Regulation of biocidal products and treated articles - continued EU market access for Thai exporters

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Steptoe & Johnson – Brussels

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Overview
What we will cover today

• Overview of EU regulation of biocidal products and critical legislative concepts
  • authorisation of biocidal products and approval of their active substances
  • new requirements under the latest EU legislation (Biocidal Products Regulation 528/2012)
• Treated articles
  • obligations for different types
  • transitional regime and related deadlines
  • labelling
• Data access and implications of mandatory data sharing

Can producers (continue to) export legally to the EU market?
Understanding EU Regulation of biocidal products – critical concepts
What are biocidal products?

• ‘Biocidal products’ (‘anti-microbials’ in US):
  • chemicals used to suppress organisms that harm human or animal health or damage natural or manufactured materials
  • examples, insecticides (fly spray), disinfectants (bleach, antibacterial hand gel), anti-foulants, anti-mould paints, biocides in paper coating, preservatives
  • regulatory categorisation into 22 ‘product types’ (PTs) under 4 main groups: disinfectants, preservatives, pest control, other
  • active substance: substance/microorganism in the product which has controlling effect on target organism
    • common examples: sodium hypochlorite in bleaches, ethanol in hand wipes, copper in antifoulants, etc.
## Biocidal Product Types

<table>
<thead>
<tr>
<th>Group 1* Disinfectants</th>
<th>Group 2 Preservatives</th>
<th>Group 3 Pest Control</th>
<th>Group 4 Other biocides</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>PT1</em>: Human hygiene</td>
<td><em>PT6</em>: Preservatives for products during storage</td>
<td><em>PT14</em>: Rodenticides</td>
<td><em>PT20</em>: Preservatives for food or feedstocks*</td>
</tr>
<tr>
<td><em>PT2</em>: Disinfectants and algacides not intended for direct application to humans or animals</td>
<td><em>PT7</em>: Film preservatives</td>
<td><em>PT15</em>: Avicides</td>
<td><em>PT21</em>: Antifouling products</td>
</tr>
<tr>
<td><em>PT3</em>: Veterinary hygiene</td>
<td><em>PT8</em>: Wood preservatives</td>
<td><em>PT16</em>: Molluscides, vermicides, and products to control other invertebrates</td>
<td><em>PT22</em>: Embalming and taxidermist fluids</td>
</tr>
<tr>
<td><em>PT4</em>: Food and feed area</td>
<td><em>PT9</em>: Fiber, leather, rubber and polymerized materials preservatives</td>
<td><em>PT17</em>: Piscicides</td>
<td></td>
</tr>
<tr>
<td><em>PT5</em>: Drinking water</td>
<td><em>PT10</em>: Construction materials preservatives</td>
<td><em>PT18</em>: Insecticides, acaricides, and products to control other arthropods</td>
<td></td>
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<td></td>
<td><em>PT11</em>: Preservatives for liquid-cooling and processing systems</td>
<td><em>PT19</em>: Repellants and attractants</td>
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<td></td>
<td><em>PT12</em>: Slimicides</td>
<td><em>PT20</em>: Control of other vertebrates (previously PT23)</td>
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<td></td>
<td><em>PT13</em>: Working or cutting fluid preservatives</td>
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</table>

* Excludes cleaning products that are not intended to have a biocidal effect, including washing liquid, powder and similar products.

* Because now covered by specific EU legislation.
Biocidal product or not?

- "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’ (Article 3(1)(a) of the BPR)

- ‘in the form in which supplied to user’ (Article 3(1)(a) of the BPR):
  - B2B and B2C
  - separates biocidal products (subject to pre-market authorisation) from active substances supplied to downstream formulators to manufacture biocidal products

- ‘intention’ (shown by claims, PT etc.) separates products which may happen to have controlling influence but not intended or presented for such use by supplier (table salt which can be used as slug repellent)

- purely mechanical or physical controlling influence — mousetrap is not a biocidal product
  - Use of paraffin oil to control the population size of nesting birds
‘As paraffin oil only constitutes a physical contact barrier to the respiratory capabilities of the target organism and no chemical or biological action of paraffin oil occurs at any moment, it cannot be regarded as being intended to act chemically on that organism.’ (Commission Decision 2016/1943)
Product s regulated under EU biocides regime for first time

• BPR definition of ‘biocidal products’ now includes:
  • biocidal products/actives generated ‘in-situ’ from non-biocidal precursors - for example, active chlorine generated from sodium chloride by electrolysis for treating swimming pool water
  • certain imported products (substances, mixtures or articles) treated with/incorporating biocidal products (‘treated articles’)
    • scientific dossier or letter of access for authorisation = significant cost!
  • Approval of actives in imported treated articles without ‘primary’ biocidal effect (for example, ‘odourless’ socks, insect repellent sleeping bags)
  • So not only sellers of
    • traditional biocidal products
    • active substances to downstream formulators
  but also other industries affected...
Product s regulated under EU biocides regime for first time

- Products under Regulation 1935/2004 on food contact materials and articles (the Framework Regulation) no longer excluded from scope under BPR

- Potential Biocidal Product Types (PT) in food contact applications:
  - Surface biocides (PT4) – intended technical effect in the food contact article;
  - Process biocides (PT 6, 7, 9, 11, 12) – not intended to have an effect and to be present in the final food contact material or article;
  - Food preservatives (in active packaging applications) – intended to be released from the packaging into food, for a technological effect in food;

- All these were previously exempt from the scope of the BPD; now they are covered by the BPR; either as Biocidal Product (BP) or Treated Article (TA)
Basic Features of Biocides Regulation in the EU

- Current legislation is Biocidal Products Regulation 528/2012
  - repealed Biocidal Products Directive 1998/8 from 1 September 2013
- Purpose of legislation:
  - single market in biocidal products (harmonised regulation of sale and use in EU)
  - human, animal and environmental safety
- Regulatory procedures (substance approvals, product autorisation) specific to ‘active substance’ and product type (‘PT)
Basic Features of Biocides Regulation in the EU

- Core structures continue under BPR:
- Pre-market authorisation regime, with two levels:
  - approval (and renewal) of active substances and inclusion on ‘Union’ positive list
    - specific active substance/product type combinations with RMM/use conditions
  - authorisation of biocidal product (national or EU)
- Distinction between ‘existing active substances’ (on EU market in biocidal products other than for R&D on 14.5.2000) and ‘new active substances’ (not on EU market on 14.5.2000)
  - existing actives: mechanisms for continued, uninterrupted market access
Basic Features of Biocides Regulation in the EU

• Commission programme for review of existing active substances
  • industry previously notified substances for review by deadlines
  • ‘participants’ (data holders) submitted application/joint dossier supporting inclusion
  • letter of access to dossier required by non-participants for BPR product authorisation
  • …and now also for inclusion on Approved Suppliers (Article 95) list

• Enforcement and ‘effective, proportionate and dissuasive’ penalties at national level (not harmonised)
New Features of the BPR

• Approved suppliers listing (Article 95) obligation
• New harmonised product authorisation procedures
  • Commission estimates EUR 2.7 million cost savings over 10 years
• New data access, data protection and mandatory data sharing obligations re active and product dossiers
• Market Access without authorisation: parallel trade permit
  • product sold in other MS and identical to that already sold on relevant MS market
• Nanomaterials
• New role of ECHA (Biocidal Products Committee)
• Option of appeal from relevant ECHA decisions (on data sharing, non-acceptance of applications, etc.)
• Central biocide registry: R4BP
New Features of the BPR

• Expanded substitution powers
  • comparative assessment during approval/renewal of product containing active which is ‘candidate for substitution’ (excluded, respiratory, sensitiser, etc.):
  • prohibit or restrict marketing or use if lower risk effective substitutes, no significant economic/practical disadvantages and low target resistance risk
  • if no appropriate substitute, maximum 5 years product authorisation/renewal

• Excluded actives (CMR, PBT, vPvB, endocrine disruptors)
  • approved only exceptionally for 5 years if negligible risk and disproportionate negative societal impact of non-approval
Approval of Active Substances
Differences between new and existing active substances

- BPR definitions for new and existing
- Distinction between ‘existing active substances’ (on market in biocidal products other than for R&D on 14.5.2000) and ‘new active substances’ (not on 14.5.2000)
- Existing actives: mechanisms to permit continued uninterrupted market access
- Commission programme for review of existing active substances
  - industry previously notified substances for review by deadline
  - ‘participants’ (data holders) submitted application/joint dossier supporting inclusion
  - letter of access to dossier required by non-participants for BPR product autorisation
  - ... and now also for inclusion on approved source list from September 2015 (Art 95)
    - addresses non-participant ‘free rider’ issue pending Commission inclusion decision

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Active approval procedure

• Transitioning from BPD to BPR: advantages and shortcomings
• Streamlined review process
• Review programme
• Exclusion and substitution: opportunities
Transitioning from BPD to BPR

• Active review process not completed by 1 September 2013: review will be done under BPR based on dossier submitted according to BPD
  • ‘completed’ means distribution of draft Competent Authority Report
  • where the evaluation identifies concerns arising from the application of provisions of the BPR which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information → review possibly extended

• ECHA becomes active and ‘responsible for coordinating the process of evaluation of dossiers submitted after 1 September 2012 and shall facilitate the evaluation by providing organisational and technical support to the Member States and the Commission’ as well as, since 1 January 2014, for dossiers whose evaluation has not been completed by 1 September 2013
Streamlined review process

Validation of submission

Evaluating Competent Authority
- Dossier evaluation
- Draft assessment & finalising the report
- 30 days to provide written comments
- 60 days

Applicant

ECHA

Biocidal Products Committee peer review

Commission
- Decision on the approval of the active substance
- 270 days

ECHA

Biocidal Products Committee opinion

Public consultation for candidates for substitution

60 days
Streamlined review process (validation)

- Application
- Payment of fees #1: 30 days of invoice
- Acceptance / ID code: 30 days
- Validation #1: 30 days
- Validation #2: 30 days
- Submission of missing information: 90 days
- Payment of fees #2: 30 days
- ECA informs of fees

Evaluating Competent Authority

€120,000
Review programme (1)

- Extension of the review programme until 31 December 2024: extension of the transitional regime
- Commission delegated regulation adopted in May 2013
- Ambitious plan of circa 50 active substance/product type combinations approved or not approved per year

<table>
<thead>
<tr>
<th>Priority</th>
<th>Existing active substances for product types</th>
<th>All draft CARs have to be submitted to ECHA by</th>
<th>The BPC have to submit all its opinions by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; priority list</td>
<td>8, 14, 16, 18, 19, 21</td>
<td>31/12/2015</td>
<td>31/12/2016</td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt; priority list</td>
<td>3, 4, 5</td>
<td>31/12/2016</td>
<td>31/12/2017</td>
</tr>
<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt; priority list</td>
<td>1, 2</td>
<td>31/12/2018</td>
<td>31/12/2019</td>
</tr>
<tr>
<td>4&lt;sup&gt;th&lt;/sup&gt; priority list</td>
<td>6, 13</td>
<td>31/12/2019</td>
<td>31/12/2020</td>
</tr>
<tr>
<td>5&lt;sup&gt;th&lt;/sup&gt; priority list</td>
<td>7, 9, 10</td>
<td>31/12/2020</td>
<td>31/12/2021</td>
</tr>
<tr>
<td>6&lt;sup&gt;th&lt;/sup&gt; priority list</td>
<td>11, 12,15,17, 22, 23 (new PT20 under BPR)</td>
<td>31/12/2022</td>
<td>31/06/2024</td>
</tr>
</tbody>
</table>
Exclusion and substitution: opportunities (1)

- Exclusion is not new under the BPR:
- Active substance cannot be included in Annex 1A if it is classified according to Directive 67/548/EEC as:
  - carcinogenic,
  - mutagenic,
  - toxic for reproduction,
  - sensitising, or
  - is bioaccumulative and does not readily degrade.’ (Article 10(1) BPD)
- BPR has broadened the scope and refers to either classification or criteria for classification under the CLP Regulation 1272/2008, or REACH:
  - carcinogen category 1A or 1B
  - mutagen category 1A or 1B
  - toxic for reproduction category 1A or 1B
  - with endocrine-disrupting properties (pending the adoption of legally binding criteria, carcinogen category 2 and toxic for reproduction category 2 / toxic for reproduction category 2 and that have toxic effects on the endocrine organs)
  - PBT
Exclusion and substitution: opportunities (2)

- Derogations to exclusion, three alternative conditions, which have to apply in MS:
  1. the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible (e.g. closed systems)
  2. evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment
  3. not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance
- The availability of suitable and sufficient alternative substances or technologies shall be a key consideration (comparative assessment?)
Exclusion and substitution: opportunities (3)

- Candidate for substitution (Article 10):
  a) meets one of the criteria for exclusion but with derogation
  b) meets the criteria to be classified, in accordance with CLP Regulation, as a respiratory sensitiser
  c) acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario (comparative assessment?)
  d) meets two of the criteria for being PBT (REACH Annex XIII)
  e) reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential or risk to groundwater, even with very restrictive risk management measures
  f) contains a significant proportion of non-active isomers or impurities
Exclusion and substitution: opportunities (4)

- Public consultation process (60 days) prior to ECHA submitting its opinion on the approval or renewal of the approval of an active substance to the Commission.
- Interested third parties may submit relevant information, including information on available substitutes. The Agency shall take due account of the information received when finalising its opinion.
- Approval for a maximum of 7 years (vs 10 years).
- Comparative assessment.
- BUT, if reviewed under the BPD criteria, maximum of
  - 10 years for substances that meet the substitution criteria.
  - 5 years for substances that meet the exclusion criteria.
  - while applying comparative assessment and SEA.
  (source: CA-March14-Doc.4.1 – Final)
Review programme (2)

• New active substances/PT combinations:
  • Regulation 613/2013 amends Re. 1451/2007 as regards additional active substances in the review programme
  • submission of dossier and inclusion in the review programme
  • eligibility:
    • *Persons relying on guidance notes published, or written advice given, by the Commission or by a competent authority designated in accordance with Article 26 of Directive 98/8/EC may therefore have failed to notify the existing active substance/product-type combination in a product placed on the market, or to take over the role of participant, in the objectively justified belief that the product is excluded from the scope of Directive 98/8/EC or that it falls under a different product-type (Recital’)*
    • no decision not to include based on an assessment report reviewed by the Standing Committee on Biocidal Products
  • Submission process is similar to that of the situation where a person wishes to take over the role of participant
Restrictions on active substances under BPR

- Excluded actives (CMR, PBT, vPvB, endocrine disruptors)
  - approved only exceptionally for 5 years if negligible risk, disproportionate negative societal impact of non-approval
- Candidates for substitution (excluded substances, respiratory sensitisers, low ADI/AOEL, specific exposure concerns)
  - approval considers ECHA consultation on substitutes (NGOs?)
  - maximum 7 years approval/renewal, ‘earmarked’ as candidate
- Nanomaterials:
  - not covered by active approval unless specified
  - separate risk assessment requirement for products containing them
Significance of active substance approval for transitional periods

• Various transitional periods under the BPR which depend on active substance dossiers having been submitted by deadlines
  • existing actives under review programme may remain on EU market until Commission inclusion decision on whether or not to include on Union List of EU approved actives which can be used in biocidal products in EU
    • now Article 95 list level playing field requirement for ‘non-participants’ to buy into data package
      + « newly in scope » products (Article 93) and certain treated articles (Article 94) require relevant active dossiers to have been submitted by certain deadlines
Alternative Supplier’s List Requirement (Article 95)
Continued market access: Approved Suppliers (Article 95) list - I

- Are you/your importers/your supplier’s importers in the EU listed?
- Condition for market access pending decision on active Union listing
- Prohibits supply of biocidal products in EU unless the ‘substance supplier’ or ‘product supplier’ is listed for relevant active substance product type (Article 95(2))
  - ‘substance supplier’ = EU entity manufacturing or importing active substance, as such or in biocidal product
  - ‘product supplier’ = EU entity manufacturing or making available (includes import) a biocidal product
  - application: fee, need to file dossier or letter of access (obtained through negotiation or mandatory data sharing)
    - addresses ‘free-rider’ issue: ‘non-participants’ benefit from continued market access for free whilst ‘participants’ committed huge resources seeking active Union listing
    - the ‘no data, no market’ of the BPR
- Not relevant for suppliers of treated articles but for active substances used
Continued market access: Approved Suppliers (Article 95) list - II

• Implications:
  • Either EU manufacturer or importer of active substance or product must be listed so that their downstream user/formulator customers can legally sell on their own biocidal products without own listing
  • EU biocidal product suppliers must ensure they purchase active or product from a listed upstream EU supplier or alternatively be listed in their own right

non-EU entity for relevant supply chain may be listed if he appoints an ‘EU representative’
  • ECHA response to criticism that:
    • no REACH ‘OR’ equivalent under BPR (control, confidentiality)
    • no means for EU traders to know that their non-EU supplier’s active is listed
    • now ‘X Europe Limited (Acting for X, Inc. (US)’
    • doesn’t need to be supply chain entity and can cover many importers (most efficient)

• ‘Automatic’ listing if previously submitted relevant active dossier/LoA under other BPD/BPR requirements, including existing actives review
  • Exceptions: suppliers of low risk actives, of treated articles with non-primary biocidal function
Enforcement of Approved Suppliers (Article 95) list requirement

- Enforcement
  - 90% non-compliance (MSCA report November 2014)
  - national competent authorities currently making distributors to confirm they or their suppliers are listed
  - competitive tool-notification of non-compliance competitors
- Pending list - now repealed
  - not the official list
  - List of persons who submitted a complete application
  - legal implications? – grey area
  - enforcement implications?
    - demonstration of intention to comply?
    - but no guarantee listing application will success
Product Authorisation under the BPR
Considerations for Thai exporters

- Who should be the authorisation holder?
- Preparing for product authorisation under BPR
- Which BPR product authorisation routes are available?
- How to choose which one?

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Who can be authorisation holder?

• Illegal to sell biocidal product in EU without authorisation (Article 17(1) BPR)

• ‘Authorisation holder’ means the person established within the Union who is responsible for the placing on the market of a biocidal product in a particular Member State or in the Union and specified in the authorisation

• European Commission guidance: any natural or legal person in EU

• Advantages to exporter of authorisation holder being agent versus EU importer (supply chain control, confidentiality)?

• Consider especially for new EU exports

• Significant exporter involvement (data access, product information), even if not authorisation holder
From national authorisation to EU harmonised BPR authorisation

- BPR harmonised product authorisation applicable only if and when Commission decides to include active on EU Union List of approved actives
  - BPR product authorisation application must be lodged before ‘date of approval’ specified in Commission inclusion decision for continued market access

- Programme for review of ‘existing’ active substances leading to decision on inclusion significantly delayed, from 2010 to 2024
  - possibly later due to ‘ambitious’ Commission review targets (50 substances a year) and implementation of criteria for identifying biocides with EDCs

- Single market for biocidal products still largely awaited (notwithstanding EU harmonised legislation since 1998!)
  - national (non-harmonised) ‘transitional’ product authorisation procedures remain pending inclusion decision for existing actives (Article 89 BPR)
  - But other elements of BPR already apply: Article 95, advertising etc.
National (non-harmonised) product authorisation procedures

Variation across individual EU Member States:

- authorisation (scientific dossier for safety and efficacy assessment), notification (lighter information requirements), or none?
- different requirements for different PTs (risk-based)
- market access as soon as:
  - granted authorisation decision?
  - default period (without authority comment) expired?
  - lodged notification?

- UK as illustration (post-BREXIT?!)  
  - pre-market approval for some PTs (Control of Pesticides Regulations 1986 (COPR)): wood preservatives, masonry biocides, antifouling products, etc.
  - other PTs subject only to general product safety and chemicals (CLP etc.) requirements
    - ...but information on file (safety, efficacy) should authorities request

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Example BPR Union list inclusion decision (adapted 24.10.13)

<table>
<thead>
<tr>
<th>Common Name</th>
<th>IUPAC Name Identification Numbers</th>
<th>Minimum degree of purity of the active substance (g/kg)</th>
<th>Date of approval</th>
<th>Expiry date of approval</th>
<th>Product type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoic acid</td>
<td>IUPAC Name: Benzoic acid</td>
<td>990</td>
<td>1 July 2015</td>
<td>30 June 2025</td>
<td>3</td>
</tr>
<tr>
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<td>EC No: 200-618-2</td>
<td></td>
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<td></td>
<td>CAS No: 65-85-0</td>
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</tbody>
</table>
Exporters should think about BPR product authorisation strategy now

• When will Commission decide on inclusion of relevant active in Union List (condition of BPR product authorisation application)?
  • triggers requirement to lodge BPR authorisation application in order to remain on market until BPR authorisation decision
  • Union Listing may be years off... but need to be ready
  • short window for lodging (20 months?) - not long for dossier preparation
  • strategic/budget planning: company resources, external advisors, fees, data costs
  • choice of authorisation procedure resource significant – do you understand the different available options?
Preparing for product authorisation under BPR

- Submission of active dossier/letter of access for product authorisation (and approved sources list (Article 95 BPR)):
  - establish who has data
  - most cost effective way to access
  - obtain LoA (relevant Task Force? fee/conditions of access?)
    - effective negotiation and knowledge of applicable rules = significant cost savings
  - compensation must be determined in a fair, transparent and non-discriminatory manner
- register for Biocidal products (R4BP’):
  - user friendly...potential for technical issues...

- BPR implications for participants supporting active Task Force Agreements?
  - dealing with data requests under mandatory data sharing?
  - balance exploitation of data with FRAND requirements/avoiding forced data sharing
Transitional product authorisation issues under BPR

• Be prepared to respond where BPD evaluation incomplete re:
  • more expansive BPR authorisation conditions (Article 19) if excluded active (for example, human health of vulnerable groups such as pregnant women and children)
  • BPR comparative assessment procedure if candidate active

• Biocidal products already authorised/registered under BPD which remain on market subject to BPR:
  • comply with supplementary Article 19 conditions when amend existing authorisations?
  • BPR extra labelling particulars?
Product authorisation options: ‘short-cut’ procedure available?

- Abbreviated procedures may be only route, or most resource efficient, for specific product characteristics/uses
  - simplified authorisation for low risk products;
  - ‘same authorisation’ for a product materially identical to another which has already been authorised/is subject to an application;
  - provisional authorisation for products not fulfilling authorisation conditions (including active approval) in limited circumstances; and
  - parallel trade permit for product already authorised in another EU MS and identical to product already authorised in intended sales market
Product authorisation options: ‘short-cut’ procedure available?

• Otherwise available procedures limited to one or two post active approval:
  • national authorisation in EU member state;
  • mutual recognition (‘in sequence’) by other MS CAs of national authorisation already granted in ‘reference’ MS;
  • mutual recognition (‘in parallel’) by MS CAs when no existing authorisation;
  • Union authorisation (EU wide) granted by European Commission on basis of ECHA opinion post MS CA evaluation.
### Comparing authorisation procedures

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</thead>
<tbody>
<tr>
<td><strong>Maximum Approval Period (Years)</strong></td>
<td>10 (5 if contains candidate for substitution)</td>
<td>10 (5 if contains candidate for substitution)</td>
<td>10 (5 if contains candidate for substitution)</td>
<td>10 (5 if contains candidate for substitution)</td>
</tr>
<tr>
<td><strong>Contents of Application</strong></td>
<td>- Dossier/LoA for product and each active (potential data waiver/adaptation)</td>
<td>- As for national or simplified product authorization, as appropriate</td>
<td>- Translation of national authorization granted in reference MS into relevant official languages</td>
<td>- Dossier/LoA for product and each active (potential data waiver/adaptation)</td>
</tr>
<tr>
<td></td>
<td>- Summary of product characteristics in appropriate language(s)</td>
<td>- List of other MSs where national authorization sought</td>
<td>- Summary of product characteristics in MS required languages</td>
<td>- Summary of product characteristics (potential data waiver/adaptation)</td>
</tr>
<tr>
<td></td>
<td>- Confirmation that not applied to other CA</td>
<td>- To chosen evaluating CA (‘reference MS’):</td>
<td></td>
<td>- Efficacy data (potential data waiver/adaptation)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- As for national or simplified product authorization, as appropriate</td>
<td></td>
<td>- Information evidencing eligible for simplified procedure in appropriate language(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- List of other MSs where national authorization sought</td>
<td></td>
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<td></td>
<td>- To other MSs where national authorization sought:</td>
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<td></td>
<td></td>
<td>- Identity of reference MS and other MSs where national authorization sought</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Summary of product characteristics in MS required languages</td>
<td></td>
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<tr>
<td><strong>Application Submitted To</strong></td>
<td>Chosen CA where want to market product</td>
<td>Simultaneously to reference MS and other MSs concerned (see above)</td>
<td>Each CA of countries (other than reference MS) where want to market</td>
<td>ECHA, with confirmation of which CA has agreed to evaluate</td>
</tr>
<tr>
<td></td>
<td>Application accepted on receipt of fee within 30 days of informing applicant</td>
<td>Application accepted if fee received within 30 days of informing applicant</td>
<td>Application accepted if receives fee within 30 days of informing applicant</td>
<td>Application accepted on receipt of fee within 30 days of informing applicant of fee</td>
</tr>
<tr>
<td><strong>Validation By</strong></td>
<td>Chosen CA within 30 days of acceptance</td>
<td>Evaluating CA (‘reference MS’) within 30 days of its acceptance</td>
<td>Each CA within 30 days of its acceptance</td>
<td>Chosen CA within 30 days of ECHA acceptance subject to payment of CA fee</td>
</tr>
<tr>
<td></td>
<td>Decline to evaluate if same product/use already subject of authorization application with another authority</td>
<td>Applicant to provide missing information normally within max 90 days</td>
<td>Applicant to provide missing information normally within max 90 days</td>
<td>Applicant to provide missing information normally within max 90 days</td>
</tr>
<tr>
<td></td>
<td>Applicant to provide missing information within normally max 90 days</td>
<td></td>
<td></td>
<td>30 days for CA to validate thereafter</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No formal validation stage</td>
</tr>
</tbody>
</table>
# Comparing authorisation procedures

## 1. National Biocidal Product Authorization

| Evaluation by | Chosen CA within 365 days of validation  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicant to provide missing information within normally max 180 days (during which 365 timer is suspended)</td>
<td><strong>Applicant to provide missing information within normally max 180 days (during which 365 timer is suspended)</strong></td>
</tr>
<tr>
<td><strong>Evaluating CA</strong> (reference MS') within 365 days of validation</td>
<td><strong>Evaluating CA</strong> (reference MS') within 365 days of validation</td>
</tr>
<tr>
<td><strong>Same coordination and resolution procedures as per “in Sequence”</strong></td>
<td><strong>Same coordination and resolution procedures as per “in Sequence”</strong></td>
</tr>
<tr>
<td>Drafts assessment report, conclusions and reasons for granting or refusing authorization</td>
<td><strong>Drafts assessment report, conclusions and reasons for granting or refusing authorization</strong></td>
</tr>
<tr>
<td>Send assessment report and summary of product characteristics to other MSs and applicant</td>
<td><strong>Send assessment report and summary of product characteristics to other MSs and applicant</strong></td>
</tr>
<tr>
<td>Other MSs CA’s to agree summary of biocidal product characteristics within 90 days of receipt of report and record agreement in Register for Biocidal Products</td>
<td><strong>Other MSs CA’s to agree summary of biocidal product characteristics within 90 days of receipt of report and record agreement in Register for Biocidal Products</strong></td>
</tr>
<tr>
<td>Reference MS to enter report and summary and any conditions on marketing and use in Register</td>
<td><strong>Reference MS to enter report and summary and any conditions on marketing and use in Register</strong></td>
</tr>
</tbody>
</table>

## 2. Product Mutual Recognition in Parallel

| **CA’s agree summary of product characteristics within 90 days of validation and record agreement in Register for Biocidal Products** | **CA’s agree summary of product characteristics within 90 days of validation and record agreement in Register for Biocidal Products** |
| **Coordination group (including applicant) and Commission resolution procedure if MS objection that safety authorization conditions not met** | **Coordination group (including applicant) and Commission resolution procedure if MS objection that safety authorization conditions not met** |
| **Commission resolution procedure (including applicant) for mutual recognition derogation (public policy, public security, protection of environment, etc.)** | **Commission resolution procedure (including applicant) for mutual recognition derogation (public policy, public security, protection of environment, etc.)** |

## 3. Product Mutual Recognition in Sequence

| **Chosen CA within 365 days of validation of application** | **Chosen CA within 365 days of validation of application** |
| **Applicant to provide missing information within normally max 180 days** | **Applicant to provide missing information within normally max 180 days** |
| **Applicant written comments on evaluation conclusions during 30 day period** | **Applicant written comments on evaluation conclusions during 30 day period** |
| **Chosen CA send assessment report and conclusions to ECHA, taking into account applicant comments** | **Chosen CA send assessment report and conclusions to ECHA, taking into account applicant comments** |
| **ECHA prepare and submit to Commission opinion on authorization of product within 180 days of receipt (including any conditions on marketing or use)** | **ECHA prepare and submit to Commission opinion on authorization of product within 180 days of receipt (including any conditions on marketing or use)** |
| **ECHA submits draft summary within 30 days in all languages** | **ECHA submits draft summary within 30 days in all languages** |

## 4. Union Authorization of Biocidal Products

| **Commission authorization approval Regulation or non-approval decision on receipt of ECHA opinion** | **Commission authorization approval Regulation or non-approval decision on receipt of ECHA opinion** |
| **Commission can require conditions particular to certain MS territory or exclude a certain territory on MS derogation request** | **Commission can require conditions particular to certain MS territory or exclude a certain territory on MS derogation request** |

## 5. Simplified Biocidal Product Authorization

| **Reduced evaluation by chosen CA (“verification of eligibility” for simplified authorization) within 90 days of accepting application (or longer where further information required)** | **Reduced evaluation by chosen CA (“verification of eligibility” for simplified authorization) within 90 days of accepting application (or longer where further information required)** |
| **Applicant to provide missing information within normally max 90 days** | **Applicant to provide missing information within normally max 90 days** |

## Approval/Non-Approval

| Chosen CA:  
| - drafts assessment report with conclusions and reasons for granting or refusing authorization;  
| - send electronic copy to applicant requesting comments within 30 days;  
| - finalizes report taking account of comments.  
| All relevant MS’s to authorize biocidal product within 30 days of agreement on summary and in conformity with summary.  
| In absence of agreement between all CAs, those CAs agreeing to summary may authorize product.  
| If absence of agreement between all CAs, those CAs agreeing to summary may authorize product.  
| Each CA to authorize biocidal product within 30 days of agreement on summary and in conformity with summary.  
| In absence of agreement between all CAs, those CAs agreeing to summary may authorize product.  
| Commission authorization approval Regulation or non-approval decision on receipt of ECHA opinion  
| Commission can require conditions particular to certain MS territory or exclude a certain territory on MS derogation request  
| Provided eligible, chosen CA must authorize within 90 days of acceptance of application or of submission of additional information requested by applicant.  

## Timeline (Days)*

| 725  
| 845  
| 905 (725 + 180)  
| 935  
| 300 |
Overview of factors relevant to choice of procedure

• Relevant product authorisation procedure will depend on:
  • nature of active substance (exclusion criteria, candidate for substitution)
  • product type (not all procedures available (yet) for all PTs)
  • intended territory of sale (EU wide, only one Member State, a few MSs?)
  • where choice of available appropriate procedures, whihc most cost and time effective?
  • much criticism/controversy concerning very significant increase in application (and annual) fees and disparity between Member States
  • ballpark figure: total fees for obtaining EU wide authorisation of single product in the range of between EUR 140,000 to 215,000
  • possibility for significant fee savings with multiple products: obtaining biocidal product family (a group of products with similar uses, active substances and compositions), ‘same product procedure’
Product authorisation options: multi-country sales?

• Intended sales territory?
  • one country only: national authorisation
  • more than one country or EU wide: Union authorisation or MR ‘in parallel’/‘in sequence’ (where existing national authorisation)

• Is Union authorisation an option?
  • not:
    • products containing actives meeting exclusion criteria (Article 5) (cat 1A or 1B CMRs, vPvBs, PBTs or considered as having endocrine disruptor properties);
    • PTs 14, 15,17, 20, 21 (rodenticides, avicides, piscicides, control of other vertebtrates, antifouling products) where harmonised conditions of use previously problematic
    • unless product has ‘similar conditions of use across the Union’ (Commission interpretation: MSs unlikely to refuse authorisation on environmental, health or public policy grounds)

• available yet for other PTs – phased in until 2020?
## Phase-in of Union Authorisation

<table>
<thead>
<tr>
<th>NOT eligible for Union authorization</th>
<th>From 1 September 2013</th>
<th>From 1 January 2017</th>
<th>From 1 January 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rodenticides</td>
<td>Biocidal products containing one or more NEW active substances</td>
<td>Disinfectants and algaecides not intended for direct application to humans or animals</td>
<td>Film preservatives</td>
</tr>
<tr>
<td>Avicides</td>
<td>Human hygiene</td>
<td>Preservatives for products during storage</td>
<td>Wood preservatives</td>
</tr>
<tr>
<td>Piscicides</td>
<td>Veterinary hygiene</td>
<td>Working or cutting fluid preservatives</td>
<td>Fiber, leather, rubber, and polymerized materials preservatives</td>
</tr>
<tr>
<td>Control of other vertebrates</td>
<td>Food and feed area</td>
<td></td>
<td>Construction material preservatives</td>
</tr>
<tr>
<td>Antifouling products</td>
<td>Drinking water</td>
<td></td>
<td>Preservatives for liquid-cooling and processing systems</td>
</tr>
<tr>
<td></td>
<td>Insecticides, acaricides and products to control other arthropods</td>
<td>Slimicides</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Repellents and attractants</td>
<td>Molluscicides, vermicides, and products to control other invertebrates</td>
<td>Molluscides</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Embalming and taxidermist fluids</td>
</tr>
</tbody>
</table>
Choice of Union Authorisation or MR – timing?

- Which quicker?
  - Union authorisation: alternative to national authorisation and MR
  - procedural timelines for Union authorisation approx. 3 months slower than MR in parallel (ECHA opinion delay)
  - but... increased potential for delay in MR procedures due to many MSs and lengthy procedures if:
    - authorisation refusal on public policy, health or environmental or animal welfare grounds (Article 37)
    - claim that authorisation conditions not met
Choice of Union Authorisation or MR – cost?

• Which cheaper? Many variables to be weighed:
  • application and annual fees of ECHA and single evaluating MS (in Union authorisation) v. fees of CAs and own resources multiplied by MS (MR), plus ECHA submission fee
  • large ECHA fee range (Regulation 564/2013) dependent on:
    • product identical to that pre-assessed for active approval (50% reduction)?
    • where comparative assessment required (punitive 50-100% fee increase)
    • single product or biocidal product family (less)?
    • SME reduction available (reduce by 10-30%)?
  • check MS fees; decided on individual non-harmonised MS basis
Multiple products – using procedures efficiently

• ‘Biocidal product family’
  • reduced authorisation costs and administrative burden for applicants and authorities
  • simultaneous authorisation of group of products:
    • same actives
    • similar uses
    • similar compositions with specified variations
    • ‘similar levels of risk and efficacy’ (BPR amendment)?
  • entrance fee cheaper? depends on number of products:
    • EUR 150,000 – 210,000 family Union authorisation v. single product Union authorisation of EUR 40,000 to 120,000 (without SME reductions)
    • ECHA annual fee for family Union authorisation only 2 x single product (EUR 20,000)
Multiple products – using procedures efficiently

• ‘Same product procedure’ cheaper alternative to family? ECHA fee for Union authorisation of same biocidal product = EUR 2,000
  • sequential, not simultaneous
  • ‘identical’ to reference product already authorised/subject to application for national or Union authorisation (only ‘administrative differences’)
Treasted Articles under the BPR
Treated articles under the old BPD

• ‘Treated articles’ or materials not explicitly covered by BPD, although extensive guidance on how addressed

• Different concept of ‘biocidal function’ under BPD:
  • internal or surface effect on the article itself as an inseparable ingredient, for example, leather treated against antimicrobial decay to increase durability (outside scope)
  • intended external effect, for example, insecticidal strips treated with insecticides to kill insects

• Articles treated outside EEA and imported from third countries not required to use EU approved actives.
## Changes in scope of BPR

<table>
<thead>
<tr>
<th></th>
<th>BPD</th>
<th>BPR</th>
</tr>
</thead>
<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>Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, <strong>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.</strong></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, <strong>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.</strong>&lt;br&gt;&lt;br&gt;<strong>A treated article that has a primary biocidal function shall be considered a biocidal product.</strong></td>
</tr>
<tr>
<td><strong>Treated article</strong></td>
<td><strong>None</strong></td>
<td>Any substance, mixture or article which has been treated with, or <strong>intentionally</strong> incorporates, one or more biocidal products.</td>
</tr>
</tbody>
</table>
DMF treated article controversy

• DMF treated leather imported into Europe in sofas and shoes causing allergic reactions and serious customer complaints

• Now a Commission marketing ban exists
Biocidal function: ‘primary’ or not?

- ‘Biocidal function’ = the function of controlling harmful organisms by other than mere physical or mechanical means
- Not merely a biocidal property only protecting article itself
- Different BPR requirements dependent on whether biocidal function of treated article is ‘primary’ or not
- Only treated articles with ‘primary biocidal function’ (e.g. impregnated biocidal wipe) are biocidal products
- Primary: ‘of first rank or importance compared with other functions’
- Not always self-evident = borderline cases, case by case approach
- Criteria considered: intended use, claim regarding function, active substance concentration, biocidal mode of action
Commission Decisions on ‘primary’ or ‘non-primary’ function (Article 3(3))

• Anti-viral tissue impregnated with citric acid with claim ‘kills 99.9% of cold & flu viruses in the tissue’ is a biocidal product
  • ‘Through such a claim, greater prominence and first importance is given to the biocidal function of the tissue than to its other functions (for example to blow the nose). The anti-viral tissue has therefore a primary biocidal function.’ (Commission Decision 2015/1985)

• Impregnated horse rug for controlling insects is a biocidal product
  • ‘Since: ...greater prominence and first importance is given in the product's information to the biocidal function of controlling insects than to other functions of the horse rug (in particular to mitigate cold weather conditions or UV-protection), the horse rug can be considered to have a primary biocidal function...’ (Commission Decision 2016/903)
Treated Articles with Non-Primary Biocidal Effect
Overview

• Objective: protection of health and environment, level playing field between production within and outside of the EU
• Allowed on the market only if all active substances are approved for relevant use
• Specific new labelling requirements
• Obligation to provide information to consumer on request
Specific requirements of Article 58 BPR

• Article 58(2):
  • all actives in treating/incorporated product must be approved (Union List of Annex I) before placed on EU market
  • for relevant product and use
  • any specific approval conditions met (use or amount limits, labelling)

• Exempted (burden on supplier to justify):
  • actives only protecting article (for example, in can preservatives)
  • biocidal actives not included with intention/purpose of conferring biocidal property (for example, lavender oil for perfuming)
  • where sole biocidal treatment is fumigation and disinfection of premises or transport storage containers where no residues remain (for example, under EU disease prevention rules)
Labelling and consumer information where claim or approval condition

• Specific new labelling particulars apply where:
  • manufacturer makes claim regarding biocidal properties of the article; or
  • conditions of substance approval so require (specific safety concern)

• Information to be provided in the national language (unless already required under other EU legislation)
  • statement that article incorporates biocides
  • substantiated biocidal property of the article
  • name of all active substances and all nanomaterials « (‘nano’) »
    • not of actives only protecting article itself (for example, in can preservatives)
    • not of actives other than those relating to claim or which approval requires
  • instructions for use including precautions

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Labelling and consumer information

• In all cases, ‘necessary’ labelling to protect humans and the environment:
  • use instructions
  • Precautions

• Labelling 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

• Supplier must provide consumers on request with information on biocidal treatment of articles – free of charge – within 45 days
‘Complex’ Treated Articles

• Complex Treated Articles = treated articles consisting of numerous components = unofficial definition
• Question: does the obligation for active substances to be approved apply where final complex article placed no market does not have any (‘non-primary’) biocidal function but where one component during the upstream manufacturing process was treated with or incorporates a biocidal product (and is therefore a treated article)?
  • Example: television components treated to give them fungicidal properties (television does not have any biocidal function)
‘Complex’ Treated Articles

- If yes, practical compliance difficulties:
  - person placing on the market in EU needs detailed knowledge of manufacturing steps to assess whether compliant
  - exporters to inform their EU importers
  - consumer information requirement!

- Initial proposal of Commission in Note for discussion with Competent Authorities said yes (whilst acknowledging compliance and enforcement issues)
‘Complex’ Treated Articles

- Commission’s Frequently Asked Questions on Treated Articles:
- Elaborated with consensus of Member States → to ensure consistent interpretations
- In the case of "complex" articles made up of different components and/or materials, it is unlikely that any treatment or incorporation of a biocidal product concerns uniformly all components/materials. Nevertheless, one or several individual components/materials of a complex article may have been treated with or incorporate a biocidal product, and the biocidal property or function conferred to these components/materials may still be beneficial for the finished good as such (e.g. by increasing overall durability of the complex article). Such complex articles are to be regarded as treated articles.
‘Complex’ Treated Articles

• Indications whether a biocidal treatment has an intentional biocidal effect in a finished good can come from various elements, e.g. a claim concerning a biocidal property or function of the finished good or part thereof, the PT of the biocidal product used for the treatment and/or the concentration of the AS in the finished good.

• In all cases where a claim concerning a biocidal function of a finished good is made $\rightarrow$ intention is obvious $\rightarrow$ = treated article, if not a BP

• unless the manufacturer/importer can present convincing justification that the claimed property is not due to a biocidal treatment that has led to the presence of the biocidal active substance

• Claims include: antimicrobial, an increased durability or anti-odour properties
‘Complex’ Treated Articles

• Important elements to consider ‘intention’:
  • Claim – but no claim does not necessarily mean no intention
  • PT of the biocidal product (likely to be intentional or not in the finished article or to make it a BP)
  • concentration of the active substance in the finished article (low? non-effective residues of active substances?) NO THRESHOLD!
• Risk issues concerning treatment of components covered by other EU regulations (REACH, General Product Safety)
‘Complex’ Treated Articles

• Article 58(1) BPR

• The purpose of this provision is to exempt from the requirements of Article 58 all goods stored or contained in a premise or, respectively, transported in a container, which was fumigated or disinfected as the sole biocidal treatment, on the condition that no residues would be expected to remain from such treatment.

• This provision can be relevant for instance for goods imported into the EU and which, by virtue of international trade agreements, have to undergo a specific treatment (i.e. fumigation or disinfection) before they can be placed on the EU market to prevent the transmission of organisms presenting a risk to animal or human health.
# ‘Complex’ Treated Articles

<table>
<thead>
<tr>
<th>Disinfecting wipe</th>
<th>Article in which a disinfectant was incorporated to generate an antimicrobial surface (e.g. chopping board or equipment in the production of foodstuff)</th>
<th>Components or intermediate forms which were disinfected (which are not themselves placed on the EU market)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disinfecting wipe</td>
<td>An article which has been disinfected (in the form as it is placed on the EU market) to render it sterile or reduce contamination</td>
<td>Wooden components of a complex article, or an intermediate form of a wooden article (which are not themselves placed on the EU market) that have been treated with an insecticide (e.g. by fumigation) in order to remove a present infestation</td>
</tr>
<tr>
<td>Disinfecting wipe</td>
<td>Wooden article, or wooden components of a complex article, impregnated with an insecticidal wood preservative in order to protect it from becoming infested</td>
<td>Wooden components of a complex article, or an intermediate form of a wooden article (which are not themselves placed on the EU market) that have been treated with an insecticide (e.g. by fumigation) in order to remove a present infestation</td>
</tr>
<tr>
<td>Disinfecting wipe</td>
<td>Wooden article treated with an insecticide (e.g. by fumigation) in order to remove a present infestation</td>
<td>Wooden components of a complex article, or an intermediate form of a wooden article (which are not themselves placed on the EU market) that have been treated with an insecticide (e.g. by fumigation) in order to remove a present infestation</td>
</tr>
<tr>
<td>Disinfecting wipe</td>
<td>Speciality paper incorporating a preservative in order to protect the finished article during use such as antimould treated papers</td>
<td>Wooden components of a complex article, or an intermediate form of a wooden article (which are not themselves placed on the EU market) that have been treated with an insecticide (e.g. by fumigation) in order to remove a present infestation</td>
</tr>
<tr>
<td>Disinfecting wipe</td>
<td>Speciality paper incorporating a preservative in order to protect the finished article during use such as antimould treated papers</td>
<td>Wooden components of a complex article, or an intermediate form of a wooden article (which are not themselves placed on the EU market) that have been treated with an insecticide (e.g. by fumigation) in order to remove a present infestation</td>
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<td>Disinfecting wipe</td>
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</tr>
<tr>
<td>Disinfecting wipe</td>
<td>Speciality paper incorporating a preservative in order to protect the finished article during use such as antimould treated papers</td>
<td>Wooden components of a complex article, or an intermediate form of a wooden article (which are not themselves placed on the EU market) that have been treated with an insecticide (e.g. by fumigation) in order to remove a present infestation</td>
</tr>
</tbody>
</table>

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## ‘Complex’ Treated Articles

<table>
<thead>
<tr>
<th>Biocidal product</th>
<th>Treated article</th>
<th>Not a treated article</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixtures like paints, glues, inks, detergents, etc. containing an in-can preservative</td>
<td>Complex articles containing 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 finished good. Paint, detergents, etc. containing an additive, and that additive had an in-can preservative added in order to protect its during storage, where this preservative has no further preserving function in the final product.</td>
</tr>
<tr>
<td></td>
<td>Paints and coatings containing a fungicide to fight existing mould infestations (anti-mould paint)</td>
<td>Paints and coatings containing a preservative that extends the durability of the applied layer.</td>
</tr>
<tr>
<td></td>
<td>Paints and coatings intended to prevent microbial settlement and growth in order to provide a germ-free environment e.g. in hospitals</td>
<td>Complex articles containing e.g. paints, adhesives which contain a film preservative in order to protect the paint/glue layer during use of the article.</td>
</tr>
<tr>
<td></td>
<td>Leather goods (shoes, seats) treated with a fungicide protecting the leather from decay</td>
<td></td>
</tr>
</tbody>
</table>
## ‘Complex’ Treated Articles

<table>
<thead>
<tr>
<th>Biocidal product</th>
<th>Treated article</th>
<th>Not a treated article</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mosquito net treated with an insecticide or insect repellent</td>
<td>Textiles, or textile components of complex articles, treated with a preservative in order to increase durability of the fabric (also when used in multi-component articles)</td>
<td></td>
</tr>
<tr>
<td>Insect-repelling bracelets</td>
<td>Textiles, or textile components of complex articles, treated with an insecticide in order to protect the fabric from destruction by insects</td>
<td></td>
</tr>
<tr>
<td>Insect-repelling bracelets</td>
<td>Clothes treated with an insect repellent</td>
<td></td>
</tr>
<tr>
<td>Kitchen sponge treated to inhibit microbial growth during use</td>
<td>Clothes treated with a biocidal product in order to control odour-forming bacteria (also when used in multi-component articles)</td>
<td></td>
</tr>
<tr>
<td>Plastic articles, or plastic components of complex articles, incorporating a preservative that protects them against harmful organisms and increases durability of the material</td>
<td>Plastic articles, made of ingredients (monomers, polymerisation aids, etc.) which contained preservatives in order to protect them during storage and manufacture, where these preservatives have no further function in the finished good</td>
<td></td>
</tr>
</tbody>
</table>
Transitional period (Article 94)

• Despite requirement for actives to be approved before treated article placed on EU market...

• Can continue placing the treated article with unapproved active substance/product type combination(s) on market if:
  • the substance/product-type combination is under review programme for existing active substance; or
  • an application for approval of the « new » substance/product-type combination was submitted before 1 September 2016

  until:
  • in case of non-approval: 180 days after any decision after 1 September [date relevant now?] not to approve, or to reject approval application of, [the] [one of the] active(s) for relevant PT and use; or
  • in case of approval: date of approval of last active to be approved for relevant PT and use (approval conditions re treated articles apply from date of approval)

• **Otherwise, treated article must not be placed on the market after 1 March 2017**
Can your treated articles be sold legally on EU market after 1 March?

• Are the active substance(s) with which your treated article sold in Europe already approved for the right product type (relatively few are)?
  • does approval impose restrictions on use in treated articles, labelling?

• Are relevant actives/PT included in the review programme?

• Has someone applied for active/PT before 1 September 2016?

• If no, treated article cannot be placed legally on the EU market after 1 March until the date of any Commission decision to include relevant new active in Union List resulting from any future application for approval (years away).
Is treated article ‘placed on the market’ before or after 1 March?

- Whether ‘placed on [EU] market’ (defined as first supplied) before or after date is critical
  - if so, can legally be supplied further downstream in EU after date

- European Commission ‘Blue Guide’ on the implementation of EU products rules 2016 (2016/C 272/01)
  - ‘placing on market’ refers to each individual product item, not type of product
  - even if a particular type/brand of treated article was placed on EU market before 1 March 2017, further individual examples cannot be after 1 March
  - import and storage in warehouse alone not sufficient
  - in warehouse plus evidence of agreement of transfer of ownership and possession (if not physical handover) sufficient
Treated Articles with Primary Biocidal Function
Treated articles with primary biocidal function

- Since BPR: ‘a treated article that has a primary biocidal function shall be considered a biocidal product’ (Article 3(1)(a) of BPR)
- subject to normal BPR biocidal product autorisation under EU or transitional (national) regime
- Full biocidal product labelling required:
  - labelling in accordance with approved summary of product characteristics:
    - hazard and precautionary statements
    - Directive 1999/45 and Regulation 1272/2008 where applicable
  - where relevant, to avoid mistaken consumption as food/feed
  - not misleading as to health/environment risks
Treated articles with primary biocidal function

- as under BPD: active components, product uses, directions for use (frequency/dose rate), batch number, user restrictions, adverse effects. **Plus new:**
  - nanomaterials and specific related risks, specified ‘(nano)’
  - authorisation holder details
- MS may require to review model labels and that appear in official language(s)
- electronic public access to up to date labelling of active held by ECHA or Commission
Transitional period (Article 93)

- Can continue to place product on the EU market under national product autorisation systems if:
  - relevant active substances (s) on EU market on 1 September 2013; and
  - applications for approval of relevant active/product type combination(s) were submitted by 1 September 2016

- Market access for ‘up to three years after date of approval’ (depends on each Member State), plus longer if lodge BPR authorisation pre date of approval

- If application for approval not submitted by deadline, no imports of product into EU permitted after 1 September 2017
Data Sharing under the BPR
Principles

• Data sharing under the BPR is mandatory when data has been submitted (article 62).
• Duty to inquire with ECHA
• Power to adjudicate a dispute if parties have made every effort to reach an agreement on sharing of data costs on fair, transparent and non-discriminatory grounds.
• ECHA can refer to data to the benefit of data access applicant even before it has fully compensated the data owner.
Data sharing rules: objectives

- Open season for competitors’ accessing data since 1 September 2013
  - New data sharing and compensation rules for all data submitted under BPD and BPR applied immediately
- Stated objectives:
  - *create a ‘level playing field... as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs, of avoiding the establishment of monopolies, of sustaining free competition between economic operators and of a fair compensation of the costs borne by data owners’* (Recital 58)
  - ‘*minimise the number of tests on animals and for testing with biocidal products, or active substances contained in biocidal products’* (Recital 57)
Data sharing and protection

Timelines for data negotiation potentially very short: as little as 1 month. ECHA acts within 60 days after negotiations fail and gives access. This may help give data accessors a slight upper hand.

Applicant asks if Test/Study already submitted

ECHA identifies if a data owner

Text/Study EXISTS

Protected

Parties make “every effort” to agree

Parties agree

Notifies ECHA no earlier than 1 month after receipt of name of data owner from ECHA

ECHA has 60 days to give access if:
- Data owners has been paid
- Every effort has been made

Text/Study DOESN’T EXIST

Applicant conducts own study

Not Protected

Applicant may refer to it if proves that “technically equivalent” for Annex II or sameness for Annex III

Funded by the European Union and implemented by a Consortium led by GOPA Consultants
Data access under the BPR

• Required:
  • for (new) active substance approval
  • for ‘Article 95’ listing
  • for BPR harmonised product authorisation submission
• Aims and features of data access and mandatory data sharing for protected data under BPR:
  • reduction of animal testing
  • statutory data protection periods
  • level playing field / end of “free riding”
  • FTAND costs sharing
  • ECHA ability to force sharing of data by data holder when holder and requestor do not reach agreement on data sharing terms
    • challengeable through the Board of Appeal and ultimately the European Courts
  • ECHA does not dictate appropriate costs (rather by national courts)
Commercially significant differences in data sharing requirements of BPR versus REACH I

• Wide scope of mandatory data sharing:
  • ECHA ability to grant right to refer includes non-vertebrate data for Article 95
  • Not included: phys-chem data, risk assessment, product-specific data
  • not limited to same substance – potential to use mandatory data sharing to access for bridging and read-across as long as dossier submitted
• Right to refer granted by ECHA for Article 95 listing can be relied on by applicant’s downstream customers seeking product authorisation
  • data holder cannot prevent this absent an agreement
Data sharing rules: LoAs ‘with legs’

Data Owner

LoA or Forced Sharing

Substance Supplier or Product Supplier included in the list

SS or PS “entitled to allow applicants to make reference”. [Art. 95(4)]

Applicant for authorisation of a BP 1

Applicant for authorisation of a BP 2

Third Party

Applicant for authorisation of a BP 3

Applicant for authorisation of a BP 4

Sub-licence to customer in own supply chain.
Data Sharing and Protection

All data protection periods start from when data under BPD or BPR is submitted for the first time.

<table>
<thead>
<tr>
<th>ACTIVE SUBSTANCE (AS)</th>
<th>BIOIDAL PRODUCT (BP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval of a NEW AS</td>
<td>BP with a NEW AS</td>
</tr>
<tr>
<td>15 years</td>
<td>15 years</td>
</tr>
<tr>
<td>from the first date of the month following the date of AS approval of each AS/</td>
<td>from the first date of the month following the first decision taken to authorize</td>
</tr>
<tr>
<td>product-type combination</td>
<td>a BP</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Approval of an EXISTING AS</td>
<td>BP with ONLY EXISTING AS</td>
</tr>
<tr>
<td>10 years</td>
<td>10 years</td>
</tr>
<tr>
<td>from the first date of the month following the date of AS approval of each AS/</td>
<td>from the first date of the month following the first decision taken to authorize</td>
</tr>
<tr>
<td>product-type combination</td>
<td>a BP either by a MS authority or by the Commission (Union authorization)</td>
</tr>
<tr>
<td>If AS is not already approved on Sept. 1, 2013, all data protection periods for</td>
<td></td>
</tr>
<tr>
<td>AS/product-type combinations still under review remain until a (longstop of)</td>
<td></td>
</tr>
<tr>
<td>December 31, 2025.</td>
<td></td>
</tr>
<tr>
<td>RENEWAL/REVIEW of an AS approval</td>
<td>RENEWAL/AMENDMENT OF BP AUTHORIZATION</td>
</tr>
<tr>
<td>5 years</td>
<td>5 years</td>
</tr>
<tr>
<td>from the first date of the month following the decision on renewal/review of a</td>
<td>from the first date of the month following the decision on the renewal/amendment of</td>
</tr>
<tr>
<td>the approval of an AS</td>
<td>a BP authorization</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Data Sharing and Protection

• General requirement that compensation must be determined in a fair, transparent and non-discriminatory manner, ‘having regard to’ the REACH guidance already established by ECHA on data sharing (Chpt. 7 – see new April Guidance from ECHA)

• Repeat players are unlikely to want to have compensation decisions to be settled by EU national courts (who have little/ no experience on these matters)

• ECHA decisions to grant data access within 60 days can be and have been challenged by data owners before the Board of Appeal: quick and cost efficient mechanism – with suspensive effect on decision
Situations concerned by transitional rules

- **Article 93 BPR:** Transitional measures concerning biocidal products not covered by the scope of Directive 98/8/EC
  - biocides used in food contact applications
  - precursors of in-situ generated active substances
  - treated articles which have a biocidal primary function
  - Member States may apply their national rules until 1 September 2017 if no submission is made by 1 September 2016

- **Article 94 BPR:** Transitional measures concerning treated articles
  - treated articles with a non biocidal primary function
  - lawfully on the market until 1 March 2017 or longer if an application for approval for the relevant product-type is submitted by 1 September 2016
Consequences of submissions

• **Article 93 BPR:** Member States may grant BP authorisations if a submission is made on 1 September 2016.
  • The active substance is treated as if it had been included in the review programme or work programme.

• **Article 94 BPR:** unless a derogation applies, Member States may not grant BP authorisations. Only *imported* treated articles can continue to be placed on the market if a submission is made on 1 September 2016.
  • The active substance is considered as “new”.

• **Article 95 BPR** (substance suppliers list) applies to suppliers of:
  • approved active substances
  • active substances in the review/work programme
  • new active substances if and when a dossier has been submitted
  • substances generating active substances if and when a dossier has been submitted
Coordination for generating data

• No coordination is foreseen in the BPR
• With the exception of certain in-situ active substances, no coordination has been foreseen by the Commission, in particular in the case of treated articles. Typically, persons who were not previously concerned by BPR.
• Companies having developed technology may be preparing dossiers in parallel – without speaking to each other
  • business secrets: Need to protect the technology – Need to protect the market strategy
Absence of coordination

• Risk of submitting uncoordinated dossiers for the same active substance
  • guidance on free radicals only submitted for endorsement at the 25-26 May 2016 CA meeting
• Risk of duplicating data, including data that is otherwise subject to mandatory data sharing
  • significant investment
  • possible unnecessary use of vertebrate animals
  • only data that has been submitted is subject to the data sharing obligation of Articles 63 and 95 BPR
• loss of opportunity for data sharing and cost sharing/financial compensation
  • upfront costs of generating dossier
  • Article 95 listing
Joint dossiers and business secrets

• Objectives:
  • protection of companies’ intellectual property
  • compliance with antitrust law: no alignment of commercial strategies, no abuse of dominant position.
• Sign cooperation and cost sharing clause
  • contents of active substance and/or precursor dossier
  • extent of data rights grated to parties and to third parties
  • data valuation and compensation
• Use an independent third party:
  • as a black box for confidential data
  • as a data submitter and contact for third party data accessors
  • as a cost and revenue centre
Where exporters to the EU need help
How can exporters be helped?

- Explanation and interpretation of obligations: treated articles, labelling etc.
- Supply chain audits
- Product authorisation strategies (national transitional or BPR)
- Assisting with Article 95 listing
- Data Access
  - data requester: negotiating terms for data access required for product authorisation and approved supplier’s listing
  - data holder
    - amendment of Task Force agreements to include BPR compliant data request response operating procedures
- Advice on letters of access to limit rights granted
How can exporters be helped?

• Appropriate BPR terms and conditions in distribution contracts
• Product defence: advocacy and regulatory strategies to prevent substitution of active substances or products
• Challenging decisions of ECHA (data sharing) before the ECHA Board of Appeal
• Representing clients before relevant authorities in enforcement investigations
Take Home Messages
Take home messages (I)

• Can your biocidal products continue to be legally supplied on EU market?
• for biocidal products (including non-primary function treated articles), is your EU importer on the approved supplier’s (Article 95) list?
• do your treated articles meet the criteria to benefit from transitional period?
• Are you prepared for BPR product authorisation to ensure uninterrupted market access?
  • relatively short time limits for application (window to access data) once active listed on Union list
  • do you understand the options available to you and the associated costs and timing?
Take home messages (II)

• New obligations for products not previously covered (treated articles)
  • including labelling requirements - easily enforced
• If not data holder, what is your company’s data access strategy (approved supplier’s listing, product authorisation) ?
  • who has the data?
  • use of experienced negotiators = big data cost savings
Thank you!