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New BPR: Treated articles, Food contact materials and other issues

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Overview

- Treated Articles – meaning under Current BPD
  - Treated Articles Vs Biocidal Products (BPD)
  - Treated Article in EU Vs Treated Article in US
  - Treated Articles imported into EU
- Treated Articles – meaning under New BPR
  - Treated Articles Vs Biocidal Products (BPR)
  - Labelling and other requirements
  - Legal uncertainties and practical issues
- Implications for Food Contact Materials
- Timelines and other issues

Treated Articles – Current BPD

Treated Articles under Current BPD

- Current BPD regulates Biocidal Products, i.e.

  "*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*" (Art. 2(1)(a) BPD)
- Treated Article not defined in BPD.
- References within BPD to biocidal products and "*materials treated with [biocidal products]*" (e.g. Paras 4, 14-15 Preamble, Article 5(1)(b), etc)
- Scope of meaning of Biocidal Products agreed between COM and MSCAs – Guidance Doc 2002/04-Rev3

Treated Articles under Current BPD

- *"If it is intended that the biocidal active substance is released from the treated article to control harmful organisms outside the treated article (external effect)* [the BPD requirements apply]*"*
- *When the article has been treated with the biocidal active substance with the intention to control organisms harmful to the treated article/materials itself (on the surface or inside), then the treated article shall not be considered as a biocidal product (internal effect)."*
- Actives have external effect = BPD does apply
- Actives have internal effect = BPD does not apply (Treated Articles)

Examples of Treated Articles under BPD

INTERNAL EFFECT

- Fungi-resistant paints
- Treated wood
- Tanned leather
- [Toilet seats]
- [Socks]

OUTSIDE SCOPE OF CURRENT BPD

Examples of Biocidal Products under BPD

EXTERNAL EFFECT (Delivery system)

- Mosquito nets containing insect repellents
- Insecticidal strips treated with insecticides
- Impregnated tissues with “anti-bacterial” properties (if not regarded as medicinal products, e.g. for certain applications in hospitals)
- Socks treated with a biocidal active substance intended to have a biocidal action on the foot.

INSIDE SCOPE OF CURRENT BPD

Treated Articles exemption in US

- Meaning in EU different to that in the US
  - Pesticides (both agricultural and non agricultural) are regulated primarily under the US Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
  - Title 40 of the Code of the Federal Regulations Parts 150-189 implement FIFRA requirements
  - Part 152.25(a) of Title 40 CFR: Registration not required if "*An article or substance treated with, or containing, a pesticide to protect the article or substance itself…, if the pesticide has been registered for such use*".
- US: Specific exemption for treated articles containing a registered pesticide. US pesticide must be registered in order to benefit from exemption.
- EU: No defined meaning of treated article or specific exemption for treated articles under BPD. Certain treated articles simply regarded as outside the scope of the BPD regardless of status of active.

Treated Articles under BPD: The problem

- BPD regulates actives and biocidal products (i.e. biocides having external effect)
- Does not regulate Treated Articles (i.e. actives having internal effect).
- In the EU, cannot use an unauthorised active / biocidal product in the manufacture ('treatment') of a Treated Article. Active must be on Annex I for relevant PT or in review programme (+ MS national law applies).
- Outside EU: "*Nothing in the current BPD prevents in principle articles/materials treated with biocides not authorised or even banned from being imported into the EU*" (Milieu Report submitted 7 Sept 2006)
- Undermines BPD objectives, discriminatory re EU suppliers / unequal protection to HH & E.

Objective of New BPR

- "*To protect human and animal health and the environment, and to avoid discrimination between treated articles originating in the Union and treated articles imported from third countries, all treated articles placed on the internal market should contain only approved active substances*" (Para (51), Preamble, 5032/2/11 Rev 2)
- "*Treated articles should not be placed on the market unless all active substances contained in the biocidal products with which they were treated or which they incorporate are approved in accordance with this Regulation*" (Para (2), Preamble, 5032/2/11 Rev 2)

Treated Articles – New BPR
(NB Citations – Council position 5032/2/11 REV 2)

Biocidal Product under New BPR

- "*"Biocidal Products" means any substance, mixture or article, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the primary 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*" (Art 3(1)(a) 5032/2/11 Rev 2).

Treated Article under New BPR

- " *"treated article" means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products*" (Art 3(1)(l) 5032/2/11 Rev 2).
- An "*Article*" has the same meaning under New BPR as REACH (Article 3(2) 5032/2/11 Rev 2).
- NB "*The Commission may at the request of a Member State, decide, by means of implementing acts, whether a specific product or group of products is a biocidal product or a treated article or neither* […]" (Article 3(3) 5032/2/11 Rev 2).

Is it a Treated Article under the New BPR? (1/3)

1. Is it a Biocidal Product?

   "*This Article shall apply exclusively to treated articles within the meaning of Article 3(1)(l) that are not biocidal products within the meaning of Article 3(1)(a)*" (Art 57(1) 5032/2/11 Rev 2).

2. Does it fulfil the Art 3(1)(l) definition of a Treated Article?

3. Does it fall within the scope of the New BPR?

NB MSs may allow exemptions to BPR in interests of defence.

Is it a Treated Article under the New BPR? (2/3)

1. Is it a Biocidal Product?

(i) It will be a biocidal product (not a Treated Article) if, amongst other things the primary intention of product is to destroy (etc) harmful organisms.

(ii) Meaning of "primary intention"?

- Intended function
- Claims made
- Internal / external effect of active not relevant?

(iii) Examples of Biocidal Products Vs Treated Articles?

Is it a Treated Article under the New BPR? (3/3)

2. Does it fulfil the Art 3(1)(l) definition of a Treated Article?

(i) Substance, mixture or article?
(ii) which has been treated with or intentionally incorporates
(iii) one or more biocidal products?

3. Does it fall within the scope of the New BPR?

(i) New BPR regulates "placing on the market" (Art 57(2) 5032/2/11):
- "*"Placing on the market" means the first making available on the market*" (Art 3(1)(j) 5032/2/11 Rev 2).
- Manufacture? Use?

(ii) Treated articles within the scope of Cosmetic Product Regulation, etc excluded from scope of New BPR (Art 2(2) 5032/2/11)

(iii) New BPR Art 57 provision does not apply to TAs where the "*sole treatment undertaken was the fumigation or disinfection [of premises or containers used for storage or transport] and where no residues are expected to remain from such treatment*" (Art 57(1) 5032/2/11).

Scope of Treated Article provisions

- Concerns raised re wide scope of TA provisions and number of products affected.
- Unclear whether apply to component part of articles and/or to articles as a whole
- Requests for Guidance on 'primary intention' and borderline products
- NB "*The Commission may at the request of a Member State, decide, by means of implementing acts, whether a specific product or group of products is a biocidal product or a treated article or neither* […]" (Article 3(3) 5032/2/11).
- Most likely to impact: Importers of TAs.
- Products most likely to affected: Articles treated with PT6 – In can preservatives, PT7 – Film preservatives, PT8 – Wood preservatives, PT9 – Fibre, leather, rubber and polymerised materials preservatives (Milieu Report 7/9/06).

New BPR requirements re Treated Articles

New (draft) BPR currently requires:

- All actives substances contained in the biocidal products that a Treated Article was treated with or incorporates are either (i) included in the Article 9(2) list; or (ii) included in Annex I BPR and any conditions or restrictions specified there in are met (Art 57(2) 5032/2/11 Rev 2).
- Notification to ECHA? COM may adopt implementing acts to ensure industry complies with 57(2) including "*appropriate notification procedures, possibly including the* [ECHA]" (Art 57(6) 5032/2/11 Rev 2) also Art 78)

  Data? Fee? Technical equivalence? Representative?
- Labelling

New BPR labeling requirements for TAs (1/2)

- "*Where the release of the active substances contained in the biocidal products with which a treated article was treated or which it incorporates, is intended or expected under normal or reasonably foreseeable conditions of use*:" – More stringent (heavy) labelling obligations apply (Art 57(3) 5032/2/11 Rev 2)
- If no intended release – less stringent (lighter) labelling obligations apply (Art 57(4) 5032/2/11 Rev 2)
- Intended or expected release under BPR = External effect under Current BPD?
- No intended or expected release = Internal effect under Current BPD?

New BPR labeling requirements for TAs (2/2)

TA with intentional release: Info on label (Art 57(3)):

(i) A statement that the treated article incorporate biocidal products;

(ii) Where substantiated, the biocidal property attributed to the treated article;

(iii) Without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;

(iv) Any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.

TA without intentional release: Info on label (Art 57(4)):

(i); website with (iii); no biocidal claim.

Other issues

- "*The Commission may also review the approval of an active substances for one or more product types at the request of a Member State if there are [serious] indications that the use of the active substance in biocidal products or treated articles raises [serious] concerns about the safety of such biocidal products or treated articles*" (Art 15(1)).

Timelines: BPD and 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

- 12 June 2009 - Commission proposal for New BPR published (COM (2009) 267)
- September 2010 – EP first reading
- 21 June 2011 – Council position on first reading (5032/2/11 Rev 2)
- [4 October 2011] – EP ENVI Comm'ee report on second reading
- If New BPR is agreed at second reading [plen session [Jan 2012]]:
- [Mid 2012] – New BPR expected to be adopted
- [1 September 2013] – Main provisions expected to apply
- Provisions on treated articles delayed application (Art 93-94 5032/2/11 Rev 2)

New BPR and food contact materials (1/3)

- Food contact materials: "*Any material or article as referred to in Article 1(2) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food*" (Art 3(1)(v) 5032/2/11 Rev 2)
- Initial proposal (COM (2009) 267) – extended scope to include food contact materials
- EP first reading: Rejected COM proposal:

  "*Food contact materials are already regulated by the Food Contact Materials Framework Regulation (EC) No 1935/2004. Should any changes be made to the rules governing food contact materials, they should be addressed through the revision of the food contact legislation, not by extending the scope of the BPR*".

New BPR and food contact materials (2/3)

- Council position on first reading:
  - Food contact materials included within the scope of the New BPR.
  - However, revised definition of Biocidal Product (primary intention).
  - No specific provisions on requirements applicable to food contact materials under BPR except transitional provisions.
- Draft EP recommend. second reading (8 Sept 2011):

  "*The definition of "food contact materials" is not necessary as food contact materials will be regarded as treated articles*" (Draft Amend. 8)

New BPR and food contact materials (3/3)

- Food contact materials = Treated articles?
  - Is it a biocidal product?
  - Primary intention of the food contact material?
    - – packaging?
    - – to destroy or exercise a controlling effect on harmful organisms by means other than mere physical or mechanical?
    - - Can a product have more than one primary intention?
  - Commission decision under Art 3(3) re food contact materials as a “group of products” needed?

Overall effect? (1/2)

Legal effects

- TAs outside the scope of Current BPD (containing actives with internal effect) likely to be TAs under New BPR.

  (+ ‘light’ labelling requirements likely to apply)
- TAs within scope of the Current BPD (containing actives with external effect) likely to be TAs under New BPR.

  (+ ‘heavy’ labelling requirements likely to apply)

  NB Biocidal Product = Primary intention?

  Examples?
- Number of other products now likely to also be regarded as TAs under New BPR.

Overall effect? (2/2)

Practical effects for industry?

- Level playing field for non EU and EU suppliers of TAs?

  Level playing field? Possibly less imports of TAs?
- TA suppliers will be required to comply with labelling requirements [+ notification requirements?]
- Increase in ECHA workload?
- No longer harmonised approach with US (although arguably TA requirements never 'harmonised'. Under New BPR – still no requirement/exemption to 'register' biocide in TA [notification?])
- TA suppliers dependent on active authorisation and Annex I entries obtained by third party notifiers

Thank you

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