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WORKSHOP:

Food Contact Regulation at the Speed of Innovation: Overview of EU Compliance

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Dr. Anna Gergely

Legal 500 EMEA has noted she “has the rare ability to give clients not only legal advice, but also a scientific interpretation of complex REACH matters,” noting that her “**excellent scientific background**” is a “**great asset**.”

Dr. Gergely is director EHS regulatory in Steptoe's Brussels office, where she is a member of the Environment & Life Sciences Practice Group. In a role equivalent to Partner, with a PhD in analytical chemistry and quantum chemistry, Dr. Gergely is a registered European patent attorney.

Dr. Gergely is particularly experienced in providing comprehensive capabilities for companies seeking compliance strategies that cover the full range of their technical and legal needs in the following areas:

Chemicals (biocides, agro-biotechnology, cosmetics), REACH and Classification, Labeling and Packaging Food and feed and food contact materials (packaging and marketing claims and hygiene rules) Regulation of medical devices and a range of consumer and industrial products.

In addition to the above areas, Dr. Gergely specializes in nanotechnologies as related to a broad spectrum of industrial sectors.

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CONTENT

- Legal Background – Food Contact Legislation
  - Framework Regulation
  - Plastics Regulation
- Compliance issues
- Challenges concerning the cross-sections with The Biocidal Product Regulation
  - Treated articles
  - Masterbatches
- Remaining questions – Open issues

The EU Food Contact Legislation

- **Objectives of EU food contact legislation (Framework Regulation):**
  - Effective functioning of internal market
    - free circulation of goods
  - The protection of consumer health
    - principle of inertness – no migration (unless exempt)
  - The protection of consumer interests
    - not to mislead consumers
- **Other objectives ensured by other EU laws:**
  - Product safety: EU Product Safety and Liability Directives
  - Food safety: EU Food Law
  - Workers' safety: EU legislation for safety of workers
  - Protection of public health and the environment: EU Chemicals Legislation: REACH; Biocidal Products Regulation

Legal Background

Relevant EU Food Contact Legislation:

➢ **Harmonized:**

- **Framework Regulation** (EC) No. 1935/2004

Covering **all materials** and articles intended to come into contact with food

- **Plastics Regulation** (EU) No. 10/2011

Covering **all plastics** applications falling under its scope – with some important exemptions

➢ **Non-harmonized:**

Member States national regimes

Framework Regulation

Definition of FCM

- **Food contact materials** = materials and articles, including active and intelligent food contact materials, which in their finished state
  - are intended to be brought into contact with food – OR
  - are already in contact with food and were intended for that purpose – OR
  - can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use

Framework Regulation

General requirements

- **Article 3: General requirements**:
  - Manufacture in compliance with good manufacturing practice so that under normal or foreseeable conditions of use, they do not transfer constituents to food in quantities which could:
    - endanger human health - OR -
    - bring about unacceptable change in composition of food - OR -
    - bring about deterioration in the organoleptic characteristics
- The labelling, advertising or presentation of a material or article shall not mislead the consumers.

Framework Regulation

Groups of materials and articles which may be covered by specific measures (Annex I)

- 1. Active and intelligent materials and articles
- 2. Adhesives
- 3. Ceramics
- 4. Cork
- 5. Rubbers
- 6. Glass
- 7. Ion-exchange resins
- 8. Metals and alloys
- 9. Paper and board
- 10. Plastics
- 11. Printing inks
- 12. Regenerated cellulose
- 13. Silicones
- 14. Textiles
- 15. Varnishes and coatings
- 16. Waxes
- 17. Wood

Framework Regulation

Specific measures for food contact materials

- **Article 5**: specific measures may be adopted for the groups of materials covered by the FR - Plastics are covered
- Such a specific measure may include the List of Substances authorized for use in the manufacturing - Union list of permitted monomers and additives in food contact plastics materials and articles
- **Article 8(2): "***no substance shall be authorized unless it has been adequately and sufficiently demonstrated that, when used under the conditions to be set in the specific measures, the final material or article satisfies the requirements of* ***Article 3*** *and, where they apply,* ***Article 4*** *of the FR"*(emphasis added).
- Designed to be fit for purpose (GMP Regulation (EC) No 2023/2006)

Framework Regulation

Specific measures for food contact materials

- **Specific measures** may include:
  - ✓ a list of substances authorised for use in the manufacturing of materials and articles;
  - ✓ special conditions of use for substances and/or the materials and articles in which they are used;
  - ✓ specific limits on the migration of certain constituents or groups of constituents into or on to food, taking due account of other possible sources of exposure to those constituents;
  - ✓ an overall limit on the migration of constituents into or on to food;
  - ✓ basic rules for checking compliance with points;
  - ✓ rules concerning the collection of samples and the methods of analysis to check compliance;
  - ➢ **All apply for Plastics**

Framework Regulation

Declaration of Compliance

- **Article 16:**
  - The specific measures referred to in Article 5 shall require that materials and articles covered by those measures be **accompanied by a written declaration stating that they comply with the rules applicable to them**.
  - Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.
  - In the **absence of specific measures**, this Regulation shall not prevent **Member States from retaining or adopting national provisions for declarations of compliance** for materials and articles.
  - **Plastics**: due to specific measures under the Plastics Regulation no national provisions are permitted

Plastics Regulation

Definitions

- **Plastic:** polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles.
- **Additive**: a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article which is intended to be present in the final material or article.
- **Plastic materials and articles:**
  - (a) materials and articles and parts thereof consisting exclusively of plastics;
  - (b) plastic multi-layer materials and articles held together by adhesives or by other means;
  - (c) materials and articles referred to in points a) or b) that are printed and/or covered by a coating;
  - (d) plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;
  - (e) plastic layers in multi-material multi-layer materials and articles

Plastics Regulation

Union list of authorized substances

Article 5: Union list –

- Only substances included in Union list may by intentionally used in manufacture of plastic layers in plastic materials and articles
- Includes:
  - Monomers and starting substances
  - Additives excluding colorants
  - Polymer production aids excluding solvents
  - Macromolecules obtained from microbial fermentation
- List may be amended

Plastics Regulation

Substances not on Union List

Article 6: Derogations for substances not included in Union List

- Colorants, solvents and polymer production aids;
  - Comply with Article 3 requirements of Framework Regulation and national law
- Salts (Aluminum, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of authorized acids, phenols or alcohols), mixtures of authorized substances;
- Polymeric additives and Polymeric starting substance
  - Mw > 1000 Da; if capable of functioning as main structural component of final materials/articles
  - Covered by authorization of monomer - restrictions and specifications of the Union list
- Non-intentionally added substances (NIAS)
- Aids to polymerization
- Substances in the Provisional List (remaining only surface biocides)

Plastics Regulation

Safety requirements for substances in food contact plastics

Article 8: General requirement on substances

"Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request".

- **Calls for safety assessment for <u>all</u> substances**

Plastics Regulation

Assessment of safety of substances

Article 19: Assessment of substances not included in the Union list

"Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances […] which are not covered by an inclusion in Annex I to this Regulation shall be ***assessed in accordance with internationally recognised scientific principles on risk assessment***.(emphasis added)

- **Possibility for the application of the TTC approach**

Plastics Regulation

Declaration of Compliance

Article 15: Declaration of compliance

- At the marketing stages other than at the retail stage, a **written declaration** in accordance with Article 16 of Regulation (EC)No 1935/2004 shall be available for **plastic materials and articles**, products from **intermediate stages** of their manufacturing as well as for the **substances intended for the manufacturing** of those materials and articles
- The written declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex IV.3.
- The written declaration shall **permit an easy identification** of the materials, articles or products from intermediate stages of manufacture or substances for which it is issued. It shall **be renewed** when substantial changes in the composition or production occur that bring about **changes in the migration** from the materials or articles or when **new scientific data** becomes available.

Plastics Regulation

Need for Supporting documents

Article 16: Supporting documents

1. **Appropriate** documentation to demonstrate that the materials and articles, products from intermediate stages of their manufacturing as well as the substances **intended for the manufacturing** of those materials and articles **comply with the requirements** of this Regulation shall be made available by the business operator to the national competent authorities on request.

2. That documentation shall contain the conditions and results of testing, calculations, including modelling, other analysis, and **evidence on the safety or reasoning demonstrating compliance**. Rules for experimental demonstration of compliance are set out in Chapter V. (emphasis added)

Plastics Regulation

Migration testing requirements

Article 18: Rules for assessing compliance with migration limits

1. Materials and articles **already in contact** with food **verification** of compliance with SMLs shall be carried out according to Chapter 1 of Annex V.

2. Materials and articles **not yet in contact** with food **verification** of compliance with specific migration limits shall be carried out in food or in food simulants set out in Annex III in accordance with the rules set out in Chapter 2, Section 2.1 of Annex V.

3. Materials and articles not yet in contact with food screening of compliance with the specific migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 2, Section 2.2 of Annex V. If a material or article fails to comply with the migration limits in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 2.

Plastics Regulation

Migration testing requirements – New rules

Article 22: Transitional provisions

*As **from 1 January 2016** the supporting documents referred to in Article 16 shall be based on the rules for migration testing set out in Article 18.*

What are the main differences in these new rules?

- Modified food simulants (20% and 50% ethanol, Tenax)
- Extended contact times and temperatures – most severe (10 days at 60C instead of 10 days at 40 C for long shelf life at room temp. unless equilibrium is demonstrated)
- Screening approaches – most severe
- Consideration of possible worst case exposure

➢ **Requires revisiting existing migration data and corresponding DoCs for all applications!**

Establishing compliance for food contact plastics

General rules:

1. Applying the **screening approaches** defined in Annex V Chapter 2.2. of the Plastics Regulation
   a. Rely on **overall migration**
   b. Rely on **worst case migration calculation** based on use level or maximum residual content
   c. Rely on **migration modelling**
   d. Rely on **migration testing** with food simulant substitutes
2. **Compare** above results with
   a. reference to the **Union list** (for monomers and additives), or
   b. reference to a **national list**, or
   c. scientifically robust **opinion on the safety** of the substance of an internationally recognized body, or
   d. provisions of **safety self-assessment**

➡ **POSSIBILITY TO RELY ON THE TTC APPROACH**

What are the new rules?
Food simulants

List of food simulants

Food simulant	Abbreviation
Ethanol 10 % (v/v)	Food simulant A
Acetic acid 3 % (w/v)	Food simulant B
Ethanol 20 % (v/v)	Food simulant C
Ethanol 50 % (v/v)	Food simulant D1
Vegetable oil (*)	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E

(*) This may be any vegetable oil with a fatty acid distribution of

No of carbon atoms in fatty acid chain: No of unsaturation	6-12	14	16	18:0	18:1	18:2	18:3
Range of fatty acid composition expressed % (w/w) of methyl esters by Gas chromatography	< 1	< 1	1,5-20	< 7	15-85	5-70	< 1,5

Food Simulants

Food simulants A, B and C are assigned for foods that have a hydrophilic character and are able to extract hydrophilic substances.

- Food **simulant B** shall be used for those foods which have a pH below 4.5
- Food **simulant C** shall be used for alcoholic foods with an alcohol content of **up to** 20 % and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic

Food simulants D1 and D2 are assigned for foods that have a lipophilic character and are able to extract lipophilic substances

- Food **simulant D1** shall be used for alcoholic foods with an alcohol content of **above** 20 % and for oil in water emulsions
- Food **simulant D2** shall be used for foods which contain free fats at the surface

Food simulant E is assigned for testing specific migration into dry foods.

Food Simulants

- For testing migration from materials and articles not yet in contact with food the food simulants that corresponds to a certain food category shall be chosen according Table 2 below

food category specific assignment of food simulants

(1)	(2)	(3)					
Reference number	Description of food	Food simulants					
		A	B	C	D1	D2	E
01	Beverages						
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.:						
	A. Clear drinks:		X(*)	X			
	Water, ciders, clear fruit or vegetable juices of normal strength or concentrated, fruit nectars, lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract						

Food Simulants

- **Food simulant assignment for testing overall migration**
- For **all type** of foods: distilled water or water of equivalent quality or food simulant **A and** food simulant **B and** simulant **D2**
- For **all types** of food **except acidic** foods: as above, but **no** simulant B
- For all **aqueous and alcoholic** foods and milk products: food simulant D1
- For all **aqueous**, **acidic and alcoholic** foods and milk products: as above, **plus** simulant B
- For all **aqueous** foods **and alcoholic foods up to an alcohol content of 20 %:** food simulant C
- There are no general provisions to substitute D2 with 95% ethanol or iso-octanol

Testing for specific migration of materials and articles already in contact with food

1.1. **Sample preparation**

Material should be stored under adequate conditions for the packaged food. The food shall be removed from contact with the material or article before its use by date

1.2. **Conditions of testing**

The food shall be treated in accordance with the cooking instructions on the package. It shall be homogenised and analysed for migration. The analytical results shall always be expressed on the basis of the food mass that is intended to be eaten, in contact with the food contact material.

1.3. **Analysis of migrated substances**

The specific migration is analysed in the food using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

Testing for specific migration of materials and articles not yet in contact with food

2.1. **Verification method**

- Verification of compliance of migration **into foods** with the migration limits shall be carried out **under the most extreme conditions of time and temperature foreseeable in actual use**
- Verification of compliance of migration **into food simulants** with the migration limits shall be carried out using **conventional migration tests** according to the rules set out in paragraphs 2.1.1 to 2.1.7. of Annex V (*see infra*).

2.2. **Screening approaches**

To apply approaches which are considered more severe than the verification method

- *Replacing specific migration by overall migration*
- *Residual content*
- *Migration modelling*
- *Food simulant substitutes*

Testing for specific migration of materials and articles not yet in contact with food (cont.)

Choice of food simulant

- Materials and articles intended for contact with all types of food shall be tested with food simulant A, B and D2. However, if substances that may react with acidic food simulant or foods are not present testing in food simulant B can be omitted.
- Materials and articles intended only for specific types of foods shall be test

Conditions of contact when using food simulants

- The sample shall be placed in contact with the food simulant in a manner representing the worst of the foreseeable conditions of use as regard contact time in Table 1 and as regard contact temperature in Table 2. (In case of physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.)

Table 1: Contact Times

Contact time	Test Time
T≤ 5 min	5 min
5 min < T≤ 0.5h	0.5h
0.5h< T≤ 1h	1h
1h < T≤ 2h	2h
2h < T≤ 6h	6h
6h < T≤ 24h	24h
24h < T≤ 3d	3d
3d < T≤ 30d	10d
T> 30d	Specific conditions

Table 2: Contact Temperatures

Contact temperature	Test Temperature
T≤ 5°C	5°C
5°C < T≤ 20°C	20°C
20°C < T≤ 40°C	40°C
40°C < T≤ 70°C	70°C
70°C < T≤ 100°C	100°C or reflux temperature
100°C < T≤ 121°C	121°C (*)
121°C < T≤ 130°C	130°C (*)
130°C < T≤ 150°C	150°C (*)
150°C < T≤ 175°C	175°C (*)
T> 175° C	Adjust T to real temperature

(*) Only for Simulants D2 and E. For Simulants A, B, C D1 use reflux temperature at 4X the suitable times in Table 1.

Testing for specific migration of materials and articles **not yet in contact** with food (cont.)

Specific conditions for contact times above 30 days at room temperature and below

- For contact times above 30 days at room temperature and below the specimen **shall be tested** for a maximum of 10 days at 60 °C based on the following formula:
- t2 = t1 * Exp ((-Ea/R) * (1/T1-1/T2))
  - Ea is the worst case activation energy 80kJ/mol
  - R is a factor 8,31 J/Kelvin/ mol
  - Exp -9627 * (1/T1-1/T2)
  - t1 is the contact time
  - t2 is the testing time
  - T1 is the contact temperature in Kelvin. (For storage at room temp. this is set at 298 K, for refrigerated and frozen conditions at 278 K (5 °C).
  - T2 is the testing temperature in Kelvin.

Testing for specific migration of materials and articles **not yet in contact** with food (cont.)

- Testing for 10 days at 20 °C shall cover all storage times at frozen condition.
- Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions **including** heating up to 70 °C for up to 2 hours, **or** heating up to 100 °C for up to 15 minutes
- Testing for 10 days at 50 °C shall cover all storage time at refrigerated and frozen conditions **including** heating up to 70 °C for up to 2 hours, **or** heating up to 100 °C for up to 15 minutes **and** storage times of **up to 6 months at room temperature**
- Testing for 10 days at 60 °C shall cover **long term storage above 6 months at room temperature and below including** heating up to 70 °C for up to 2 hours, **or** heating up to 100 °C for up to 15 minutes.
- The maximum testing temperature is governed by the phase transition temperature of the polymer. **At the test temperature the test specimen should not undergo any physical changes**.
- For storage at room temperature testing time can be reduced to 10 days at 40 °C if there is scientific evidence that migration of the respective substance in the polymer has **reached equilibration** under this test condition.

Testing for specific migration of materials and articles not yet in contact with food (cont.)

- ***Testing for overall migration***

Standardised testing conditions

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at Contact temperature in [°C]	Intended food contact conditions
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions.
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.
OM3	2 h at 70 °C	Any contact conditions that include heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage.
OM4	1 h at 100 °C	High temperature applications for all food simulants at temperature up to 100 °C.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions with food simulants A, B or C, at temperature exceeding 40 °C.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5

Do these changes matter?

- Yes, they do.
- **From 1 January 2016** all DoCs for food contact plastics falling under the scope of the Plastics Regulation **need to be supported by migration data based on the rules of Annex V of Regulation 10/2011**.
  - **confirmation** that the plastic materials or articles, products from intermediate stages of manufacture or the substances **meet relevant requirements** laid down in this Regulation and Regulation (EC) No 1935/2004;
  - **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**;
  - **adequate information** relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration **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;
  - **specifications on the use** of the material or article, such as: (i) type or types of food with which it is intended to be put in contact; (ii) time and temperature of treatment and storage in contact with the food; (iii) ratio of food contact surface area to volume used **to establish the compliance** of the material or article;

What if the DoC is no longer correct?

- Some of the changes in the test conditions of Annex V are quite **drastic** – materials in compliance before may fail
- How "flexible" are these new test conditions?
- Is it possible to provide proper scientific justification in case of non-compliance?
- What is "proper"?

➢ There are some answers in the **JRC Technical Guidance for compliance testing guidelines** (100 pages + 260 pages of Annexes)

➢ **REQUIRES FURTHER FINETUNING; DISCUSSIONS…**

Overlap with other regulatory measures

The Biocidal Product Regulation (BPR)

- **Regulation (EU) No 528/2012**
- The aim of the BPR is to regulate those active substances and biocidal products which are used for **intended** biocidal effects and **not** to protect the health of people and the environment in the EU from **unintended** biocidal effects**.**
- For these effects there are other safety/regulatory measures:
  - REACH
  - Product specific requirements
  - Specific workers' and consumer protection legislation
  - Transport requirements etc.

Extension of the scope of the BPR

	BPD	BPR
Food Contact materials and articles	**Article 1(j)** The Directive shall **exclude products** that are defined or within the scope of Council Directive 89/109/EEC (now Regulation 1935/2004) on materials and articles intended to come into contact with foodstuffs	**Article 2(2) ..**this Regulation shall not apply to biocidal products or treated articles that are within the scope of the following instruments: **No exemption for FCM under Regulation 1935/2004**
Biocidal product	Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, **intended to** destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.	Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or **generating** one or more active substances**, with the intention of** destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism by any means other than mere physical or mechanical action. **A treated article that has a primary biocidal function shall be considered a biocidal product.**
Treated article	None	Any substance, mixture or article which has been treated with, or **intentionally** incorporates, one or more **biocidal products**.

Food contact materials and articles and Biocides

- Products within the scope of Regulation 1935/2004 on Materials and articles intended to come into contact with food (the Framework Regulation) are **no longer excluded from the scope of the BPR**
- Annex I of Regulation 1935/2004 lists 17 groups of materials covered by its scope; including Plastics, Paper, Rubber, Glass, Ceramics, Silicones, Textiles, Wood; but also Printing inks, Adhesives, and Coatings
- Biocidal Product Types (PT) in food contact applications in any material category:
  - Surface biocides (PT4) – intended technical effect in the food contact article;
  - Process biocides (PT 6, 7, 9, 11, 12) – not intended to have an effect and to be present in the final food contact material or article;
  - Food preservatives (in active packaging applications) – intended to be released from the packaging into food, for a technological effect in food;
- All these were previously exempt from the scope of the BPD; now they are covered by the BPR; either as Biocidal Product (BP) or Treated Article (TA)

Regulatory considerations for food contact plastics materials and articles

- Plastics Regulation 10/2011 has a positive list for all authorised additives (with some important derogations) – the Union list
  - 'additives' means a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article;
  - 'polymer production aid' means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article;
- Surface biocides are considered additives, so for plastics applications they should be listed on the Union list
- Process biocides may still be used as Polymer Production Aids (PPAs) are under derogation from the Union list
- (Food preservatives still excluded from the scope of the BPR, as covered by Regulation (EC) No 1333/2008 on food additives)

Regulatory considerations for food contact plastics materials and articles (cont.)

Regulatory overlap:

- Dual regulation:
  - Under the Food contact legislation:
    - Process biocides as PPAs are also under derogation from Union list, only subject to national law and FR
    - Some surface biocides as additives are under derogation from the Union list: listed in the so called Provisional list, permitted in food contact plastics, their use is subject to national law and FR
    - All other surface biocides as additives are not under derogation from Union list, hence cannot be used
  - Under the BPR most of these applications are considered **treated articles**, subject to Article 58 requirements under the BPR, harmonised at EU level

What is a “treated article”?

- **New definition under the BPR:** Any substance, mixture or article which has been treated with, or **intentionally** incorporates, one or more **biocidal products**.
- **Treated articles** were not explicitly covered by BPD - but extensive guidance on how to address individual examples in the Manual of Decisions (MoD)
- **MoD focused on the biocidal effect of treated articles, contrasting:**
  - Internal effect: intended to preserve the article itself, the treated article is **not a biocidal** product (e.g. treated paper or wood)
  - External effect: treated article is intended to act as a **biocidal product**
- **BPR introduced changes that explicitly addressed treated articles:** Article 58 deals with treated articles which are not biocidal products (no primary biocidal function)

Treated articles under the BPR

- Article 58(2) – as amended: A treated article shall not be placed on the EEA market unless all active substances contained in the biocidal product that **it** was treated with or incorporates are EU approved for the relevant PT and use; and the restrictions are met (exception: fumigation and disinfection of premises)
  - placed on the market means: first making available as the treated article **itself**
  - contained in the biocidal product:its presence in the treated article is not the requirement
  - it was treated with or incorporates means: the treated article **itself** and not of its component parts (see *infra* relevance for Complex articles)
  - EU approved for the relevant PT and use means: 0% threshold on all active substances which are not permitted pursuant to Article 58(2).
- **Double intention:**
  - First, the intention to use the active substance in the biocidal product is required
  - Second, the intention to use this biocidal product to treat with or incorporate into an article is required
- Article 94 – as amended: Has provided transitional measures concerning treated articles

Treated articles under the BPR (cont.)

- Article 94: **Transitional measures concerning treated articles**

o By way of derogation from Article 58(2), a treated article treated with or intentionally incorporating one or more biocidal products containing **only** active substances that are under examination for the relevant product-type in the work programme **or** for which an application for approval for the relevant product-type is submitted by that date, may be placed on the market until one of the following dates:

  – in the case of a decision adopted after 1 September 2016 to **reject the application** for approval of, or not to approve, one of the active substances for the relevant use, the date falling **180 days after such a decision**;

  – in other cases, **the date of approval** for the relevant product-type and use of the **last** active to be approved and contained in the biocidal product.

  – In **any other cases** placing on the market of treated articles is permitted until **1 March 2017**

Regulatory analysis – What would be needed?

- Most of the food contact applications falling under the Framework Regulation would be Treated articles under the BPR – with the **dual obligation** to only use approved active substances under the BPR and also with a binding positive list for additives in plastics materials and articles under the Plastics Regulation
- To avoid legal uncertainty in a dual approval process - beyond the existing uncertainties related to complex articles - it would be necessary:
  - Exclude surface biocides for use in food contact plastics materials and articles from the scope of the Union List under the Plastics Regulation and refer their authorization to their authorization under the BPR
  - Review derogation under Article 6 of the Plastics Regulation for Provisional list
  - Coordinate ECHA and EFSA for the active substance authorisation and restrictions in food contact use (SMLs)
- Specific legislative changes in national legislation for incorporating the new biocides measure under the BPR – replacing potential binding national rules for biocides in food contact uses

What is happening instead:

- The aim is to develop a focused and risk based approach for **ALL sources of active substance residues**, in order to identify the active substances which require MRL setting
- Balanced approach between the risk of biocides residues **vs.** the risk of microbial contamination
- Proposed Way Forward: 3 categories
  - 1) Consumer exposure unlikely: **No further action required** for certain PT groups
  - 2) Consumer exposure likely, but considered safe under other legislation: **No further action required** (approved food and feed additives, BPR Annex I and REACH Annex IV substances, approved microorganisms and all other AS where the exposure is negligible
  - 3) Consumer exposure likely, and with appreciable risk: **Need further action**

Biocides in food contact plastics materials and articles – The way forward?

- FCMs – may fall under **Category 3** (except Treated articles!)
- Almost no comments in the present discussion document from either MSs or industry; FCM manufacturers and users should be **more actively involved** in the MRL discussions
- Other controversial topic: Masterbatches

Is a Masterbatch a Biocidal Product, a Treated Article or none?

- **Biocidal product** – by definition of the BPR is: *Any substance or **mixture**, in the **form in which it is supplied to the user**, consisting of, containing or generating one or more active substances, **with the intention** of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism by any means other than mere physical or mechanical action.*
  - If the Masterbatch in the form it is supplied to the user is **not intended** to have a biocidal effect; it is **not a Biocidal Product**
  - This part of the definition has **not** been modified under the BPR, so the interpretation was the same under the BPD
- **What is the new issue then?**

The “Masterbatch” question – What is the issue?

- Masterbatches as such are not addressed by the BPR
- Legal certainty is needed for determining “*whether or not a masterbatch of an active substance falls under the scope of the BPR; and if so, as a Biocidal product or a Treated article*”?
- Facts:
  - Masterbatches are tailored for specific downstream needs – great variety in composition. If Biocidal products: large number of authorization needed
  - It is the user of a Biocidal product who exploits its biocidal property
  - Masterbatches are typically interim products: their potential authorisation requiring efficacy testing “in the form as supplied to the user” is meaningless
- Principle requirement:

In a supply chain where an active substance is used for a biocidal intention, **at least one - but only one! - biocidal product should get authorised**

(postulated by the Note for Guidance CA-May15-Doc.6.2)

Proposed way - Note for Guidance CA-Sept15-Doc.6.2-rev1

- Whether the Masterbatch of an active substance **itself** is a Biocidal product falling under the BPR **or** a simple mixture, depends on the intention of its use
  - ✓ When the Masterbatch is used to manufacture a Biocidal product, it should be considered a simple mixture
  - ✓ In a Masterbatch a biocidal active substance may be present at a high concentration and exhibit biocidal activity, **but** if this activity is **not intended** to be beneficial in **this form**, the Masterbatch is **not** a Biocidal product
  - ✓ An intermediate masterbatch intended for further processing is **not** a Biocidal product

❖ **BUT:** A Masterbatch used to **confer a biocidal property** to mixtures or articles which are not biocidal products themselves **is a Biocidal product** (even if also confers other functions) – *see infra*

Proposed way - Note for Guidance CA-Sept15-Doc.6.2-rev1

IMPORTANTLY, ALSO:

*"A Masterbatch **imported** into the EU that will be used in the EU to confer a biocidal property or function to a mixture or an article shall be **regarded as a biocidal product**, even if it might confer non-biocidal functions as well."*

NEVERTHELESS:

*"By considering the above elements, **economic operators should be able to determine** whether the masterbatch they may use fall into the scope of BPR and if so, shall be **considered as biocidal products or not**."*

HOW?

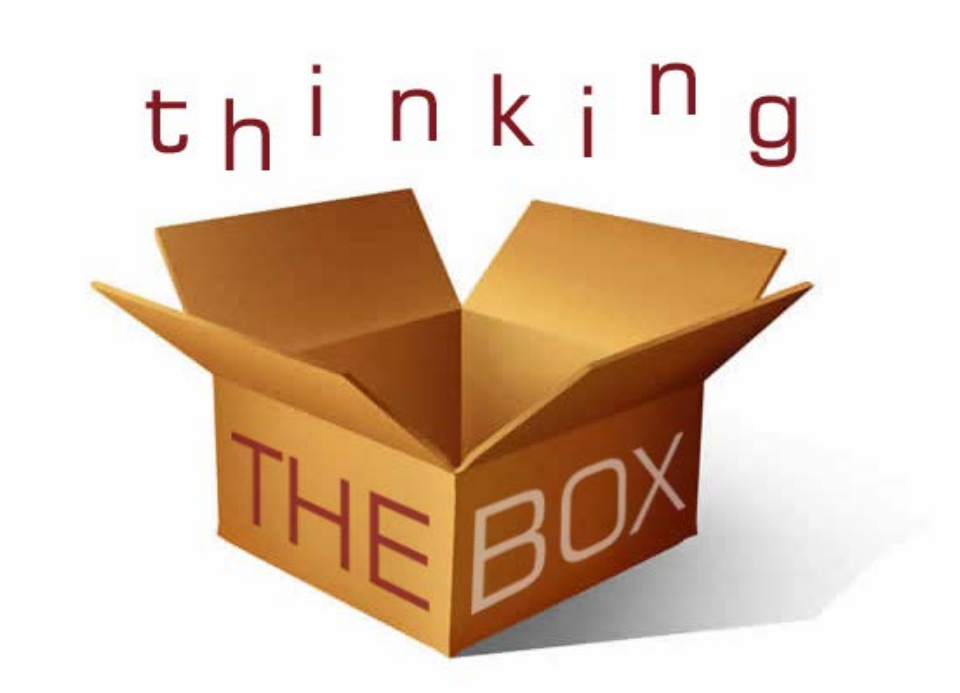
The “Masterbatch question”

- **Is a Masterbatch incorporating an active substance a treated article?**
- Treated article: “..*treated with, or intentionally incorporates .. biocidal products”*
  - **Double intention:**
    - First, the intention to use the active substance in the biocidal product is required
    - Second, the intention to use this biocidal product to treat with or incorporate into an article is required
    - This means that the biocidal product (and hence the active substance) must have been applied with the intention of exerting a biocidal effect in the treated article itself.
- **As a Masterbatch** does not incorporate an active substance with the intention of exerting a biocidal effect in the Masterbatch itself, it is **not a treated article**

Commission's revised interpretation on Treated Articles CA-Sept13-Doc.5.1.e Rev 1, December 2014

- *The provisions of Article 58 apply to treated articles* ***in the form in which they are placed on the EU market*** *(in the following also referred to as "finished goods")*, i.e. it does not concern directly components of complex articles or intermediate forms which are not themselves placed on the EU market.
- The intentional incorporation of a biocidal product in a component of an complex article seems to imply a beneficial effect for the **finished article**.
- In applications where the incorporation of biocidal products into individual components of complex articles was merely in order to perform a specific biocidal function at that stage of the process, but **without an intended function in the finished article as placed on the EU market should not be considered as a treated article.**

LET'S START



QUESTIONS?

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