History and Scope of the Biocidal Products Regulation (BPR) -- And What Happens Next

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About The Acta Group (Acta®)

- A global scientific and regulatory consulting firm
- Strategic, comprehensive support
- Scientists, regulatory and legal experts, and business strategists
- Experience in industry, research, and government
- Acta offices in Beijing, China; Manchester, United Kingdom (UK); and Washington, D.C., U.S.
- Chemical regulation -- BPR; Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation; Plant Protection Products (PPP) Regulation; K-REACH; China Order No. 7; Toxic Substances Control Act (TSCA); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
History of Biocides Regulation in the European Union (EU)

- **Timeline for Directive 98/8/EC (Biocidal Products Directive (BPD))**
  - Entered into force on May 14, 1998
  - Member States required to implement BPD before May 14, 2000
  - BPD required that “new” active substances (AS) (i.e., ASs not on the EU market before May 14, 2000, or identified/notified) be reviewed and included in Annex I BPD prior to placement on the EU market
  - All “existing” ASs (i.e., ASs on the EU market before May 14, 2000) required to be identified/notified by March 28, 2002
  - Biocidal products containing ASs that were not identified/notified required to be withdrawn from the EU market by December 14, 2003
  - Products containing ASs that were identified required to be withdrawn from the EU market by September 1, 2006
  - Products containing ASs that were notified, and for which relevant data were submitted in the Review Programme, able to stay on the market pending an Annex I inclusion/non-inclusion decision -- “transitional period”
History of Biocides Regulation in the European Union (EU) (cont’d)

- **Scope and processes of BPD**
  - "Biocidal products" covered
    - Excluded PPPs -- Directive 91/414
    - 23 product-types (PT) covered (Annex V)
  - Two-step authorisation procedure under BPD
    - AS inclusion in Annex I BPD for PT
    - Product authorisation
      - Two-tier approval system retained in BPR
Scope and Functioning of BPR

- BPR (Regulation (EU) 528/2012) text adopted on May 22, 2012 -- Repealed and updated BPD from September 1, 2013

- Important changes:
  - Expanded scope includes treated articles, food contact materials, and *in situ* generated biocidal products
  - Product authorisation procedure regarding biocidal products -- National Authorisation and Mutual Recognition vs. Union Authorisation
  - Exclusion criteria for high risk ASs
  - Substitution of high risk biocides
  - Provision for low risk biocides
  - Provisions relating to nanomaterials
  - Role of the European Chemicals Agency (ECHA), Biocidal Products Committee (BPC), and ECHA’s Board of Appeal
  - Changes to PTs
  - New data requirements
  - Strengthened data compensation provisions
Scope and Functioning of BPR (cont’d)

- BPR covers the placing on the market and use of biocidal products that are used to protect humans, animals, materials, or articles against harmful organisms (e.g., pests or bacteria) by the action of the ASs contained in the biocidal product.

- BPR aims to:
  - Improve the functioning of biocidal products in the EU, while ensuring a high level of protection for humans and the environment.
  - Harmonise the market at the “Union level”.
  - Simplify approval of ASs and authorisation of biocidal products.
  - Introduce timelines for Member State evaluations, opinion-forming, and decision-making.

- Some important definitions for interpretation (Article 3 BPR) -- “biocidal product,” “active substance,” “existing active substance,” “new active substance,” “making available on the market,” “placing on the market,” “treated article,” “biocidal product family,” “national authorisation,” “Union authorisation,” “product-type,” and “nanomaterial.”
Scope and Functioning of BPR (cont’d)

- What PTs are covered by BPR?
  - Annex V: Very wide scope -- four main groups (containing 22 PTs):
    - Disinfectants for home and industrial use
    - Preservatives for manufactured and natural products
    - Pest control products
    - Other specialist biocidal products (e.g., antifouling products)

- What is excluded from BPR?
  - Non-biocidal uses of products and ASs (e.g., use of an essential oil as a fragrance rather than as an insect repellent)
  - Products that destroy, deter, render harmless, prevent action of, or otherwise exert a controlling effect on a harmful organism by physical or mechanical action (i.e., no chemical or biological activity involved)
    - E.g., fly swats and sticky boards for rodents
Scope and Functioning of BPR (cont’d)

What is excluded from BPR? (cont’d)

- Uses of products that are regulated under certain other European legislation
  - PPPs (e.g., algaecides applied on soil or water to protect plants)
  - Human medicines (e.g., anti-lice shampoo)
  - Veterinary medicines
  - Medical devices
  - Cosmetics (e.g., anti-dandruff shampoo)

What does BPR provide rules for?

- AS approval
- Biocidal products authorisation
- Placing treated articles on the market
Scope and Functioning of BPR (cont’d)

■ AS Approval

- Biocidal products to be placed on the market require authorisation, and authorisation can only be obtained once the ASs contained in that biocidal product have been approved (included on the Union list) under BPR.

- The approval of ASs occurs at the Union level and the subsequent authorisation of the biocidal products takes place at the Member State level or the Union level.

- Generally, ASs meeting the exclusion criteria under BPR Article 5 are not approved (i.e., carcinogenic, mutagenic, and reprotoxic (CMR) substances under Categories 1A or 1B in the Classification, Labelling and Packaging (CLP) Regulation; endocrine disruptors; persistent, bioaccumulative, and toxic (PBT) substances; very persistent and very bioaccumulative (vPvB) substances)

- Article 95(2) BPR -- Since September 1, 2015, a biocidal product “consisting of, containing or generating a relevant substance,” included in the Article 95 List, shall not be made available on the market unless the substance or product supplier is included in the list for the appropriate PT.
Scope and Functioning of BPR (cont’d)

Biocidal Products Authorisation

- A biocidal product must be authorised to be placed on the market

- Generally, BPR authorisation requirements become applicable to a product when:
  - The AS(s) within the product is/are listed in the Union list
  - The entry covers the PT appropriate for that product
    - If an AS is listed in the Union list for use as a wood preservative (PT 8), it may be authorised for use in a wood preservative product, however, it may not be authorised for use in an antifouling product (PT 21) until that PT is included in the Union list

- When a biocidal product contains more than one AS, it cannot be authorised until all of the contained ASs are on the Union list
Types of Product Authorisation Applications

- National Authorisation
  - Article 3(1)(m) BPR -- “Administrative act by which the competent authority of a Member State authorises the making available on the market and the use of a biocidal product or a biocidal product family in its territory or in a part thereof”
  - Once National Authorisation is granted, the applicant can ask for the National Authorisation to be “Mutually Recognised”
    - Apply to Member States for the product to be authorised via the “Mutual Recognition in Sequence” process (Article 33 BPR)
  - If an applicant wants products authorised in another Member State at the time of National Authorisation, the “Mutual Recognition in Parallel” process applies (Article 34 BPR)
  - If a biocidal product/biocidal product family was on the market before the approval of the AS(s), transitional provisions may apply
Scope and Functioning of BPR (cont’d)

- Types of Product Authorisation Applications (cont’d)
  - Union Authorisation
    - Union Authorisation allows access to the EU market through a single authorisation -- no need for Mutual Recognition of a National Authorisation (Article 41 BPR)
    - Union Authorisations are for biocidal products with similar conditions of use across the Union
    - Depending on the PT, Union Authorisation occurs in three stages (Article 42 BPR):
      - From September 1, 2013, for biocidal products containing one or more new ASs and biocidal products of PTs 1, 3, 4, 5, 18, and 19
      - From January 1, 2017, for PTs 2, 6, and 13
      - From January 1, 2020, for PTs 7, 8, 9, 10, 11, 12, 16, and 22
    - Union Authorisations are not possible for:
      - Biocidal products containing ASs meeting the exclusion criteria (Article 5 BPR)
      - Biocidal products covered under PTs 14, 15, 17, 20, and 21
Scope and Functioning of BPR (cont’d)

- Types of Product Authorisation Applications (cont’d)
  - Simplified Authorisation
    - BPR Annex I identifies ASs that are eligible for the simplified authorisation procedure outlined in Articles 25 and 26 of BPR
    - A biocidal product is eligible for the simplified authorisation procedure if all of the following conditions are met (Article 25 BPR):
      - All ASs in the biocidal product appear in Annex I BPR and satisfy any restrictions specified in the Annex
      - The biocidal product does not contain any substance of concern
      - The biocidal product does not contain any nanomaterials
      - The biocidal product is sufficiently effective
      - The handling of the biocidal product and its intended use does not require personal protective equipment
    - A biocidal product authorised in accordance with Article 26 may be made available on the market in all Member States without the need for mutual recognition (Article 27 BPR)
      - Authorisation holder must notify each Member State at least 30 days before placing the biocidal product on the market within its territory
Scope and Functioning of BPR (cont’d)

- Placing Treated Articles on the Market
  - Definition: “Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products” (Article 3(1)(l) BPR)
    - “Substance,” “mixture,” and “article” as defined under REACH (Article 3(2) BPR)
  - If the article has a primary biocidal function, it would be regarded as a biocidal product (Article 3(1)(a) BPR)
    - Interpretation can be challenging in practice
  - Article 3(3) BPR: The European Commission may decide in an implementing act and following a Member State’s request whether a specific product or a group of products is a biocidal product, a treated article, or neither
  - To protect human health, animal health, and the environment, and to avoid discrimination between treated articles “originating in the Union” and treated articles imported from third countries, all treated articles placed on the European Economic Area (EEA) market should contain only approved ASs (BPR Recital 52)
Scope and Functioning of BPR (cont’d)

- Placing Treated Articles on the Market (cont’d)
  - BPR Article 58 (Chapter XIII)
    - Regulates the placing on the market of treated articles
      - Means first making available on the market of a treated article
    - Chapter not applicable to certain treated articles
      - Those articles: (i) where the sole treatment undertaken was fumigation or disinfection of premises or containers used for storage or transport; and (ii) where no residues are expected to remain from such a treatment
    - Composition requirements for treated articles (Article 58(2) BPR)
      - To be lawfully placed on the market, all ASs in the biocidal products the treated article has been treated with or incorporates must be included in the Union list, for the relevant PT and use, or in Annex I BPR, and all the specified conditions or restrictions must be met
Scope and Functioning of BPR (cont’d)

- Placing Treated Articles on the Market (cont’d)
  - Labelling
    - The person responsible for the placing on the market of a treated article must ensure that the label contains specified information in two instances (Article 58(3) BPR):
      - When a claim is made regarding the biocidal properties of the treated article; or
      - When the conditions associated with the approval of the contained AS(s) so require
  - Labelling requirements
    - Statement that the treated article incorporates biocidal products
    - Where substantiated, the biocidal property attributed to the treated article
    - Names of all ASs contained in the biocidal products
    - Names of all nanomaterials contained in the biocidal products, followed by the word “nano” in brackets
    - Any relevant instructions for use, including necessary precautions
    - Clearly visible, legible, and appropriately durable labelling
    - Where necessary, labelling information must be printed on the packaging, on the instructions of use, or on the warranty in the official language(s) of the Member State of introduction, unless that Member State provides otherwise
    - For treated articles not produced as part of a series (designed and manufactured to meet a specific order), the manufacturer may agree other methods of providing the customer with the relevant information
September 1, 2016, Deadlines

Article 93 BPR -- Transitional Measures Concerning Biocidal Products Not Covered by BPD

- If an AS in a product was on the market on September 1, 2013, and has not already been supported in the relevant PT under the Review Programme, companies are required to submit applications for approval of the AS by September 1, 2016.

- If an application for approval of the AS and PT combination is not made by September 1, 2016, the derogation applies until September 1, 2017.
  - Products containing the AS can no longer be made available on the market after September 1, 2017, for the relevant PT.

- If an application for approval of the AS for the relevant PT is submitted by September 1, 2016, timeframes under BPR Articles 89(2), (3), and (4) apply as appropriate.
  - Transitional measures in BPR Article 89 allow biocidal products containing an AS included in the Review Programme (for a given PT) to be made available on the market and used, subject to national rules, until three years after the date of their approval (shorter timeframes apply for non-approval).
September 1, 2016, Deadlines (cont’d)

- Article 93 Applicability
  - In Situ Generated ASs (Article 3(1)(a) BPR expanded definition of “biocidal product”)
    - *In situ* generation of a biocide where there is no supply of a precursor chemical (e.g., sodium hypochlorite generated from sea water)
    - *In situ* generation of a biocide where there is supply of a precursor chemical, but that precursor is not itself supplied for the purpose of generating a biocide (e.g., sodium hypochlorite generated from tap water and table salt where neither the water or salt were supplied with the intention of creating sodium hypochlorite)
  - Vermicides
    - Used to kill or control worms and other invertebrates
    - Not covered by BPD -- now within the description for PT 16
  - Working or Cutting Fluid Preservatives
    - BPD included in its scope “Metalworking-fluid preservatives” in PT 13 -- “[p]roducts used for the preservation of metalworking fluids by the control of microbial deterioration”
    - Under BPR, PT 13 is expanded to include “[p]roducts to control microbial deterioration in fluids used for working or cutting metal, glass or other materials”
September 1, 2016, Deadlines (cont’d)

- **Article 94 BPR -- Transitional Measures Concerning Treated Articles**
  
  - If appropriate steps are taken, Article 94 BPR allows for treated articles to continue to be placed on the market until the approval of the AS(s) for the relevant PT for the biocidal product that the article was treated with.
  
  - If the AS is not already in the Review Programme for the relevant PT, the application for approval of the AS(s) for the relevant PT must be submitted to ECHA by **September 1, 2016**.
  
  - If an application is not submitted, any article treated with a biocide that has not been approved may not be placed on the market after **March 1, 2017**.
  
  - If an application for the approval of an AS for the relevant PT is submitted before **September 1, 2016**, the treated article may still be placed on the market after **March 1, 2017**, until a decision is taken on approval/non-approval.
  
  - If a non-approval decision is taken for an AS before **September 1, 2016**, the treated article can continue to be placed on the market until **March 1, 2017**.
  
  - If a non-approval decision is taken for an AS after **September 1, 2016**, the treated article can be placed on the market for 180 days after the decision.
September 1, 2016, Deadlines (cont’d)

- Article 94 BPR -- Transitional Measures Concerning Treated Articles (cont’d)
  - If an application for approval of an AS contained in a treated article is submitted after September 1, 2016, the treated article can only be placed on the market once the AS has been approved for the relevant PT

- Article 94 Applicability
  - Fishing or aquaculture equipment treated with antifouling products
  - Kitchen sponge treated to inhibit microbial growth during use
  - Clothes treated with an insect repellent
  - Leather goods treated with a fungicide to protect the leather from decay
  - Paper incorporating a preservative to protect the finished article during use
  - Athletic clothing impregnated with antimicrobials to reduce odour during use
Next Steps and Further Deadlines

- Companies should implement comprehensive BPR compliance strategies for their ASs, biocidal products, and treated articles
- Industry must assess the implications of BPR in light of their uses
- Companies can benefit from reviewing ECHA’s guidance and explanatory notes
- Organisations should prevent the restrictive impact of the aforementioned March 1, 2017, and September 1, 2017, deadlines by taking action before September 1, 2016
Thank You

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