BPR amendments and implementing legislation

Biocides Stakeholders' Day

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Camilla Buchanan
Legal Advisor, Legal Affairs Unit
ECHA

Overview

- Legislative framework
- BPR amendments: certain key provisions
- Annex I inclusion → *active substances*
- Changes Regulation
- Same Products Regulation →
- Renewal of Mutual Recognition →

Product authorisations

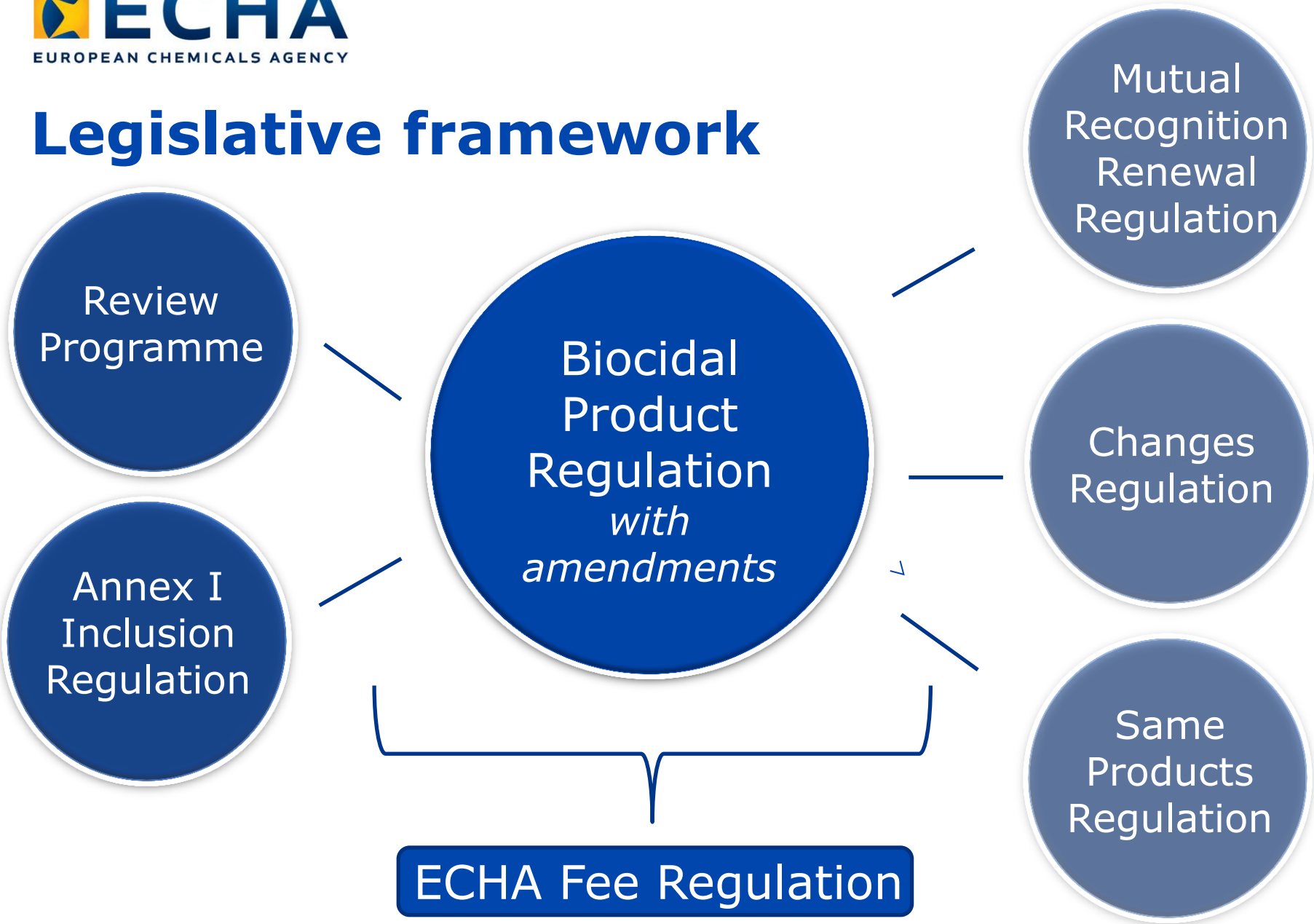
Introduction to the legal framework

- **Regulation (EU) No 528/2012** concerning the making available on the market and use of biocidal products ("BPR") => *replaced the BPD and has applied since 1/9/13, already amended three times*

- **Regulation (EU) No 334/2014** [amending the BPR] with regard to certain conditions for access to the market => *entered into force on 25 April 2014, in particular affects the transitional provisions of the BPR*

- **BPR is the tip of the iceberg**: five other applicable legal instruments (implementing and delegated acts), as well as the Review Programme => *applies to active substances (Annex I) but mainly product authorisation procedures*

Legislative framework



BPR amendments

Three sets of amendments so far

Consolidated text available at
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1409322218709&uri=CELEX:02012R0528-20140425
(non-authentic text)

BPR amendments

1) Commission Delegated Regulation (EU) No 736/2013 amending [the BPR] as regards the **duration of the work programme** for examination of existing biocidal active substances (OJ 2013 L 204/25, EiF 20.8.2013) => ***2024***

BPR amendments cont.

2) Commission Delegated Regulation (EU) No 837/2013 **amending Annex III** to [the BPR] as regards the information requirements for authorisation of biocidal products (OJ 2013 L 234/1, EiF 23.9.2013) => *proof of technical equivalence*

BPR amendments cont.

3) Regulation (EU) No 334/2014 of the European Parliament and of the Council with regard to **certain conditions for access to the market** (OJ 2014 L 103/22, EiF: 25 April 2014) => *in particular affects the transitional provisions*

Regulation (EU) No 334/2014 with regard to certain conditions for access to the market

Regulation (EU) No 334/2014
General

- **Product authorisation**: possible where active substance is on Annex I to the BPR (in addition to "approved") - Article 19(1)
- **Product family**: definition amended (Article 3(1)); conditions for authorisation have been changed - Article 19(6)(7)
- **Publication by ECHA of information on the active substance**: brought forward from date of approval to date of the approval decision – Article 67(1)

Regulation (EU) No 334/2014
Transitional provisions

Application of national laws during the transition period

- can apply to making available and using a biocidal product - extended from two to three years after the date of approval of the (last) active substance – Article 89(2)
- also time for granting a national authorisation extended from two to three years after the date of approval of the active substance - Article 89(3)

Regulation (EU) No 334/2014
Transitional provisions

Products not covered by the BPD but falling under the BPR (e.g. food contact material)

- new text requires an application for active substance/PT approval (by 1 September 2016) rather than an application for biocidal product authorisation **-** *Article 93*

Article 95 obligations apply as from the date the application for approval of the new active substance/PT is accepted (may be later than 1 September 2015).

Regulation (EU) No 334/2014
Transitional provisions

Treated articles (Articles 58 and 94)

- The active substance/PT must be approved
- Derogation: allows treated articles to be placed on market where the active substance/PT approval has been applied for by 1 September 2016

➢ **New text**

- the transitional derogation applies to all treated articles (not only those on the market at 1 September 2013)
- clarifies that the labelling obligations apply

Regulation (EU) No 334/2014
Transitional provisions

- **Article 95:** all companies which submit a complete dossier under BPD or BPR will be listed, product-type to be indicated, date of inclusion, new categories of substance and product supplier, extension of mandatory data sharing

The amendments to Article 94 and Article 95 apply retroactively from 1 September 2013.

Implementing and delegated acts

- Annex I Inclusion Regulation
- Changes Regulation
- Same Products Regulation
- Renewal of Mutual Recognition Authorisations Regulation

Annex I inclusion

Commission Implementing Regulation (EU) No 88/2014 on the procedures for the inclusion of active substances into Annex I of [the BPR] (OJ 2014 L 32/3, EiF 21.2.2014)

Annex I inclusion

Regulation (EU) No 88/2014 – certain key points

- Annex I to the BPR is a list of active substances "which do not give rise to concern" *(Art. 28 BPR)*
- Divided into seven categories, restrictions can apply
- Inclusion of the active substance is the basis for simplified product authorisation *(Art. 25 BPR)*
- Annex I application procedure is similar to active substance approval but less information is required (except category 6)

Annex I inclusion application

Categories 1, 2, 3, 4 or 5 of Annex I – the application must contain:

1. evidence that the substance complies with the description of the relevant category
2. the identity of the substance and the intended uses of the products
3. conclusive evidence that there is a robust consensus of expert opinion that the substance does not give rise to concern

Annex I inclusion application: cat 6

Category 6 of Annex I – application:

- A dossier containing a data package equivalent to that submitted for active substance approval (see Article 6 of the BPR).
- Allows a full risk assessment for the intended use.

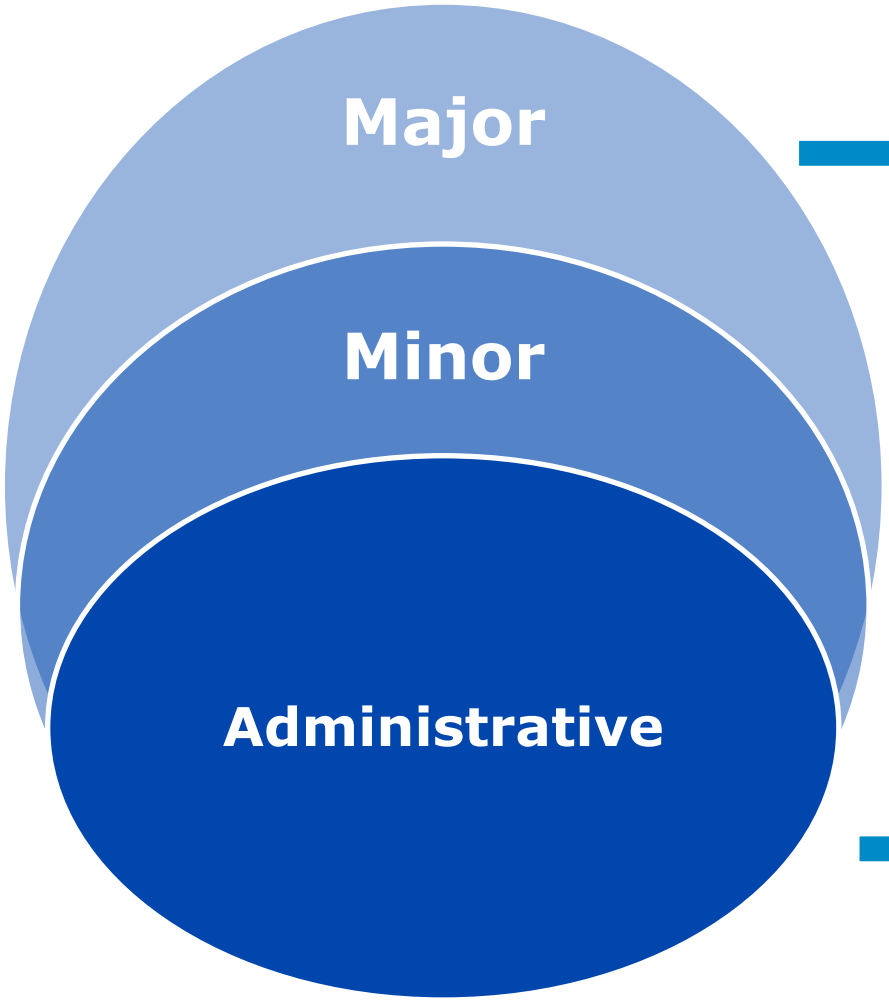
Changes Regulation

Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 (OJ 2013 L 109/4, applies since 1.9.13)

Changes: Regulation (EU) No 354/2013 – certain key points

- Concerns changes to existing biocidal product authorisations (**national or Union**) requested by the product authorisation holder
- Apply simultaneously to all Member States where a change to an authorisation is sought
- For Union authorisation change, apply to ECHA
- The change can be **administrative, minor or major**. If unsure, request opinion from ECHA.
- Procedure and information requirements are set out in the regulation.

Changes Regulation: categories



Neither administrative nor minor

Requires limited assessment of properties or efficacy

No change to properties or efficacy

Administrative change
Art. 6 (national), Art. 11 (Union)

Example a: prior notification (Annex, title 1, sect. 1)

- Company A has an authorisation for product X.
- It wants to change the name of the product

➢ Notify: the change can be implemented when the CA agrees

Administrative change
Art. 6 (national), Art. 11 (Union)

***Example b**: notified afterwards*
(Annex, title 1, sect. 2)

- Company B has a product authorisation for product Y.
- It wants to change the name of the formulator (composition and process remain the same)

➢ Implement: the change can be notified afterwards

Minor change
Art. 7 (national), Art. 12 (Union)

Example of minor change to national authorisation (Annex, title 2)

- Company A has an authorisation for product X
- It wants to change the instructions for use (no effect on exposure)

➢ Apply for a minor change. Implement when the Member State(s) agrees.

Major change
Art.8 (national), Art. 13 (Union)

A major change is one which affects the conditions for the authorisation

Example of major change to national authorisation

- Company A has an authorisation for product X
- It wants to increase the concentration of the active substance

➢ Apply for a major change. Implement when the Member State(s) has agreed.

Same Products Regulation

Commission Implementing Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 (OJ 2013 L 125/4, 7.5.2013, applies since 1.9.13)

Same Products: Regulation (EU) No 414/2013 – certain key points

- Apply for authorisation of a product which is **identical** to a product already authorised/pending authorisation
- Saves time (and expense) on duplicate assessments
- Relevant for national authorisation (in the same Member State) or Union authorisation
- Differences limited to those which could be the subject of an administrative change under Regulation (EU) No 354/2013

Example A

Company A has an authorisation for product X.

Company B want an authorisation for an identical product but with a different trade name

- R4BP 3 process “NA BBS”
- Result is a **separate** (different) authorisation

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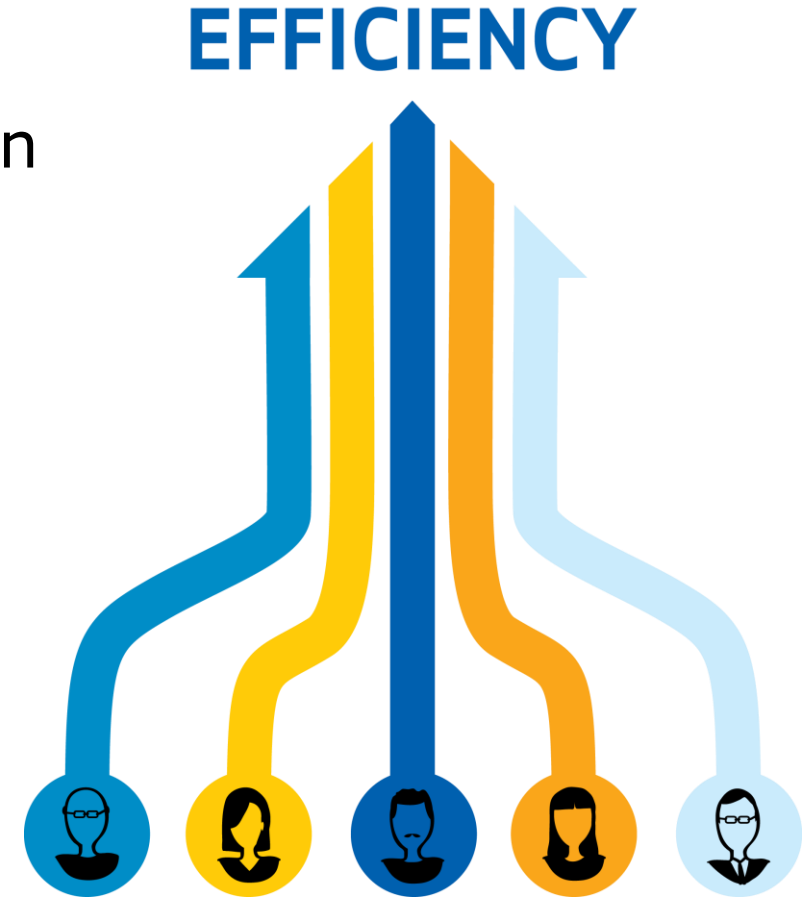
Example B

Company C has applied for an authorisation for product Y.

Company D want an authorisation for an identical product but with a different trade name.



- R4BP3 process "NA BBP"
- Result is a **separate** (different) authorisation

Renewal of mutual recognition authorisations

Commission Delegated Regulation (EU) No 492/2014 as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition (OJ 2014 L 139/1, EiF 3.6.2014))

Renewal of authorisations subject to mutual recognition: Regulation (EU) No 492/2014 – certain key points

- Applies to national authorisations subject to or granted through mutual recognition
- A "reference" Member State carries out the assessment to save time on duplicate assessments
- Apply at least 550 days before the earliest expiry date
- Authorisations must have been granted under the same terms and conditions (limited exceptions).

Renewal application (mutual recognition)

- "Reference Member State" and concerned Member States": apply at same time
- Data requirements similar to Article 31 of BPR
- Draft SPC (different language versions)
- Details of any changes made
- Full evaluation may not be needed
- Concerned Member States agree on SPC

➢ Authorisations renewed

The application requires coordination between the relevant authorisation holders

Further relevant legal acts

- Commission Implementing Regulation (EU) No 564/2013 on the **fees** and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 (OJ 2013 L 167/17)
- Commission Regulation (EC) No 1451/2007 as regards work programme for examining all existing active substances, as amended by Commission Regulation (EU) No 613/2013 of 25 June 2013
- *DRAFT* Commission Delegated Regulation on the work programme for examining all existing active substances: *=> repeals and replaces Commission Regulation (EC) No 1451/2007 to fit Review Programme to BPR procedures. Expected to be published in OJ 10 October 2014 and EIF 20 days later*

Further information

- The relevant **legal texts** are available in all official EU languages on ECHA's website:
  http://echa.europa.eu/regulations/biocidal-products-regulation/legislation
- ECHA new "**practical guides**" for each application type are available on ECHA's website
- Also, the **R4BP3 submission manuals** are available to help make the applications:
  http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals

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camilla.buchanan@echa.europa.eu

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