



# Transitional Measures Under the BPR: In-situ Generated Active Substances and Food Contact Materials

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# Extension of the Scope of the BPR

	BPD	BPR
Active substance	A substance or microorganism including a virus or a fungus having general or specific action on or against harmful organisms.	A substance or a microorganism that has an action on or against harmful organisms.
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.  <b>A treated article that has a primary biocidal function shall be considered a biocidal product.</b>
Treated article	None	Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.

# Extension of the Scope of the BPR

	BPD	BPR
Food Contact materials and articles	<p><b>Article 1(j):</b> The Directive <b>shall exclude products</b> 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</p>	<p><b>Article 2(2)</b> ..this Regulation <b>shall not apply</b> to biocidal products or treated articles that are within the scope of the following instruments: ...<b>[Regulation 1935/2004]</b>  <b>No exemption for FCM</b></p>

# In-Situ Generated Active Substances

# In-situ Formed Active Substances: Definitions

- Biocidal product **definition is expanded**: also covers substances or mixtures **generating** active substances. But the emphasis on **intention** to destroy etc. remains unchanged
- On the basis of the **BPD** definition **precursors were not considered biocidal products**. The MoD interpretations – further confused the situation. As a result, applicants have submitted dossiers for the authorisation of
  - Precursors
  - Generated active substances
  - Both
  - Neither
- The extended **BPR** definition clarified this situation – however, **no clarity** whether some **precursors had to already be covered by the BPD** – issue of “**biocidal intention**”
- Direct impact of the interpretation – **confusion** whether the **transitional measures under Article 93** of the BPR apply or not for in-situ generated substances

# In-situ Formed Active Substances: New Requirements

- Under the BPR it is foreseen that **both** the precursor and the *in-situ* generated active substance would go through approval
- Commission's Call for information on in-situ generated active substances (published January 2014) has requested feedback from companies on:
  - Active substances (AS)/PTs supported under the review program
  - New authorisation requests for other precursor/AS pairs – whether or not the company is participant already in the review program
  - Other precursors for the same AS
- Based on input from industry the Commission issued its revised position on the **management of in-situ generated substances** in Nov 2014; **updated in March 2015** focusing on active substances under the Review Program
  - Substances generated in-situ (and their precursors)
  - Active substance releasers
  - Specific substances (ozone, OH<sup>\*</sup>) are not yet addressed in the final document

# March 2015 Commission Note (Final)

- In-situ generated substances need to be defined by reference to the precursor(s). The precursor is a biocidal product.
- Precursor is already in the Review Program – Article 95 listing is required by September 2015 (**need MS review as well?**)
- Active substance is on the Review Program but needs to be redefined – Article 13 of the new Review Regulation (Regulation 1062/2014) applies (**any deadline for review?**)
- New Precursor/AS combinations need dossiers to be submitted during the transition period – as per Article 93 (**need to select MS to review?**)
- The **biocidal product** subject to authorisation is
  - **EITHER** the precursor itself;
  - **OR** the active substance generated from precursor substances or mixtures, which themselves cannot be authorised as biocidal products (as ambient air or sea water)
- Does the **REACH derogation** from registration of the **active substances cover the precursors** as well?

# Food Contact Materials



# Food Contact Materials and Articles and Biocidal Products

- 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
- Scope of the Framework Regulation:
  - Materials and articles, including active and intelligent food contact materials and articles, **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
- **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

# Framework Regulation

## *Specific Measures*

- For the groups of materials and articles in Annex I **specific measures** may be adopted
  - Positive list with specific restrictions – **as the Union list for plastics**
  - Specific provisions protecting human health
  - Basic rules for checking compliance
  - Rules for sampling and methods of analysis
  - Specific provisions for traceability; publicly available Community Registers
  - Individual authorization, if necessary
- **National measures**
  - In the absence of specific measures, Member States may maintain or adopt national provisions (subject of the **Principle of Mutual Recognition**)

# 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 labeling, advertising or presentation of a material or article shall **not mislead** the consumers.

# Plastics Regulation

## *Union list of Authorized Substances*

### **Article 5: Union list:**

- Only substances included in Union list may be 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

### **Article 6: Derogations for substances not included in Union List:**

- Polymer Production Aids; Salts; Polymeric additives; Aids to polymerization and NIAS
- Substances in the **Provisional List** (remaining **only surface biocides**)

# Food Contact Materials and Articles and Biocides

- Potential **Biocide 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 Biocides in 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 Biocides in Food Contact Plastics Materials and Articles (cont.)

## Multiple regulatory overlap:

- **Dual authorization** is the proposed approach in Discussion document from the Commission: **July 2013**:
  - **ECHA** for authorising the active substance
  - **EFSA** for establishing use restrictions
- **Dual regulation**:
  - Under the Food contact legislation:
    - **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**
    - **Process biocides** as PPAs are also under derogation from Union list, **only subject to national law and FR**
  - Under the BPR most of these applications are **considered treated articles**, subject to Article 58 requirements under the BPR, harmonised at EU level

# Draft Measure for Setting Limits on Biocides in Food Contact Materials and Articles

- To **regulate the overlap** between the dual requirements
  - Requirement for the approval of the active substance under the BPR
  - Quantitative restriction on specific migration under the food contact legislation
- Proposal for quantitative restrictions:
  - Migration < **10 ppb**; OR
  - QM < **1 ppm**; OR
  - **Specific limits** determined by the new regulation (CMRs, endocrine disruptors, nano: only this option)
- Requires the amendment of the **Plastics Regulation** (10/2011):
  - Excluding biocides from the Union list
  - Review the Provisional List
  - Requires modification of **national measures**



# Food Contact Materials as Treated Articles

- **Treated articles** were **not explicitly covered by BPD** - but extensive guidance on how to address individual examples in the Manual of Decisions (MoD)
- BPD did **not cover imported articles** treated with an active substance outside the EEA for an **internal effect**. No requirement to use EU approved actives.
- **BPR introduced changes that explicitly addressed treated articles**
- **Specific chapter for treated articles** which are **not biocidal products**
- Article 58(2): 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)

# Treated Articles: Commission's New Approach

## Final Note for Guidance on Treated articles - December 2014

- *Article 3(1) (l) of the BPR defines a treated article as '...any substance, mixture or article which has been treated with, or intentionally incorporates one or more biocidal products'. As indicated in Article 58 (2) to (4), 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 a 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**

# Treated Articles: Commission's New Approach

- Important elements to consider “**intention**” when making a decision on a treated article:
  - **Claims** (both on biocidal function and biocidal property) – no claim does not automatically mean no intention
  - **PT** of the biocidal product (likely to be intentional or not in the finished article)
  - **Concentration** of the active substance in the finished article (low concentration, non-effective residues of active substances mean no intention)
- The onus is on the manufacturer or importer of the finished articles to provide **justification** whether the presence of a biocidal active substance is intentional or not
- If the remaining presence of an active substance in the finished article is **not intentional**, the **article does not qualify as treated** and the residual active substance should not be approved.

# Summary Conclusions

- Most of the **food contact** applications falling under the **Framework Regulation** would be **Treated articles** under the **BPR** – with a binding **positive list for plastics** materials and articles
- **To avoid legal uncertainty** in a **dual approval** process - beyond the potential **uncertainties related to some complex treated articles** - it is 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**)
- **Transition** regulated by the BPR rules – **Article 93 applies**
- Specific **legislative changes in national legislation** for incorporating the new biocides measure under the BPR – replacing binding national rules for biocides

# Questions?

