition of supplied materials to his customers
- full NDA cannot be used for certain substances, e.g. EDs, CMRs
- Parties shall always disclose all information to Competent Authorities
- Commission and Competent Authorities are no part of NDAs and they don't apply

Amendment of legislation

- Need to amend Article 15 and Annex IV of Regulation (EU) 10/2011
- Section 2 definitions will not be immediately available under specific measures
  - Union Annexes (other than under R 10/2011 and R 282/2008) not immediately established
  - same for National legislation
- Need to consider proper transition
  - Possibly section 1 and 4 to function as 'envelope'.

Short discussion

- What is your view?
- *Do you prefer approach:*
  - *A: only amendment of R 10/2011*
  - *B: full harmonisation of DoCs*
- *The result of approach A will be use of template based DoCs in plastics only*
- *Approach B will create by same logic of R 2023/2006 (GMP) a third general measure on FCMs*

Risk assessment policy

Reminder – Discussed in previous WG

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Risk Assessment Policy ('RAP')

- Presently unclear mandate for risk assessment
- Discussion with EFSA whether to define a RM Policy
- Basis is Codex Manual

'…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…'*

Approach to RAP

- Discussion with EFSA first
- Reflection with MS
- Act Amending Article 5 of Regulation 10/2011 + new Annex

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Recycling

State of play

- First phase of amendments
  - Internal consultation on text finishes on Monday
  - Once comments (including yours) are processed public feedback mechanism
    - Comments from stakeholders – 4 weeks
  - Preparation for vote in PAFF – possibly still in March
  - Adoption 3-4 months thereafter
- Authorisations in Q4
- Second phase in 2022 (to bring all processes and plastics in scope)

Latest version of text

- text nearly final, but three commenting stages
  - comments from Commission services
  - your comments
  - comments from stakeholders in feedback
- Notable provisions
  - Article 3, Article 3a, Article 9a-10b, Annex
- Discussion of text

AoB points

Bamboo

SML Formaldehyde

Coordinated Control Plan

EDs (FR)

European Commission

Bamboo

- Round table on state of play in the Member States
- Common communication approach, main elements (in our view)
  - A polymer with added bamboo is a plastic
  - This applies in general, to all polymers, to all fillers (not specific to bamboo powder in melamine)
  - No publication of a Regulation banning bamboo will be published; it is not authorised
  - Without authorisation health risk cannot be excluded, in practice a health risk was shown
  - Business operators are invited to apply for authorisation; thereafter products can be placed on the market subject to authorisation conditions

SML Formaldehyde

- A small history
  - October 2018 – RASFF notification triggers internal verification of limit – limit seems high
  - Informal check with Denmark (who worked on it) indicates no immediate concern
  - November 2019, BfR report, indicates limit is too high
    - 10,4 mg/kg instead of 15 mg/kg
  - verification with EFSA, re-evaluation needed, however no priority
    - oral vs. inhalation
    - risk management considerations (Bamboo)
    - EFSA resources

    → focus on enforcement (Bamboo)
- Present approach
  - Formaldehyde would need re-evaluation, other substances need it more
- Discussion on Dutch views → determine position