The New Biocidal Products Regulation:
Applicable in Six Months and Counting

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Treated Articles and Nanomaterial under the BPR

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New Provisions for Treated Articles under the BPR
## Some Key Definitions

<table>
<thead>
<tr>
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<th>BPD</th>
<th>BPR</th>
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<tbody>
<tr>
<td><strong>Active substance</strong></td>
<td>A substance or microorganism including a virus or a fungus having general or specific action on or against harmful organisms.</td>
<td>A substance or a microorganism that has an action on or against harmful organisms.</td>
</tr>
<tr>
<td><strong>Biocidal product</strong></td>
<td><strong>Active substances</strong> 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.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Treated article</strong></td>
<td>None</td>
<td>Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.</td>
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</table>
Biocides under the BPD (Directive 98/8/EC)

- **Treated articles** not explicitly covered by BPD - but extensive guidance on how to address individual examples in the Manual of Decisions (MoD)
  - MoD focuses 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 leather)
    - *External effect:* treated article is intended to act as a biocidal product

- **BPD does not cover imported articles** treated with an active substance outside the EEA for an internal effect. No requirement to use EU approved actives.

- **Biocidal products** when used in materials and articles intended to come into contact with foodstuffs are excluded from the scope of the BPD

- **BPR makes changes that explicitly address treated articles**
Biocides under the BPR (Regulation 528/2012)

- Biocidal product **definition is expanded**: also covers substances or mixtures **generating** active substances. But the emphasis on **intention** to destroy etc. remains unchanged.

- **Treated articles** are explicitly defined and addressed by the BPR. Treated article only falls within the “Biocidal Products” definition if it has a “**primary biocidal function**”

- Primary biocidal function is **not defined** – open for interpretation.

- **Biocidal product**: materials and articles intended to come into contact with foodstuffs are **not excluded from the scope of the BPR** – Product Type (PT) 4
Definition: Extended terminology under draft Note for Guidance on Treated Articles

- Treated article: “...treated with, or intentionally incorporates...”
  - intentionally incorporates: it is intended to become part
  - treated with: it is not intended to become part, but is applied with intention: see Proposed answer on Page 9: Article 58 of BPR only applies where the article was treated with a biocidal product. This means that the product (and hence the active substance) must have been applied with the intention of exerting a biocidal effect.

- In agreement with Article 58(2) on treated articles, which applies for active substances contained in the biocidal product it was treated with it or incorporates. Based on this interpretation, even active substances which do not remain in the treated article do require authorization.

- Interpretation for certain industry examples:
  - Complex articles
  - Imported articles
  - Treated article with primary biocidal function is a biocidal product.
Principles: Extended interpretation under draft Note for Guidance on Treated Articles

- **Biocidal function** Page 5: *By analogy with the definition of a biocidal product*

- **Biocidal property** Page 8: *A property resulting from the fact that the object has been treated with or intentionally incorporates a biocidal product.*
  - The intention is missing from both interpretations!!
  - Confusion between treated articles with a biocidal property and treated articles with primary biocidal function. The first one is not a biocidal product.
  - Confusing reference to “internal” and “external” effect

- **Silent active substances??**
  - Do not contribute to the biocidal functions of the treated article
  - **But:** Needs to fulfil the definition of **biocidal product**, including
    - **intention**
    - **In the form it is supplied to the user**
Principles: Extended interpretation under draft Note for Guidance on Treated Articles (cont.)

- Primary biocidal function: Function of first rank, importance or value

- No definition, but proposed criteria
  - Prominence of the claim made on biocidal function
  - Public health claim
  - Other circumstances

- Confusion between biocidal product and treated article
  - Biocidal product which consists of, contains or generate an active substance
  - Treated article which is treated with or incorporates a biocidal product

- Relevance of:
  - intention
  - the form it is supplied to the user
Treated Articles under the BPR

- BPR devotes a specific chapter (Chapter XIII) to treated articles which are not biocidal products (no primary biocidal function):
  - A treated article cannot be placed on 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.

- Transitional provisions under Article 94 (draft modifications for derogations):
  - May continue until 180 days after 1 September 2016 for any treated article
  - Until 180 days after an approval decision on the AS/PT combination, provided the application was submitted by 1 September 2016

- Article 93: for treated articles with primary biocidal function, not covered by the BPD but covered by the BPR, if available on the market on 1 September 2013, application for authorization must be submitted by 1 September 2017 – covers Food contact articles
Food contact treated articles under the BPR

- Affected by change of scope between BPD and BPR related to food contact materials and articles
- Discussion document from the Commission: Draft February 2013
- Framework Regulation 1935/2004 covers all food contact materials and articles
- Biocides in food contact applications:
  - Process biocides (PT 6, 7, 12)
  - Surface biocides (PT 4)
  - Food preservatives (in active packaging applications) – still excluded from the scope of the BPR
- Plastics Regulation 10/2011 has a positive list for all authorized additives and monomers (with some derogations) – the Union list
- Surface biocides are considered additives, so they should be listed on the Union list
Food contact treated articles under the BPR (cont.)

- Proposed new measure specifically for **surface biocides** (PT 4 applications)
  - **Exclude** surface biocides from the scope of the Plastics Regulation
  - Create **positive list** of approved surface biocides
  - Establish safe use by appropriate **SMLs**

- **Dual approval process:**
  - **ECHA** for the active substance authorization
  - **EFSA** for appropriate restrictions in food contact uses

- **Transition regulated by the BPR rules**

- Specific **legislative changes** for incorporating the new measure
Complex treated articles under the BPR

- Question: Does the preservative in a glue which is used to bound the woodchips to make a table which is then imported into the EU need authorization?

- Proposed answer by the Draft Guidance:
  - In theory - Yes
  - In practice – No (it is difficult to identify the treatment)

- Our interpretation:
  - In theory and in practice – No
  - The definition of treated article includes the notion of intentionally incorporating or being treated with a biocidal product. The bound woodchip is not a biocidal product, hence the glue preservative is not an active substance in this use.
Labelling of Treated Articles

- Labeling requirements triggered when:
  - biocidal claim is made, or
  - conditions of approval of AS require labeling because of conditions of use

- Mandatory label content (unless equivalent requirements under EU regulation on the article in question):
  - statement that the article incorporates a biocidal product
  - biocidal properties attributed to the AS contained therein
  - name of all active substances in the treated article
  - name of all nanomaterials in the BPs followed by “[nano]”
  - any relevant instructions for use and precautions
Labelling of Treated Articles

- In all cases, treated articles must include “necessary” labeling to protect humans and the environment:
  - use instructions
  - precautions
- Labeling on article can be replaced by packaging, instructions or warranty but only if “necessary” due to size/function:
  - other media in case of ‘tailor made’ products
  - in official language(s) of countries where marketed
- 45 day information obligation to consumers on biocidal treatment of articles – free of charge (like REACH communication on SVHCs in articles).
Nanomaterials under the BPR
Nano under the BPR - Definition

- Nanomaterial = “a natural or manufactured (incidental not included!) active substance or non active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm-100nm. Fullerenes, graphene flakes, and single wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered nanomaterials” (Article 3(1)(z))
Scope and definition might be changing…

- Commission shall be empowered to adopt delegated acts in accordance with Article 82 in order to *adapt this definition* (Article 3(5))

- Commission may, at the request of a Member State, *decide* by means of implementing acts *whether a substance is a nanomaterial* and whether a specific product or group of products is a biocidal product or a treated article or neither. (Article 3(3))
Nanomaterials in AS and BP

Nanomaterials are treated differently under the BPR:

- **In active substances**
  - Approval of the active substance shall **not cover nanomaterials** except where explicitly mentioned. (Article 4(4))
  - Existing review process does **not indicate** particle size

- **In biocidal products**
  - Product authorization **only if** nanomaterials have been addressed in substance evaluation – what if non-active?
  - **New actives in nano-form:** no transitional period
  - The risk to the environment and health must be assessed **separately**. (Article 19(1)(f))
Nanomaterials in treated articles

- Requirements under the BPR (Art. 58):
  - Treated articles can only be placed on the market if nano materials in the active substances contained in the biocidal product are explicitly authorized – what about the non-active?
  - existing review process does not indicate particle size

- Transitional measures under Art. 94(1)
  - If application for authorization was submitted by 1 September 2016; until 180 days following the decision
  - If no application: until 180 days after 1 September 2016
  - Nano-forms of existing active substances are legally on the market today based on existing Regulation
Proposed transitional measures

- Substances already included in Annex I are not considered to cover nano-forms

- Nano-forms of existing active substances - Opportunity to submit an application under the review program for existing AS/PT combinations
  - Issue with sameness?
  - Issue of joint submission

- Notification is requested from applicants supporting nano-forms – with accurate substance identification

- Similar procedure as for other additional active substances to be included in the review program

- Specific Annex for nanomaterials under the review program

- Only these nanomaterials can remain on the market during the transition
Specific labeling requirements for nanomaterials

- **Treated articles** (Article 58(3)(d))
  - must contain the name of all nanomaterials contained in the biocidal products, followed by [nano]

- **Biocidal products** (Article 69(2)(b))
  - Must state that product contains nanomaterials
  - Identify specific related risks (?)
  - Following each reference to nanomaterials [nano]
Specific testing requirements for nanomaterials

- **Active substances**: Where test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials and where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials.

- **Biocidal products**: Common principles on the evaluation of dossiers for biocidal products will need to be adapted and elaborated in technical guidance to take account of the latest scientific information.
Specific nanomaterials “safeguards”

- Products containing nanomaterials are not eligible for simplified authorization procedure (Article 25)

- Monitoring and reporting – Member States shall report every 5 years on the implementation of the BPR, including information on the use of nanomaterials in biocidal products and the potential risks (Article 65(3)(d))

- Work in progress: Commission paper discussing nanomaterials under the BPR and relevant transition from BPD
Dr. Anna Gergely

- Director, EHS regulatory in Steptoe’s Brussels office where, in a role equivalent to partner, she is the firm’s principal scientist

- Practice covers chemicals with a sharp focus on nanotechnology; including food contact materials, REACH regulation, agro-biotechnology, biocides, cosmetics, food and feed, medical devices, and a range of consumer and industrial products

- Recommended by Legal 500 EMEA for EU Regulator: Environment and Chemicals (REACH)

- Chair of European Commission NANOfutures Regulation working group and AMCham EU’s Nanotechnology Task Force

- PhD in analytical chemistry and quantum chemistry, and a registered European patent attorney
THANK YOU FOR YOUR ATTENTION

Questions?

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