The Use of Biocides in the EU

Biocidal Product Directive and Borderline Issues with the Cosmetic Regulation

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The EU Biocidal Products Directive (BPD)

EU Directive 98/8/EC
- Published 24 April 1998.
- Implementation by Member States by May 15th, 2000
- Concerns placing of biocidal products on the market
- Affects products where intent and/or claim is biocidal
- Biocidal Product Regulation (BPR) due from 1.1.2013

Objectives
- Harmonised regulatory and approval scheme for biocides
- Ensure high level of protection for man and the environment
  - Must demonstrate that biocides can be used safely
- Preventing barriers to trade – some member states already have biocides regulatory schemes for some uses
Definition of Biocidal Products (98/8/EC - BPD)

“Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means”
So, what is a biocide then?

Biocides covered by the EU BPD are:

- Active substances and preparations
- Containing one or more active substances
- **Intended** to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism
- Active by chemical or biological means

The BPD **does not cover**:

- Biocides for personal care product (EU Cosmetics Directive)
- Biocides for medical instrument disinfection (EU Medical Devices Directive)
- Plant protection products (EU PPP Directive)
- Medicinal or pharmaceutical products (EU Medicines regulations)
How does the BPD work?

- BPD differentiates between
  - **Active substances** (a.s.) and
  - **Biocidal** (end-use) **products** (b.p.)

- Approval process has two stages
  1. First the a.s. has to be approved → listing on “Annex 1” of the BPD
  2. Then the b.p. has to be approved

- But the a.s. and b.p. are not approved for every use or application
  - a.s. are approved for specific Product Types (PTs) i.e. groups of general uses
  - b.p. are approved for **specific described uses** (specific applications)
Approval process for active substances

- From **1998-2002**, suppliers **identified** to the European Commission all biocide a.s. on the market
  - Identification – simple, no cost procedure
  - About 1200 individual chemicals were identified

- In **2002-2003** suppliers **notified** to the European Commission the combinations of a.s. and PT (Product Type) which they intended to get approved.
  - Notification required a basic toxicological package (value €300K)
  - 370 of the 1200 a.s. were **notified** in various PTs
  - Non-notified a.s were withdrawn from the market by 1\textsuperscript{st} Sept. 2006
  - But “**free-riders**” could carry on selling if another supplier had notified
## BPD Product Types

### Main Group 1: Disinfectants and general biocidal products

<table>
<thead>
<tr>
<th>Number</th>
<th>Product Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Human hygiene biocidal products</td>
<td>Used for human hygiene purposes.</td>
</tr>
<tr>
<td>2</td>
<td>Private and public health area disinfectants and other biocidal products</td>
<td>Used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public or industrial areas, including hospitals, as well as products used as algaecides. Usage areas include swimming pools, aquariums, bathing and other waters, air-conditioning units, walls and floors in health and other institutions, chemical toilets, waste water, hospital waste, soil and other substrates (in playgrounds).</td>
</tr>
<tr>
<td>3</td>
<td>Veterinary hygiene biocidal products</td>
<td>Includes products used in areas in which animals are housed, kept or transported.</td>
</tr>
<tr>
<td>4</td>
<td>Food and feed area disinfectants</td>
<td>Used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage, or consumption of food, feed or drink (including drinking water) for humans and animals.</td>
</tr>
<tr>
<td>5</td>
<td>Drinking water disinfectants</td>
<td>For both humans and animals.</td>
</tr>
</tbody>
</table>
## BPD Product Types

**Main Group 2 Preservatives**

<table>
<thead>
<tr>
<th>No.</th>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>In-can preservatives</td>
<td>Used for the preservation of manufactured products, other than foodstuffs or feeding stuffs, in containers by the control of microbial deterioration to ensure their shelf life.</td>
</tr>
<tr>
<td>7</td>
<td>Film preservatives</td>
<td>Used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works etc.</td>
</tr>
<tr>
<td>8</td>
<td>Wood preservatives</td>
<td>For wood from and including saw-mill stage, and wood products (including preventative and curative products).</td>
</tr>
<tr>
<td>9</td>
<td>Fibre, leather, rubber and polymerised materials preservatives</td>
<td>Includes the preservation of fibrous materials, such as paper or textile products.</td>
</tr>
<tr>
<td>10</td>
<td>Masonry preservatives</td>
<td>Used for the preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological algal attack.</td>
</tr>
<tr>
<td>11</td>
<td>Preservatives for liquid-cooling and processing systems</td>
<td>Use for the preservation of water and other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels (not drinking water preservation products).</td>
</tr>
<tr>
<td>12</td>
<td>Slimicides</td>
<td>Used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, eg on wood and paper pulp, and porous sand strata in oil extraction.</td>
</tr>
<tr>
<td>13</td>
<td>Metalworking-fluids preservatives</td>
<td>Products used for the preservation of metalworking fluids by the control of microbial deterioration.</td>
</tr>
</tbody>
</table>
# BPD Product Types

## Main Group 3: Pest Control

<table>
<thead>
<tr>
<th></th>
<th>Product Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>Rodenticides</td>
<td>Control of mice, rats or other rodents.</td>
</tr>
<tr>
<td>15</td>
<td>Avicides</td>
<td>Control of birds.</td>
</tr>
<tr>
<td>16</td>
<td>Molluscicides</td>
<td>Control of molluscs, e.g., snails that may clog pipes.</td>
</tr>
<tr>
<td>17</td>
<td>Piscicides</td>
<td>Control of fish; excludes products for the treatment of fish diseases.</td>
</tr>
<tr>
<td>18</td>
<td>Insecticides, acaricides and to control other arthropods</td>
<td>For example insects, arachnids and crustaceans</td>
</tr>
<tr>
<td>19</td>
<td>Repellents or attractants</td>
<td>Used to control, harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.</td>
</tr>
</tbody>
</table>

## Main Group 4: Other biocidal products

<table>
<thead>
<tr>
<th></th>
<th>Product Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>Preservatives for food and feedstocks</td>
<td>Used for the preservation of food or feedstuffs by the control of harmful organisms.</td>
</tr>
<tr>
<td>21</td>
<td>Antifouling products</td>
<td>Used to control growth and settlement of fouling organisms (microbes and higher forms of plant and animal species) on vessels, aquaculture equipment or other structures used in water.</td>
</tr>
<tr>
<td>22</td>
<td>Embalming or taxidermist fluids</td>
<td>Used for the disinfection and preservation of human or animal corpses, or parts of them.</td>
</tr>
<tr>
<td>23</td>
<td>Control of vertebrates</td>
<td>Used to control vermin</td>
</tr>
</tbody>
</table>
Approval process for active substances

- Final stage of a.s. approval: in-depth assessment of information (dossiers) provided by suppliers
  - The a.s. are divided amongst the EU member states ("Rapporteurs" or "RMS = Rapporteur Member State") for assessment (one country per active substance)
  - If the assessment is favourable then the a.s. is listed on Annex 1

- Full Dossier submission was done in phases according to application (Product Type = PT)
  - Part A: Wood treatment and rodenticides by 28 March 2004
  - Part B: Pesticides and antifouling products by 1 May 2006 (PT 21)
  - Part C: Disinfection, preservation and metalworking fluids by 31st July 2007 (PT 1, 2, 3, 4, 6, 13)
  - Part D: Slimicides, oilfield biocides and cooling water by 31st October 2008 (PT 7, 9, 10, 11, 12)

- In many cases the full dossier for a special a.s. in a Product Type was not submitted (→ resulted in phase out of active)
BPD registration requirements for a.s.

- Obtaining a BPD Approval for an active substance (a.s.) requires a big investment in time and money
  - Expensive information required
    - Physico-chemical studies and measurements on the a.s.
    - Toxicological studies on the a.s.
    - Environmental studies on the a.s.
    - Descriptions of how the biocide is used
    - Proof of microbiological efficacy
    - Environmental and human risk assessments
  - Official fees to pay, consultants...
  - Potential costs: €3Mio to €5 Mio per a.s.
Approval process for active substances for PT1 (Human Hygiene Uses)

- **Dossier submission** for a.s. was done in phases according to application group (Product Type) between 2004 and 2008
  - Submission of dossiers for PT1 a.s. had to be done by 31st July 2007
  - Active substances for PT1 which were not supported by a dossier submission are not allowed for use anymore

- **Progress by the Rapporteurs is slow due to extreme workload on the authorities**
  - No a.s. from PT1 has yet been listed on Annex 1
What about biocidal product registrations?

- The biocide product (b.p.) registration process can only begin after the relevant active substance is listed on “Annex 1” of the BPD for that PT
  - After inclusion of the active substance on Annex 1, there is a 2-years time window for review of the b.p.
- Registrants can choose the EU Member State for the b.p. registration
  - “Mutual recognition” by other Member States. Fees to pay in each country.
- Registrants must submit data on the b.p.
  - In general less costly than for the active substance
  - Registrants will need a “Letter of Access” for the active substance from a supplier who registered the active substance under the BPD
Biocidal Products covered by Product Type 1

- Definition
  Biocidal products used for human hygiene purposes

- Examples
  - Disinfecting hand wash products such as soaps with disinfecting and or other microbicidal claims
  - Disinfecting body showers or baths
  - Disinfecting or microbicidal gels, creams or lotions for treatment of hands or other parts of the body
A cosmetic product means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.”
A cosmetic product means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, **protecting them, keeping them in good condition or correcting body odours.**
Cosmetic Preservatives or Biocides for cosmetics?

- Within Europe under the enforcement of the BPD (98/8/EC) the use of biocides in handwashes or other products for the treatment of the skin up to a proposed concentration can be claimed as a biocidal product, if the requirements for testing meeting the high efficacy claims.

- And

- Under the current European Cosmetics Regulation (EC/1223/2009), the use of preservatives (listed in Annex 5 of the Cosmetic Regulation) up to a defined concentration is already allowed in leave on and rinse off cosmetic products, such as deodorants, hand washes, body washes etc. Moreover actives with antimicrobial efficacy are allowed for deodorants and hygienic claims (main use !!)
Current interpretation of the boundaries between the two directives within Europe

- The product can not be a cosmetic product and a biocidal product at the same time
  - Active substance in use can not be recommended to be used in the same way under these two directives
- The use of preservatives for cosmetics is EXcluded from the BPD
- The over-riding directive rules are based on what the INTENTIONAL use is
- The marketing characteristics of the product must not mislead the consumer
  - A pig in a dress is still a pig!
Main Distinctions for preservatives in consumer products under Cosmetics Regulation or BPD (check with your local authority if in doubt):

<table>
<thead>
<tr>
<th>Potential claims</th>
<th>Cosmetic Regulation</th>
<th>BPD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>Lower</td>
<td>Higher</td>
</tr>
<tr>
<td>Effect</td>
<td>Preservation or bacteriostatic</td>
<td>Bactericidal/fungicidal/virucidal</td>
</tr>
<tr>
<td>Labelling</td>
<td>INCI Listing</td>
<td>Use instructions, CLP labelling</td>
</tr>
<tr>
<td>All secondary:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibacterial</td>
<td>(i.e. mild liquid soap with antibacterial effect)</td>
<td></td>
</tr>
<tr>
<td>Freshness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hygienic</td>
<td></td>
<td></td>
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<tr>
<td>Refreshing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supporting healthy skin (e.g. Avoiding skin disorders by keeping “balanced skin flora”, avoiding development of unwanted microorganisms, avoiding impure skin and pimples etc.) and hair (e.g. preventing dandruff…)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main claim:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antimicrobial</td>
<td>(i.e. antibacterial hand soap)</td>
<td></td>
</tr>
<tr>
<td>Bactericidal</td>
<td>/ Fungicidal / Virucidal</td>
<td></td>
</tr>
<tr>
<td>Kills bacteria and/or fungi and/or viruses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disinfecting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decontaminating</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Different Requirements on Efficacy Testing

- With exception of the preservative challenge test as standard method for proofing the preservation of a product, for **Cosmetic Products** no special process for claim substantiation are required.
  - Producer can use literature data (if relevant for his product)
  - Or
  - Experimental data which are generated by suitable “state of the art” test methods e.g.:
    - Determination of the Minimum Inhibitory Concentrations (MIC) of the product to substance bacteriostatic or microbistatic activity claims
    - In-use sniffing tests for deodorant and freshness claims

- Under the BPD, for each **Biocide Product** efficacy has to be proven preferably by approved standard methods (European Norms, OECD norms…)
  - For PT1 products (hand disinfectants, skin antiseptics) according to EN 14885
    - Suspension Tests (e.g. EN 1276 and EN 1650) to show fast killing activity
    - In-use test to show efficacy under practical conditions (e.g. EN 1499 for hand washes and EN 1500 for hand rubs)
More than One Borderline for Cosmetic Products to Other Legislations

- Medical Devices
- Pharmaceuticals
- Food
- Biocides
- Toys

1. Kozmetik Kongresi, 18-20 Subat 2011, Antalya
Borderline discussions Cosmetic Regulation and BPD

- Standing working group of the EC with industry and competent authorities
  - Development of guidelines
  - Assessment of different borderline cases
  - Working on manual of decisions

→ Access to documents via

MANY THANKS
FOR YOUR ATTENTION