The New EU Rules on Articles Treated with Biocidal Products

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European Food Law Conference 2014

ERA, Trier

May 5, 2014

Outline

1. The Biocidal Products Regulation
2. New Rules for Treated Articles
3. The Commission's Current Interpretation
4. Food Contact Materials

Biocidal Products Regulation 528/2012 ("BPR")

- EU approval of active biocidal substances ("AS")
  - Per Product Type ("PT")
- Authorization of biocidal products ("BP") containing AS
  - EU authorization
  - National authorization
- BP – "any substance or mixture […] 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" […]
  - Also products generated *in situ*

Biocidal Products Regulation 528/2012 ("BPR")

- BPR takes over review of existing AS under Biocidal Products Directive ("BPD")
- Procedures are managed by ECHA and MS Competent Authorities
- Most requirements apply as of Sept. 2013
  - With transitions (e.g., substances under review, products newly in scope, treated articles)

The BPR and Treated Articles

- BPR introduces new rules (Art. 58) for "treated articles"
  - Eliminates "internal" v. "external" (BP) effect of BPD
- "Treated article" -- "any substance, mixture, or article which has been treated with or intentionally incorporates one or more biocidal products"
  - Unless the sole treatment is the fumigation or disinfection of premises or containers used for the storage or transport and where no residues are expected to remain from such treatment
  - Treated article that has a primary biocidal function must be considered a BP
    - Member States may request the Commission to decide whether group of products is a BP or treated article

The BPR's Requirements on Treated Articles (Art. 58)

1. Treated articles may be placed on the market only if all AS contained in the BPs used on the treated article are approved for the relevant PT
   - BPR does not refer to concentration limits
   - Biggest impact on imported treated articles
   - Very difficult to comply with the Commission's current interpretation on complex articles

The BPR's Requirements on Treated Articles (Art. 58)

2. Treated article must be labeled if:
   a. A claim is made on the biocidal properties of article
      - Note that a material may be a treated article even if no biocidal claim is made
   b. The approval of the AS requires the labeling

- Label must include: (i) statement that article incorporates BP, (ii) biocidal property claimed, (iii) name of all AS, (iv) name of all nanomaterials ("nano"); (v) any relevant instructions for use

3. In addition: Label with instructions for use, including precautions, if necessary to protect humans, animals or the environment

The BPR's Requirements on Treated Articles (Art. 58)

4. Supplier of treated article must provide consumer, upon request, with information on the biocidal treatment of the article
   - Within 45 days of consumer's request

5. In addition, Commission may adopt implementing acts
   - Notification requirements for treated articles with AS
   - Detailing labeling requirements

Commission Note for Guidance on Treated Articles (Sept. 2013)

- Identification of treated articles
  - As soon as the material (substance, mixture or object) has been treated with or intentionally incorporates a BP
    - Even if AS is no longer present
    - But not residues from production process (e.g., BP applied to the manufacturing equipment)
    - Also exemption for fumigation or disinfection of premises or containers
  - Complex articles
    - Complex articles are treated articles if their components have been treated with or intentionally incorporate a BP
      - E.g., glue with an additive in packaging material
      - No concentration limits
      - Significant impact on importers

Commission Note for Guidance on Treated Articles (Sept. 2013)

- Treated Articles as Biocidal Products

  - If a substance or mixture (e.g., paint) has a biocidal function (≠ biocidal property) (even if it is not primary) – BP

    - But it must have been treated with or intentionally incorporate a BP

    - E.g., wall paint with mosquito repellent (not primary biocidal function) v. wall paint with preservative (biocidal property)

Commission Note for Guidance on Treated Articles (Sept. 2013)

- Treated Articles as Biocidal Products
  - Treated articles (objects) with primary biocidal function are BPs -- to be decided on a case-by-case basis
    - Target species, concentration of AS, mode of action of AS, intended use and purpose of treated article
    - Claims – predominance of claims
      - "Claims of public health relevance", i.e., statement that treated article will provide benefits against pathogens of public health relevance, e.g., influenza virus, E. coli, pathogenic bacteria

Treated Articles – Complex Articles Recent Commission Proposed Approach

- Acknowledgment of significant international trade impact of Commission's current interpretation on complex articles
- "*The scope of the provisions of Article 58 is restricted to treated articles in the form in which they are placed on the EU market*"
  - "*it does not concern directly components of complex articles or intermediate forms which are not themselves placed on the EU market*"
- Principal criteria seems to be whether the biocidal product still performs a biocidal function when the complex article is placed on the EU market
- Member States and industry are expected to comment on the proposed approach

Treated Articles – Complex Articles Recent Commission Proposed Approach

- "Intentionally Incorporating" a BP
  - Complex article is a treated article if the biocidal product in the component continues to have a biocidal function when the complex article is placed on the EU market
  - Treated article: "*complex articles including e.g., paints, adhesives which contain a film preservative in order to protect the paint/glue layer during the storage/use of the article*"
  - Non-treated article: "*complex articles including e.g. glues, inks, paints which had in-can preservatives added in order to protect them during storage, where these preservatives have no further function in the final product*"

Treated Articles – Complex Articles Recent Commission Proposed Approach

- "Treated With" a BP
  - Complex article is a treated article only if the finished product as placed on the market is treated
  - Non-treated article: "*Disinfection of components or intermediate form (which are not themselves placed on the EU market)*"

Food Contact Materials

- BP used in food contact materials ("FCM") are now subject to the BPR
  - Were exempted from the BPD
  - FCM that are treated articles are subject to BPR
- BPR continues to exempt biocides used in food and feed
  - and (food and feed) processing aids
  - and food and feed used as repellents or attractants

Food Contact Materials

1. Process biocides -- used as components in the manufacture of FCM but not intended to be present in the FCM
   - Preservatives for products during storage (PT 6), film preservatives (PT 7), slimcides (PT 12)
   - Materials or preparations (e.g., pre-polymer solutions) incorporating these products --- treated articles
   - Not approved for "use in" FCM (PT 4)
2. Food preservatives -- incorporated into final FCM but intended to be released into the food to preserve it
   - Excluded from BPR
   - Covered by the Regulation on Active and Intelligent Materials and Articles
3. Surface biocides -- intended to be present in the FCM in order to keep their surface free from contamination
   - Materials "intentionally incorporating" or "treated with" them – treated articles
   - Also subject to FCM rules authorization if FCM made of plastic or regenerated cellulose film

Food Contact Materials
Surface Biocides

- Surface biocides must be approved for PT 4 ("products used to impregnate materials which may enter into contact with food")

- Specific Migration Limits must be established when substance is approved (See Article 19(1)(e) BPR)

- Approval will provide: "*Products containing substance X shall not be incorporated in materials and articles intended to come into contact with food within the meaning of [Food Contact Materials Regulation] unless the Commission has established specific limits on the migration of substance X into food or it has been established pursuant to such Regulation that such limits are not necessary*."

Food Contact Materials Transitions for Surface Biocides

Treated Articles (FCM)

1. Possibility to present an application for use of AS in treated articles until Sept. 2016
2. If application is submitted by Sept. 2016 – AS may be used in treated article until (i) 180 days after rejection, or (ii) date of final approved use (approval Regulation will establish 2 years deadline for application for BP)
3. If no application is submitted by Sept. 2016 – AS may be used in treated article until March 2017

- Importantly, transitional provisions apply only to use of substance in treated article – not to labeling and other information requirements

Products that Were Out of Scope (BPs used in the Manufacture of FCM)

1. For BPs that were on the market or used as BPs in Sept. 2013 but were not subject to BPD
2. MS may continue to apply their own regimes until
   - Sept. 2017 if application for approval of use is not submitted by Sept. 2016
   - If application submitted by Sept. 2016
     - Until 3 years after approval
     - Until 12 months (marketing) after rejection

Food Contact Materials
Transitions for Surface Biocides

1. Check if AS is supported under review program for PT 4
2. If application for PT 4 has been submitted (AS supported under review program), FCM treated with BP containing AS may be placed on the market until decision of AS for PT 4 is made
   - But would still have to be labeled?
   - If application for PT 4 has not been submitted – it must be submitted by Sept. 2016
   - If application for PT 4 is not submitted by Sept. 2016 – FCM may be marketed until March 2017
3. Once the AS is approved for PT 4, EU companies marketing the BP containing the AS will have to apply for an authorization (within 2 years from approval)
4. If approval for AS is rejected – FCM may not be marketed after 180 days from rejection

Thank you

Questions?

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