The New EU Biocidal Product Regulation (BPR) Changes the Regulatory Landscape Webinar
11 September 2012

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BPR– What’s New and Different

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Current Biocidal Products Directive (BPD)

- Biocides currently regulated under:
  - Directive 98/8/EC (Current BPD)
  - National legislation (e.g. KeMI Biocidal Products Ordinance (2000:338))
- BPD regulates “biocidal products”:
  - Active substances and preparations containing one or more active substances put up in the form on 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.
  - Excludes plant protection products (Directive 91/414 – PPPD)
  - 23 Product Types (PTs) covered (Annex V)
- Two step authorization procedure under BPD
  - Active inclusion in Annex I BPD for Product Type (PT)
  - Product authorization
Current BPD

- BPD came into force 14 May 1998. MSs required to implement before 14 May 2000.
- BPD requires that ‘new’ active substances (i.e. not on EU market before 14 May 2000 or identified/notified) be reviewed and included on Annex I BPD prior to placement on EU market.
- All ‘existing’ active substances (i.e. on EU market before 14 May 2000) required to be identified or notified by 28 March 2002.
- Biocidal products containing active substances not identified or notified, required to be withdrawn from EU market by 14 December 2003.
- Products containing actives that were identified, required to be withdrawn from the EU market by 1 September 2006.
- Products containing actives that were notified, and relevant data submitted in review programme, able to stay on the market pending an Annex I BPD inclusion/non inclusion decision (subject to national law) – ‘transitional period’.
- Notified actives currently being reviewed under the BPD review programme; Second Review Regulation as amended (Regulation 1451/2007).
- Mini review - extended the BPD transitional period from 14 May 2000 to 14 May 2014.
New BPR: Main Differences with Current BPD

- Legal framework regarding regulation of biocidal products remains largely intact except as regards:
  - Expanded Scope including Treated Articles, Food Contact materials, in-situ generated biocidal products
  - Product authorization procedure regarding biocidal products – National Authorisation and Mutual Recognition vs. Union Authorisation
  - Exclusion criteria regarding high risk actives
  - Substitution regarding high risk biocides
  - Provision for low risk active biocides
  - Provision relating to Nanomaterials
  - Role of the ECHA, Biocidal Products Committee, and ECHA Board of Appeals
  - Changes to PTs
  - New Data Requirements
  - Strengthened Data Compensation Provisions
BPR introduces new requirements regarding the inclusion of approval of actives on the Union list of approved active substances.

BPR is designed to phase out the use of:
- Substances classified as 1A or 1B CMRs under the CLP (Art. 5(1))
- Substances considered endocrine disruptors (Art. 5(1))
- PBTs/vPvBs (Art. 5(1))
- Provisionally Cat. 2 CMR (Art. 5(3))

BPR does this by way of so-called “exclusion criteria”

Exclusion criteria (Article 5) only allows the inclusion of these substances on Annex I BPR if:
- There is negligible exposure to humans under realistic worst case conditions of use;
- There is proof that the active substance is essential to prevent or control a serious danger to human health, animal health or to the environment; or
- Excluding the substance would have a disproportionate negative impacts for society when compared to the risk to human health, animal health or the environment arising from the use of the substance; or
  - In all cases a key consideration is the availability of suitable alternatives.
  - Use subject to appropriate risk mitigation
New BPR – Substitution (Art. 10)

- Under the BPR, if a Decision to include an active substance on the Union list of approved actives is adopted, a substance may be identified as a “candidate for substitution”.

- An active will be a candidate for substitution if it:
  (a) Meets the exclusion criteria under Article 5(1) but still approved for use
  (b) Classified as a respiratory sensitizer under CLP
  (c) Its acceptable daily intake level, acute reference dose, or acceptable OEL is significantly lower than the majority of other actives in same PT
  (d) Meets at least two PBT criteria (e.g. P and B, B and T, etc).
  (e) Other reason for concern
  (f) It contains a significant proportion of non-active isomers or impurities.

- If a substance is considered a candidate for substitution, products containing that substance may only be authorized or re-authorized after comparative assessment with products containing substances of lower risk (Annex VI) (Art 23).

- If the product containing a candidate for substitution presents significantly higher risk than the alternatives, product authorization must be refused or cancelled.
Technical equivalence

- Similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the
  - manufacturing process and/or manufacturing
  - location, compared to the substance of the reference
  - source in respect of which the initial risk assessment was carried out.
- Agency responsible for establishing technical equivalence (Article 54).
New BPR – Data protection (Art 59-68)

- New BPR provisions regarding data protection aim at ensuring data owners are compensated by others relying on same data (Art 63). Include provisions regarding content of a letter of access (Art 61), etc.
- 10-year data protection for an existing active from the date of approval for a particular PT
- 15-year data protection for an existing active from the date of approval for a particular PT
- 5-year data protection for renewal or review of an active from the date of decision.
- Similar periods for data submitted in connection with biocidal product authorisations.
- Art. 61 specifies the content of a letter of access
- Data sharing procedures similar to provisions under REACH for non-phase-in substances
Article 95

- As of 1 Sept. 2013, manufacturer or importer of actives or importer of biocidal products containing actives to submit a dossier (or reference to existing dossier if all data rights have expired) or a letter of access on the active to ECHA.
- ECHA to publish list of submitters.
- Mandatory data and fair costs sharing to apply to the all tox and ecotox studies.
- Data protection for existing actives under BPD review until 31 Dec. 2025.
- Biocidal products containing active substances from suppliers not listed by ECHA shall not be placed on the market after 1 Sept. 2015 (exception biocidal products newly within scope of BPR and low risk actives listed in categories 1-5 and 7 of Annex I)
- Disposal, storage and use of existing stocks of unsupported products allowed until 1 Sept. 2016.
New BPR – Other Changes (Many are REACH like)

- New BPR provides that the ECHA will play an active role in the active substance approval process, inter-party disputes regarding data access, etc.
- New BPR partially harmonises fees payable for active substance approval and product authorization applications.
- New BPR contains data-sharing provisions to prevent unnecessary testing on vertebrate animals.
- Creates a Peer-review in the Biocidal Products Committee
- Disclosure of Information on ECHA Website (Art. 66 (3)), Register of Biocidal Products established
- Data entry by IUCLID
- Member States to establish penalty legislation
- Member State helpdesks
- Applies Art. 45 CLP (Poison control) to biocides
Transitional Procedures – Active Substances

- Incomplete evaluation of active substance will be completed according to BPR:
  - applicant able to submit further info to address new requirements
- New role of Biocidal Products Committee:
  - evaluation coordination and technical support of MSs and Commission for active
- Dossiers submitted post September 1, 2012
- For earlier incomplete BPD dossiers, evaluation coordination with technical support from January 1, 2014
- Existing actives review completion target of May 2014 (very likely extended)
- Deadlines for withdrawal following active non-approval or dossier rejection for approved active product authorization application in order to stay on market
Transitional Procedures – Biocidal Products

- Authorized products remain on market until authorization expiry/cancellation (subject to BPR from September 1, 2013)
- Incompletely evaluated product dossiers subject to BPD, except:
  -- BPR authorization procedure if excluded active
  – comparative assessment procedure if contains substitution candidate active
  – applicants able to submit further info in these cases
- Biocidal products not expressly under BPD (in situ products, dual use, treated articles with a primary biocidal function etc.):
  – may stay on market until product authorization decision provided application submitted by September 1, 2017

- Treated articles containing biocides have special transitional procedures.
Provisions of the BPR Relating to Treated Articles and Food Contact Materials

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Agenda

- Treated articles under the BPR
  - Definition
  - Applicable rules
- Food Contact Materials and articles treated with or intentionally containing biocidal substances and the implications of the BPR
  - Specific examples of biocides’ uses and discussions on regulatory classification
  - Questions still unanswered
Treated Articles
-- Definition

• Defined as “any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products”
  – “substance”, “mixture” and “article” as defined under REACH
  – “biocidal products” (as explained by my colleagues)
Treated Articles

-- Definition

- Different thus, by definition, from a biocidal product
- if the treated article has a primary biocidal function, it would be regarded as a biocidal product
  - Interpretation not so easy in practice
Treated Articles
-- Definition and borderline products

- Article 3.3: The Commission may decide in an implementing act and following a Member State’s request whether a specific product or a group of product is a biocidal product or a treated article or neither.
Treated Articles
-- Scope: EU or non-EU Articles

- To protect human 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 EU market should contain only approved active substances
  - In the past, not applicable to imported treated articles
  - See Recital 52
Treated Articles

-- Chapter XIII of BPR or Article 58 of BPR

- Regulates the placing on the market of treated articles
  - = first making available on the market of a treated article
  - "any supply of (...) a treated article for distribution or use in the course of a commercial activity, whether in return of payment or free of charge"

- Chapter not applicable to certain treated articles
  - Those (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
Treated Articles
-- Composition requirements

- To be lawfully placed on the market, all active substances in the biocidal products the treated article has been treated with or it incorporates must be included in the list to be drawn up, for the relevant product-type and use or in Annex I and all the specified conditions or restrictions must be met
  - Article 58.2
Treated Articles
-- Labeling requirements

- The person responsible for the marketing must ensure that the label contains specified information in two instances:
  - when a claim is made with regard to the biocidal properties of the article or
  - When the authorization requirements for the biocidal substances so require
Treasted Articles

-- Labeling requirements

- Statement that the treated article contains a biocidal product
- Where substantiated, the biocidal property attributed to the treated article
- Name of all active substances
- Name of all nanomaterials in the biocidal products with the word « nano »
- Any relevant instructions for use
### Treated Articles

#### Labeling requirements

- Clearly visible, legible and appropriately durable
- Where necessary, labeling information must be printed on the packaging, on the instructions of use or on the warranty in the official language or languages of the MS « of introduction » unless that MS provides otherwise
- Treated articles not produced as part of a series but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information
Treasured Articles

-- Other requirements

- The supplier of a treated article must, upon consumer’s request, provide within 45 days, free of charge, with information on the biocidal treatment of the article.
Treated Articles

-- Transition period (Article 94)

- Treated articles available on the market on 1 Sept 2013 may, until the date of a decision concerning the approval for the relevant product type of the active substances contained in the biocidal products, continue to be placed on the market if the application for such approval is submitted before 1 Sept 2016
Agenda

- Treated articles under the BPR
  - Definition
  - Applicable rules

- Food Contact Materials and Articles treated with or intentionally containing biocidal substances and the implications of the BPR
  - Specific examples of biocides’ uses and discussions on regulatory classification
  - Questions still unanswered
Food Contact Within the Scope of BPR

- No longer expressly excluded from scope; thus within

- Food contact materials or articles containing biocidal substances would be regarded as “treated articles”
  - Thus besides the EU and national rules applicable to FC, the BPR provisions apply
  - But possible Commission’s decision on classification under BPR

- In BPR (annex V), various product-types relevant to FC:
  - **Product-type 4**: disinfectants – food and feed area: products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food/feed (incl. Drinking water) for humans or animals
  - and products used to impregnate materials which may enter into contact with food
  - **Product-type 7**: film preservatives, i.e. products used for the preservation of films or coatings by control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects, such as, plastics, sealants, binders, papers etc…
Food Contact Within the Scope of BPR

- **Product-type 9**: Fibre, leather, rubber and polymerized materials preservatives, i.e. products used for the preservation of fibrous or polymerized materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration (includes biocidal products which antigenise the settlement of micro-organisms on the surface of materials and thereafter hamper or prevent the development of odour and/or offer other kinds of benefits)

- **Product-type 12**: Slimicides: products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g., on wood and paper pulp
Food contact and biocides’ uses

- Biocides are used in various ways and for various purposes in food contact materials.
- Assessment of the applicable regime to be done under the various regulatory classifications existing in the food contact legislation and the BPR requirements.
- Several potential uses and issues are discussed here.
Examples of Possible Uses

- Process biocides used in food contact manufacture
- Biocides used for the protection of the food contact material or its surface
- Biocides used for the protection of the packed food
- Biocides in Cleaning Liquids for FCM
Process Biocides

- Used during the manufacture of food contact materials and articles
- Intended to keep the materials or preparations to be processed into final food contact materials (e.g., pre-polymer solutions) free from microbial contamination during the production, storage or handling process
- Assessment under the food contact legislation
  - Intentionally used as components in the manufacture of such materials
  - But not intended to be present in the final food contact material
• As no antimicrobial function is exerted on the final food contact material, the substance would be regarded, according to the European Commission’s draft guidance and from the FC legislation point of view, as a **polymer production aid**, which would be unintentionally and unavoidably carry-over in the final food contact article
Process Biocides

- **Assessment under the BPR:**
  - Pre-polymer solution treated with or containing a biocidal product, if placed on the EU market, could be a « treated article »
    - Note: that the definition of treated article includes « substances » and « mixtures » as defined in REACH (and not only « articles » as defined in REACH)
    - Note that, based on the language, the processing aids exclusion seems to only refer to those biocides used as such in food and feed processing => clarification needed
  - Such biocides would fall under product-type 6
Protection of the Food Contact Material

- Biocides can be used to protect the food contact material itself against harmful organisms
- No intended effect on the food
- E.g., the use of biocides in a water borne coating or inks
- Under the FC legislation:
  - In such applications, the biocide is an additive to food contact materials
Protection of the Food Contact Material

- Assessment under the BPR
  - If marketed in the EU, such FCM could also be regarded as a treated article
  - The biocides used would fall under product-type 6 (preservatives for products during storage)
Protection of the Surface of a FCM

- “Surface biocides” (defined in draft Commission guidance of 30/04/2012)
  - Not intended to have an effect in the food
  - E.g., Use of silver molecules in conveyor belts, chopping boards, inner surfaces of fridges etc…

- Under the FC legislation:
  - Would be food contact additives

- Under the BPR:
  - If marketed in the EU, such FCM would also be regarded as a treated article
  - The biocides used would fall under Product-type 7 “film preservatives” of the BPR
Protection of the Packed Food

- Biocides can be added to packaging to intentionally migrate into food
- The biocide will protect the food itself against harmful organisms
  - E.g., Addition of benzoic acid to a multilayer plastic, which will migrate into the food when the packaging is in contact with the food. Benzoic acid is intended to act as a preservative of the food
  - This use is regulated by the Active and Intelligent Packaging Regulation 450/2009
- The biocidal substance will be in this case regarded as a food additive
- It must be listed in the EU food additives positive lists
- Excluded from the scope of the BPR due to the exclusion of food additives
Biocides in Cleaning Liquids for FCM

- Biocides can be used to protect the surface of the food packaging itself against harmful organisms
  - Not intended to migrate into food
  - E.g., Use of biocides in cleaning solvents for kitchen surfaces
- As the biocide is not used/added in the production of the food contact material, it is not covered by the food contact legislation
- Have always been and remain within the scope of the biocidal products legislation
- Product-type 4 under Annex V of the BPR
Biocides in paper pulp?

- Example of food contact paper
- Not regulated at EU level (except for the general requirements of the Framework Regulation and the GMP requirements)
- Some national legislation in the NL, Italy and BfR Recommendations which may regulate the use of slimicides, e.g., the Dutch legislation; the BfR Recommendations

Under BPR:
- How about paper pulp?
- See in particular Slimicides / Product-type 12
  - Not clearly worded
  - Potential concerns
So What then?

- How to navigate between the two sets of legislation?
  - The FC legislation does not subject the granting of the clearance of a substance subject to authorization at EU level to the condition that the substance has been cleared under the BPR.

- Will the FC legislation be amended to reflect the fact that the clearance of a substance with biocidal properties used in food contact would be granted only after the requirements of the BPR are met?
So What then?

- Will a substance falling under the FC plastic additive definition be included in both the Plastics Regulation and the BPR? Or would it be included in one of them with a cross-reference?
- How will the clearance of substances used in FCM and subject to national legislation be handled?
- What about, e.g., preservatives in FCM that are currently permitted for use but would now fall also under the BPR?
  - Would the FCM be regarded as treated articles?
  - Would the biocidal substances have to be listed in the BPR for the relevant product type?
    - Transition period of time
Conclusions

- Treated articles and food contact materials and articles falling under that category are going to be significantly impacted by the BPR
- Industry must assess the implications of the BPR in light of their uses
- Transition period in place but no time to waste
New BPR: Union Authorisation and Mutual Recognition

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Overview

- **Current BPD – Refresher**
  - Current Product Authorisation and Mutual Recognition provisions
  - Transitioning to BPR

- **New Biocidal Products Regulation (New BPR)**
  - Product authorisation provisions - Aim/scope, etc
  - Union Authorisation
    - Legal framework
    - Process
    - Timelines
  - Mutual Recognition provisions
    - Legal framework
    - Differences with BPD
    - Simplified procedure
    - In sequence / in parallel
  - Related provisions

- **Other related issues (Guidance, updates, etc)**

- **Summary / conclusion**
Acronyms

- **BPD**: Biocidal Products Directive
- **BPR**: Biocidal Products Regulation
- **BP**: Biocidal Product
- **TA**: Treated Article
- **PT**: Product Type
- **MSCA**: Member State Competent Authority
- **RMS**: Rapporteur Member State
- **MR**: Mutual Recognition
- **CAR**: Competent Authority Report
- **EU**: European Union
- **ECHA**: European Chemicals Agency
- **MS**: Member State
- **LOA**: Letter of Access
- **REACH**: EU Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals
- **CLP**: Regulation on Classification, Labeling and Packaging Regulation
- **CMR**: Carcinogenic, mutagenic, reproductive toxin
- **PBT**: Persistent, Bio-accumulative and Toxic
- **vPvBs**: very Persistent and very Bioaccumulative
- **SEAC**: SocioEconomic Analysis Committee
Current BPD – Refresher

Current BPD - refresher

- Biocides currently regulated under:
  - Directive 98/8/EC (Current BPD)
  - National legislation (e.g. UK - Control of Pesticides Regulations (COPR))

- BPD regulates “biocidal products”:
  - Active substances and preparations containing one or more active substances put up in the form on 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.
  - Excludes pesticides (agricultural use)
  - 23 Product Types (PTs) covered (Annex V)

- Two step authorization procedure under BPD
  - Active inclusion in Annex I BPD for Product Type (PT)
  - Product authorisation

- NB BPD mini review – extension of time re review of actives by MSCAs
Product Authorisation comes after Annex I inclusion

Article 9 BPD
Whereas it is appropriate that the applicant submit dossiers which contain information which is necessary to evaluate the risks that will arise from proposed uses of the product; whereas a common core data set for active substances and for biocidal products in which they are contained is necessary so as to assist both the applicants seeking authorisation and those carrying out the evaluation to decide on the authorisation; (Preamble, para (7) BPD)

Data requirements depend on which Annex active included in
Whereas, when due account is taken of products which pose only a low risk, their active substances should be incorporated in a specific annex; (Preamble, para (13) BPD)

Applications for product authorisation
Application for authorisation shall be made by, or on behalf of, the person who will be responsible for the first placing on the market of a biocidal product in particular Member State and shall be to the competent authority of that Member State. Every applicant shall be required to have a permanent office within the Community. (Article 8(1) BPD)
Current BPD; Product authorisation – refresher

Data required includes LOA/rights to data used for Annex I inclusion

Member States shall require that an applicant for authorisation of a biocidal product shall submit to the competent authority: […] (b) for each active substance in the biocidal product, a dossier or a letter of access satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex IIA and, where specified, the relevant parts of Annex IIIA. (Article 8(2) BPD)

Authorisations granted for a maximum period of 10 years and are subject to cancellation and review

(Articles 3(6), 6 and 7 BPD)

MSs required to ensure Biocidal Products are “properly used”

i.e. Biocidal products must comply with conditions of use, labelling requirements, etc as prescribed in Product Authorisation, etc (Article 3(7) BPD)
Product Authorisation required in each and every MS where biocidal product placed on the market. (Article 3, etc BPD)

Re: Mutual recognition:
Without prejudice to Article 12, a biocidal product that has already been authorised or registered in one Member State shall be authorised or registered in another Member State within 120 days, or 60 days respectively, of an application being received by the other Member State, provided that the active substance of the biocidal product is included in Annex I or I A and conforms to the requirements thereof. For the mutual recognition of authorisations, the application shall include a summary of the dossier as required in Article 8(2)(a) and Annex II B, Section X and a certified copy of the first authorisation granted. For mutual recognition of registration of low-risk biocidal products, the application shall include the data requirements of Article 8(3), except for the efficacy data for which a summary shall suffice. (Article 4 BPD)

NB Article 13 BPD – cooperation in use for second and subsequent applications for authorisation

NB Whereas it is in the interest of the free circulation of biocidal products, as well as of materials treated with them, that authorisation granted by one Member State should be recognised by other Member States subject to the specific conditions contained in this Directive (para (12) Preamble BPD)
Transitioning from Current BPD to New BPR

BPD and mini review

- 14 May 1998 - BPD came into force
- 14 May 2000 - MSs required to implement BPD
- Directive 2009/107/EC (Mini review) extends BPD review programme to 14 May 2014

New BPR

- September 2010 – EP first reading
- 21 June 2011 – Council position on first reading
- 19 January 2012 – EP vote at second reading
- 27 June 2012 - Published in OJ
- 1 September 2013 – Main provisions apply from 1 September 2013 (Arts 96-97 BPR)
- Provisions on treated articles delayed application (Art 94 BPR)
New BPR

New BPR: Aims and objectives

- October 2008, EU Commission published a report on the implementation of the Current BPD. The report identified a number of weaknesses as regards Current BPD.
- BPR aims to address weaknesses identified in report and comments made during the consultation process.
- Retains two tier approval system
- Aims to:
  (i) Improve functioning of the single market and improve/resolve problems faced by industry, e.g.
   - Discriminatory effect of TA provisions
   - Improve product authorisation process
   - Improve application of EU principle of mutual recognition, etc
   - Harmonise costings
   - Improve provisions re data protection and free riding
  (ii) Improve protection to HH & E, e.g.
   - Substitution criteria
   - Exclusion criteria
   - Provisions re nanomaterials
   - Labelling
New BPR: Union Authorisation
New BPR – Union Authorisation (Arts 41-45) (1/3)

- New BPR aims at improving the functioning of the EU single market.

- Under Current BPD, once an active is included in Annex I BPD, a company requires separate product authorizations in each MS it sells into from respective national authorities.

- New BPR establishes a new EU (centralized) system of product authorization whereby Commission/ECHA - not national authorities – issue product authorizations – so-called “Union Authorisation”

- Union authorisation defined as:
  “…an administrative act by which the Commission authorises the making available on the market and the use of a biocidal product or a biocidal product family in the territory of the Union or in a part thereof;”
  (Article 3(n) BPR)
New BPR – Union Authorisation (Arts 41-45)  (2/3)

- Union Authorisation means:
  “A Union authorisation issued by the Commission in accordance with this Section shall be valid throughout the Union unless otherwise specified. It shall confer the same rights and obligations in each Member State as a national authorisation. For those categories of biocidal products referred to in Article 42(1), the applicant may apply for Union authorisation as an alternative to applying for a national authorisation and mutual recognition” (Article 41 BPR).

- Union Authorisation is an alternative mechanism to national authorisation + mutual recognition;

- Industry can chose to obtain Union Authorisation if, amongst other things:
  (a) the BP has ‘similar conditions of use across Union’;
  (b) actives are not excluded under Article 5 (e.g. CMRs 1A/1B, etc);
  (c) the product falls within certain PTs i.e. NOT PT14, 15, 17 20 or 21 – although NB subject to review in 31 December 2017 – para 27 Preamble BPR).
Basic procedure:
(1) Submit application to ECHA (Article 17(2) BPR);
(2) Pay ECHA (admin) and MSCA (evaluation) fee;
(3) State which MSCA should carry out evaluation;
(4) MSCA must evaluate within a year;
(5) Applicant comments on MSCA conclusions;
(6) MSCA informs ECHA of conclusions from evaluation;
(7) Peer-review in ECHA Biocidal Products Committee;
(8) ECHA drafts an opinion on authorisation and submits to Commission;
(9) Commission either grants authorisation (implementing Regulation) or does not grant authorisation (implementing Decision);
(10) Union Authorisation subject to renewal.
(Articles 41-45 New BPR)

NB Applicant to submit summary of BP characteristics in all EU official languages (Article 20(3) BPR)

Union Authorisation can be obtained from Commission/ECHA for biocidal products in certain product types as from certain dates (Article 42 New BPR) and under certain conditions.
New BPR - Union Authorisation (Art 42 New BPR)

- From 1 September 2013:
  - PT 1: Human hygiene
  - PT 3: Veterinary hygiene
  - PT 4: Food and feed area
  - PT 5: Drinking water
  - PT 18: Insecticides, acaricides and products to control arthropods
  - PT 19: Repellents and attractants
  - Biocidal Products with new active substances

- From 1 January 2017:
  - PT 2: Disinfectants and algaecides not intended for direct app to H/A
  - PT 6: Preservatives for products during storage (In-can)
  - PT 13: Working or cutting fluid preservatives

- From 1 January 2020: All other PTs except:
  - PT 14: Rodenticides
  - PT 15: Avicides
  - PT 17: Piscicides
  - PT 20: Control of other vertebrates
  - PT 21: Antifouling products
New BPR – Union Authorisation (Costs) (1/3)

- DRAFT Regulation on fees payable to ECHA for Union Authorisation.

- Lays down the amounts, and rules for payment, of the fees and charges levied by the ECHA under New BPR

- Fees for Union authorisation of a biocidal product detailed in: Article 4; Table 1 of Annex II; and Annex III of DRAFT Regulation

- NB Does not cover fees charged by MSCA appointed to evaluate Union Authorisation - those to be fixed by MSCA and charged directly by MSCA.

- Basic ECHA Fee structure for Union Authorisation: Initial Fee + Annual Fee – Reductions (e.g. as SME)
### ANNEX II

**Table 1**

Fees for biocidal products

<table>
<thead>
<tr>
<th>Description</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Union authorisation, single product (Article 43(2) of Regulation (EC) No 528/2012)</td>
<td>80,000 EUR</td>
</tr>
<tr>
<td></td>
<td>40,000 EUR when product is identical to the representative product assessed for the purpose of the substance approval</td>
</tr>
<tr>
<td></td>
<td>Additional fee when comparative assessment is required 40,000 EUR</td>
</tr>
<tr>
<td>Union authorisation, biocidal product family (Article 43(2) of Regulation (EC) No 528/2012)</td>
<td>120,000 EUR</td>
</tr>
<tr>
<td></td>
<td>Additional fee when comparative assessment is required 60,000 EUR</td>
</tr>
<tr>
<td>Union authorisation of a biocidal product which is the same biocidal product in relation to a reference biocidal product</td>
<td>5,000 EUR</td>
</tr>
</tbody>
</table>
New BPR – Union Authorisation (Costs)  (3/3)

[EXTRACT FROM DRAFT REGULATION]

ANNEX III
Miscellaneous fees

| Annual fee for biocidal products authorised by the Union (Article 80(1)(a) of Regulation (EC) 548/2012) | 10,000 EUR (per Union authorisation for a biocidal product)  
20,000 EUR (per Union authorisation for a biocidal product family) |
New BPR – Union Authorisation (Other issues)

- When to apply for Union Authorisation?
  Technical Notes for Guidance of June 2012: Agreement that “application for [product authorisation for existing BP] …should be submitted before formal inclusion in Annex I of the active substance it contains”

- Derogations to Union Authorisation:
  The Commission shall, at the request of a Member State, decide to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or decide that a Union authorisation shall not apply in the territory of that Member State, provided that such a request can be justified on one or more of the grounds referred to in Article 37(1). (Article 44(5) para 2 BPR)

  Grounds for derogation under Article 37(1) BPR:
  (a) the protection of the environment;
  (b) public policy or public security;
  (c) the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants;
  (d) the protection of national treasures possessing artistic, historic or archaeological value; or
  (e) the target organisms not being present in harmful quantities.
New BPR: Mutual Recognition
New BPR alters the rules on mutual recognition (i.e. process whereby one MS recognizes the product authorization of another MS)

Under New BPR, an applicant seeking product authorization can:

- Apply for mutual recognition of a product authorization already granted in another MS (mutual recognition in sequence)
- Apply for mutual recognition of a product authorization being granted at the same time and in parallel to product authorization in another MS (mutual recognition in parallel).
Procedure for Mutual Recognition in sequence

(1) Applicant to submit application to each MS(s) concerned (including initial authorisation from RMS and translation of authorisation) + pay fee

(2) Concerned MS “accepts” application

(3) Concerned MS has 30 days to “validate” application

(4) Concerned MS has 90 days to agree on BP characteristics and record agreement in R4BP

(5) Concerned MS has 30 days from agreement to “authorise” BP
procedure for mutual recognition in parallel

1. Applicant to submit full application to RMS and list of other MSs concerned to RMS
2. At same time applicant to submit application for MR to other MS(s) concerned (i.e. name of RMS and summary of BP characteristics – in relevant language)
3. Applicant pays fees
4. RMS and other MSs concerned “accept” applications
5. RMS “validates” application
6. RMS “evaluates” application and within 365 days of validation sends draft assessment report to other MSs concerned with summary of BP characteristics
7. RMS and other MS(s) concerned agree on (i) summary of BP characteristics and (ii) final assessment report - recorded in R4BP (90 days)
8. RMS and other MS(s) concerned “authorize” BP (30 days after agreement)
Disputes re applications for MR arising under Art 33 and 34 BPR

- If a concerned MS considers BP assessed by a RMS does not meet conditions for authorisation, MS to send a “detailed explanation of the points of the disagreement and the reasons for its position” to RMS and to applicant/authorisation holder (Article 35(2) BPR).
- Disagreements referred to coordination group (Art 35 New BPR).
- Coordination group examines matters regarding applications for MR. Compiled of representatives of Commission, MSs. ECHA is secretariat.
- MSs to use “best endeavours” to reach agreement
- Applicant must be allowed to “make its point of view know” within coordination group.
- If agreement: recorded in R4BP
- If continued disagreement (i.e. “unresolved objections”); issue referred to Commission (Art 36 New BPR)
- Commission may ask ECHA for opinion on scientific and technical questions.
- If ECHA opinion not requested by COM, applicant/authorisation holder able to comment
- COM Decision addressed to MS.

NB If COM requests ECHA opinion on technical or scientific questions, applicant/authorisation holder able to provide written comments (Article 38(2) BPR).
Mutual recognition (Art 32-40 BPR)  

- General requirement: All MSs which receive applications for MR to authorise BP under same terms and conditions (Article 32(2) BPR)

- Derogation from general requirement: MS can refuse to grant authorisation or adjust terms and conditions of authorisation on certain grounds detailed in Art 37(1) BPR:
  (a) the protection of the environment;
  (b) public policy or public security;
  (c) the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants;
  (d) the protection of national treasures possessing artistic, historic or archaeological value; or
  (e) the target organisms not being present in harmful quantities.

E.g. BP contains actives meeting exclusion criteria or substitution (Article 37(1) para 2 BPR)

- Procedure re derogations:
  - MS to provide applicant “detailed statement” regarding grounds for seeking derogation
  - MS to seek agreement with applicant on proposed derogation
  - No agreement within 60 days Commission decides (Article 37 BPR)
  - Commission can ask for ECHA opinion on scientific and technical questions
  - Commission Decision addressed to MS and applicant informed of Decision
New Requirements for Nanomaterials and In-Situ Generated Biocides, and Reduced Data Requirements for Low Risk Substances

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Overview

- The new BPR and Nanomaterials
- In-Situ Generated Biocides
- Requirements for Low Risk Substances
Nanomaterials - Definition

BPR Article 3(1)(z)

‘nanomaterial’ means a natural or manufactured 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 1-100 nm.

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.
Nanomaterials - Definition

BPR Article 3(1)(z) (continued)

For the purposes of the definition of nanomaterial, ‘particle’, ‘agglomerate’ and ‘aggregate’ are defined as follows:

— ‘particle’ means a minute piece of matter with defined physical boundaries,

— ‘agglomerate’ means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components,

— ‘aggregate’ means a particle comprising strongly bound or fused particles;
Nanomaterials - Definition

- As per BPR Article 3(3), the Commission may decide, by means of implementing acts, whether a substance is a nanomaterial.
- As per BPR Article 3(4), the Commission shall be empowered to adopt delegated acts in order to adapt the set definition of nanomaterials.
- The BPR not only defines nanomaterials, but also stipulates specific provisions regarding their application in biocidal products.
Nanomaterials - Approvals

- As per BPR Article 4(4), the approval of an active substance shall NOT cover nanomaterials except where explicitly mentioned.

- As per BPR Article 19(1)(f), conditions for granting authorization of biocidal products provide that – when containing nanomaterials - a separate risk assessment is carried out, considering human/animal health and environmental risks.
Nanomaterials - Labelling

- As per BPR Article 58(3)(d), placement on the market of treated articles requires the label to provide, among other, the name of all nanomaterials contained in the biocidal products, followed by the word ‘nano’ in brackets, i.e., [nano].
- As per BPR Article 69(2)(b), regarding the EU CLP of biocidal products labels shall not be misleading about risks or efficacy; as such, the label MUST show information re the nanomaterials contained in the product, and any specific related risks.
Nanomaterials - Information requirements

- As per BPR Annex II, tests submitted for the purpose of the approval of an active substance shall be conducted according to ‘REACH-compliant’ methods (Regulation (EC) 440/2008).
- When 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.
Nanomaterials biocidal products dossier evaluation

- As per BPR Annex VI regarding common principles for the evaluation of dossiers for biocidal products, in the case of biocidal products containing nanomaterials, the Annex VI principles will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information.
Overview

- The new BPR and Nanomaterials
- In-Situ Generated Biocides
- Requirements for Low Risk Substances
In-Situ Generated Biocides

- As per BPR Preamble (9), this Regulation should apply to biocidal products that, in the form in which they are supplied to the user, consist of, contain or generate one or more active substances.
In-Situ Generated Biocides - Definition

As per BPR Article 3(1)(a), a ‘biocidal product’ 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,

- any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used 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.
**In-Situ Generated Biocides - Dossier evaluation**

- As per BPR Annex VI regarding common principles for the *evaluation* of dossiers for biocidal products, for in-situ generated active substances the *risk assessment* shall also *include the possible risks from the precursor(s)*
Multiple discussions re in-situ generated biocides during CA meetings: 9 examples discussed in the BPD Manual of Decisions (MOD)

Guidance document (Doc-Biocides-2002/05-rev1 of 30/07/2002) provides general principles, i.e., data on precursor chemicals and the in-situ generated substance(s) are necessary for complete evaluation.
Draft Technical Notes for Guidance (CA-Sept10-Doc.6.2a) endorsed during 38th CA meeting for stakeholders consultation (until April 2011):

- **Products placed on the market with the intention to be used as biocidal products** fall within the scope of the BPD, and such products need to be authorised.

- **Biocidal active substances that are not directly put on the market in biocidal products but are formed in-situ at the place of intended use** are, in many cases, also within the current scope of the BPD and therefore need to be evaluated.

- When the use falls within the scope of the BPD, the precursor(s) and, if appropriate, the in-situ generated active substance need to be listed in the Annex I entry of the BPD.

- The dossier and the assessment report need to contain the appropriate information on both precursor and in-situ generated active substances in order to properly assess the safe use of the biocidal product.
Draft TNG defines an in-situ generated active substance as:

- a substance that is **not directly placed on a market**. The active is generated intentionally via a chemical reaction, or other means, as a result of direct manipulation on the site of use prior to or during its intended application from one or several other chemicals, called precursor active substances, and which exerts a biocidal activity during its application, where the biocidal effect is desired.
Draft TNG defines three different cases of precursors:

- **Case 1**: An active substance, placed on the market, may also generate other active substances (AS) in situ: no need to cover the in-situ AS in Annex I listing.

- **Case 2**: Not-active precursor releases AS: relevant Annex I entry is for the precursor placed on the market, and in-situ AS could be included.

- **Case 3**: Two (or more) precursors (A&B), placed on the market, generate – when combined – AS X: Annex I entry shall link X to A&B.
Overview

- The new BPR and Nanomaterials
- In-Situ Generated Biocides
- Requirements for Low Risk Substances
Low Risk Substances - Background

**BPD Failure!!!**

- BPD special provision for low risk substances, i.e., establishment of so-called Annex IA
- Few applications for listing of active substances in Annex IA as a FULL dossier was required
- Due to NO reduction in data requirements and/or costs removal from the market of many commodity chemicals that are considered low-risk biocides happened
Low Risk Substances under the BPR

- As per BPR Preamble (38),

  Where possible, the presence of harmful organisms should be avoided by means of suitable precautionary steps, such as proper warehousing of goods, compliance with relevant hygiene standards and immediate disposal of waste. As far as possible, biocidal products that pose lower risks for humans, animals and the environment should be used whenever they provide an effective remedy, and biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress should be used only as a last resort.
Low Risk Substances under the BPR

- BPR establishes an Annex I list of low-risk actives
- Currently 19 substances on Annex I, falling into following categories
  - Cat 1 - Food additives (Regulation 1333/2008)
  - Cat 2 - REACH Annex IV-listed substances
  - Cat 3 – Weak acids
  - Cat 4 – Traditionally used Substances of Natural Origin
  - Cat 5 – Pheromones
  - Cat 6 – BPD Annex I/IA-listed substances
  - Cat 7 - Other
Low Risk Substances - Authorization

Simplified Authorization Procedure

- As per BPR Article 25, biocidal products containing Annex I actives are eligible for a simplified authorization procedure if all of the following conditions are met:
  - (a) all active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex;
  - (b) the biocidal product does not contain any substance(s) of concern;
  - (c) the biocidal product does not contain any nanomaterials;
  - (d) the biocidal product is sufficiently effective; and
  - (e) the handling of the biocidal product and its intended use do not require personal protective equipment.
Low Risk Substances - Authorization

Simplified Authorization Procedure (BPR Article 26)

- Submission of an application to the European Chemicals Agency (ECHA)
- Provision of summary re the biocidal product characteristics (composition, hazard, use, etc.) along with efficacy data, and justification that the biocidal product is eligible for simplified procedure
- Payment of evaluation fee
- Within 90 days of payment, evaluating Competent Authority must authorize the biocidal product if Art. 25 conditions are satisfied
- A biocidal product authorized i.a.w. Article 26 may be made available on the market in all Member States without the need for mutual recognition. The authorization holder must notify each Member State no later than 30 days before placing the biocidal product on the market.
Low Risk Substances – New additions to Annex I

- As per BPR Art. 28 the Commission is authorized to add substances to Annex I provided they do not give rise to concern

- Active substances DO give rise to concern* if:

  (a) they meet the criteria for classification according to CLP as:
  
  - explosive/highly flammable/organic peroxide/Acute Tox Cat. 1, 2 or 3/corrosive of category 1A, 1B or 1C/resp. or skin sensitiser/CMR Cat. 1 or 2/ with effects on or via lactation/STOT (SE or RE)/Aquatic acute Cat. 1

  (b) they fulfil any of the substitution criteria (BPR Art. 10(1)); or

  (c) they have neurotoxic or immunotoxic properties

  (*) where a level of concern equivalent to that arising from points (a) to (c) can be reasonably demonstrated

- The Commission shall act at its own initiative or at the request of an economic operator or a Member State
Thank you!

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