New review programme Regulation

Biocides Stakeholders' Day

24 September 2014

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Biocidal Products Committee
European Chemicals Agency

Content

1. **Why a new Review Regulation?**
2. Content of the new Review Regulation
3. ECHA preparations

Content

- *Commission delegated Regulation (EU) No ../.. on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council*

  - Entry into force: end of October 2014
  - Regulation (EC) No 1451/2007 is repealed (including Regulation (EU) No 613/2013)
  - (CA-Sept14-Doc.3.1)

Why a new Review Regulation?

- Procedures of ’old’ Review Regulation are not entirely in line with the procedures of the BPR

- Legal deadline of finalisation of Review Programme by 31 December 2024

- Establish processes and procedures for inclusion of additional existing active substances to the Review Programme as otherwise these substances would be illegally on the market

Content

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Topics new Review Regulation

- Process and procedures Review Programme: Article 3 – 9
- Joining or replacing participant: Article 10
- Withdrawal of a participant: Article 11 – 12
- Redefinition of active substance: Article 13
- Taking over role of participant: Article 14
- Eligibility for inclusion Review Programme: Article 15
- Declaration of interest to notify: Article 16
- Notification: Article 17
- Follow-up notification process: Article 18 – 20
- Transitional measures including phase-out periods: Article 21
- Essential use: Article 22

Topics new Review Regulation

- Annex I: information requirements notification

- Annex II:
  - Part 1: remaining active substance product-type combinations Review Programme
  - Part 2: active substance product-type combinations not supported

- Annex III: time limits Review Programme for submission evaluation and BPC opinion

➢ Not included in new Review Regulation: active substances generated in situ

New rules Review Programme

- The same rules and procedures as for applications under the BPR for active substance approval:
  - Exclusion and substitution criteria have to be assessed including public consultation for potential candidates for substitution
  - Submission of a dossier on Harmonised Classifciation and Labelling (CLH), consultation on PBT or Endocrine Disrupter Expert Group by Member State competent authority (MSCA) required before submitting evaluation to ECHA
  - Opinion of the Biocidal Products Committee (BPC) in 270 days

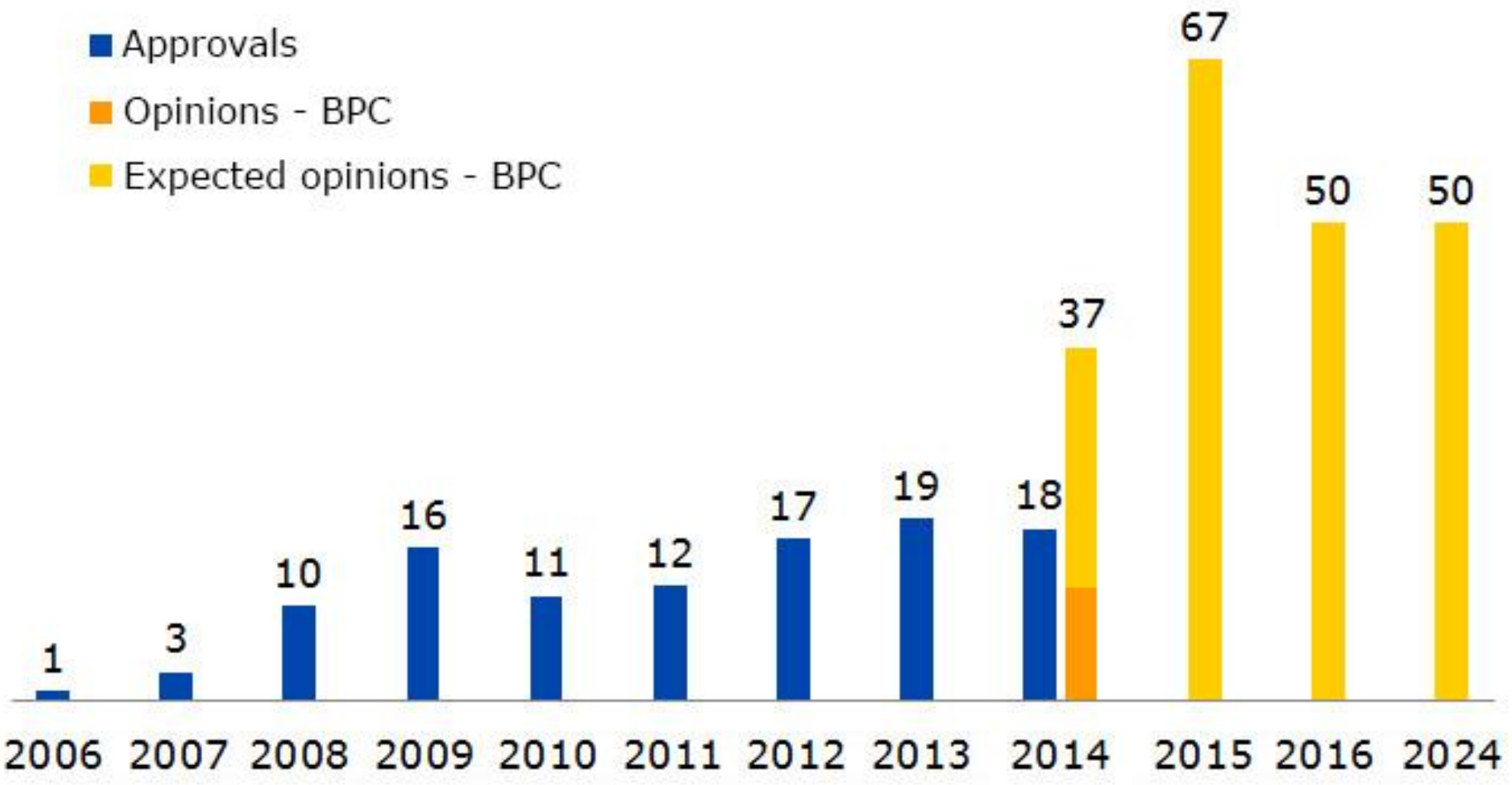
- Time limits for MSCA to submit their evaluation and for BPC to start preparation of opinion in Annex III in order to finish the Review Programme by 31 December 2024

Annex III: time limits

Priority list	Product Type	Evaluation	Start BPC opinion
1	8, 14, 16, 18, 19 and 21	31/12/2015	31/03/2016
2	3, 4 and 5	31/12/2016	31/03/2017
3	1 and 2	31/12/2018	31/03/2019
4	6 and 13	31/12/2019	31/03/2020
5	7, 9 and 10	31/12/2020	31/03/2021
6	11, 12, 15, 17, 20 and 22	31/12/2022	30/09/2023

The Review Programme

- Annex II Part 1 lists the remaining active substance PT combinations in the Review Programme: total 516
- Achieving the 31 December 2024 deadline means ~ 50 opinions per year adopted in the BPC
- 2014: 12 opinions adopted in BPC and 25 more scheduled for the next two BPC meetings


Approvals
Opinions - BPC
Expected opinions - BPC
1
3
10
16
11
12
17
19
18
37
67
50
50
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2024

Review Programme: active substances not supported

- Annex II Part 2 lists:
  - several active substance product-type combinations
  - nanomaterial forms of several active product-type combinations listed in Annex II Part 1 and 2

- A non-approval decision will be taken by the Commission for all active substance product-type combinations in Annex II Part 2 if no notification is made (or if the notification is rejected) to ECHA by 12 months after entry into force

So if you have an interest in any active substance product-type combination in Part 2 of Annex II you have to act now!

By submitting a notification to ECHA

Notification

- Submission to ECHA, fee is reimbursed after submission of the actual dossier
- Information requirements in Annex I:
  - Prepare dossier in IUCLID and submit through R4BP
  - Evidence it is an existing active substance: present on the EU market before 14 May 2000 for biocidal purposes
  - Include information on the applicant, substance indentity and intended use
- Compliance check by ECHA with possibility for appeal
- Similar to notification process under BPD for the Review Programme

Notification: cases

1. For active substance product-type combinations of Part 2 of Annex II

2. For taking over the role of the participant or redefinition of the active substance following publication by ECHA

3. For active substance product-type combinations eligible for inclusion in the Review Progamme

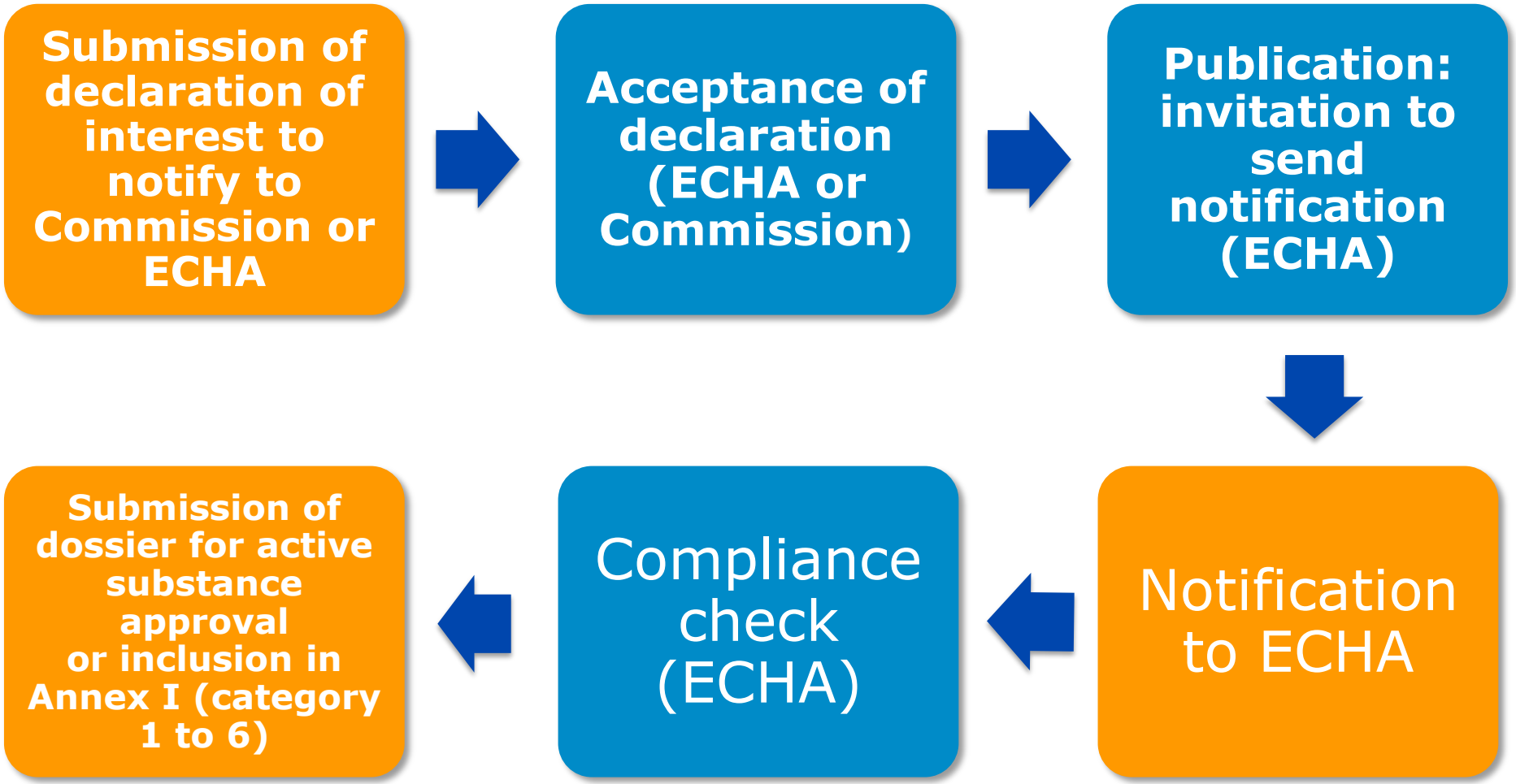
Inclusion in Review Programme: cases

1. Placing a biocidal product on the market which you thought was outside the scope of the BPD or BPR but this is no longer the case

2. You benefit from a derogation for food and feed used as attractant or repellent under the 'old' Review Regulation

3. Due to modification of scope of a product-type under the BPR, your active substance is not included in the Review Programme for this 'new' product-type: e.g. algaecides moved from product-type 10 to 2

Inclusion in Review Programme



So if you have a food and feed derogation under the ’old’ Review Regulation or are affected by the change of scope of a product-type under the BPR you have to act now!

By submitting a declaration of interest to notify to either ECHA or the Commission

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3. **ECHA preparations**

ECHA preparations

- Migration of Review Programme to R4BP
- Instructions will be available on ECHA's website in October:
  - Notifications: submission through R4BP
  - Declarations of intentions to notify: submission through webform
- All other processes described in the Review Regulation such as withdrawal and taking over the role of the participant will be through webforms

Further information

- Biocidal Products Committee: http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee
  - For BPC opinions and work programme -> when will an active substance product-type combination be discussed?
- ECHA website: http://echa.europa.eu/
  - News alerts and detailed instructions for each process
- Food and feed derogation:
  - Commission note for guidance: (CA-Dec13-Doc.11.3 – Final) http://www.hse.gov.uk/biocides/derogation.htm
  - Guidance web page of HSE of the UK

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