Update from the Commission: latest developments in the biocides field

Comité d'avis sur les produits biocides
Adviescomité inzake biociden

Forum du 30/11/2017

Brussels

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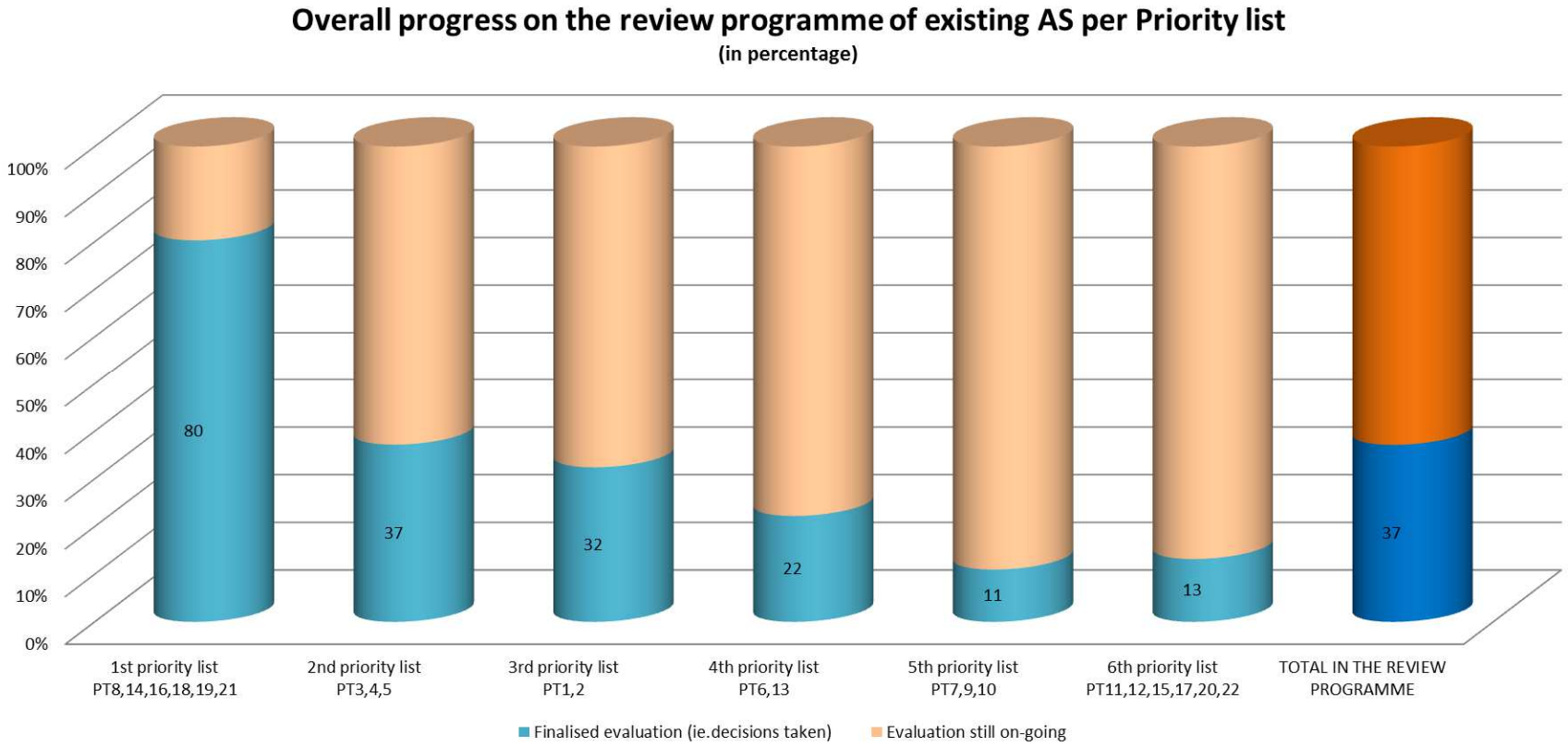
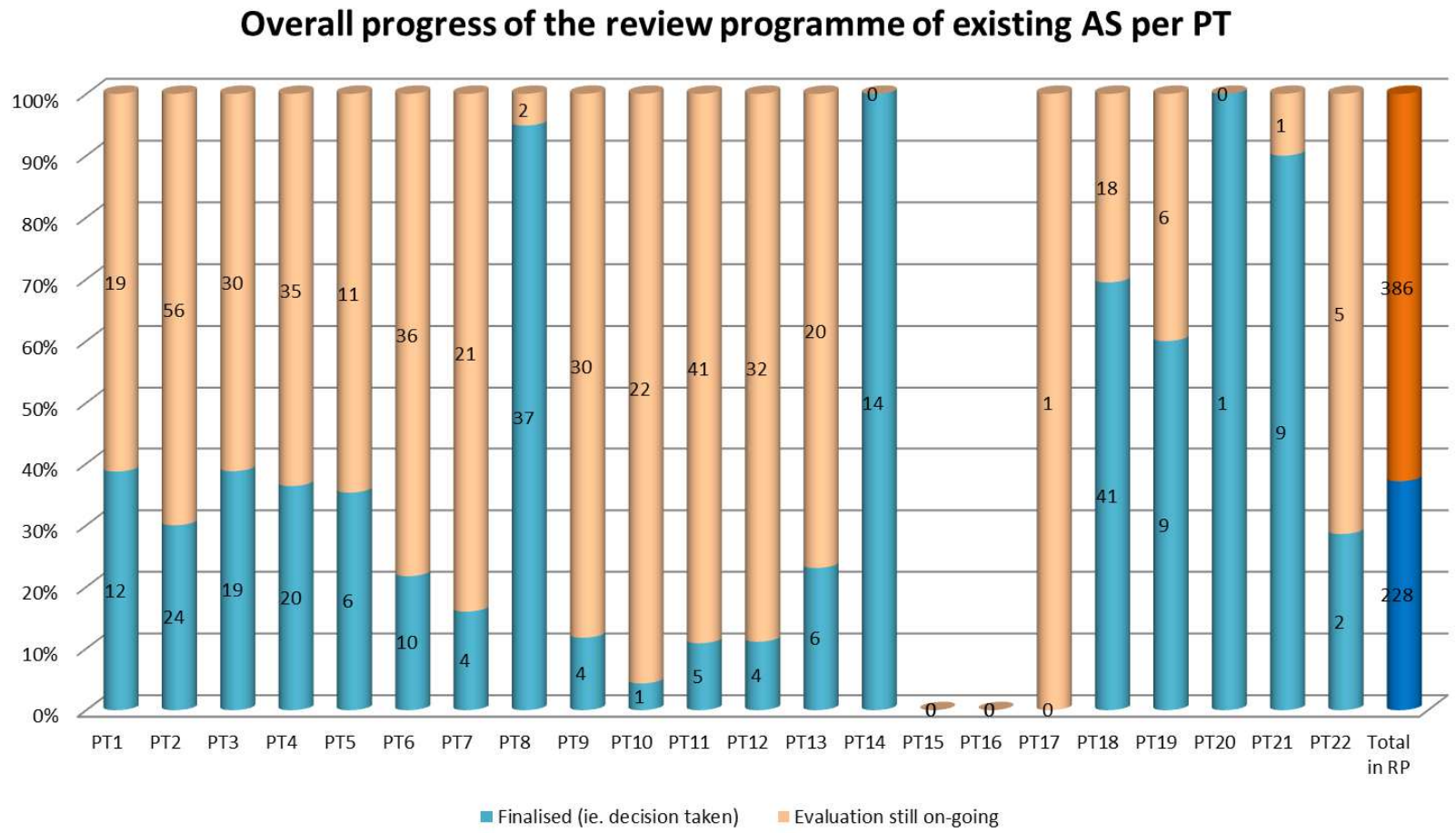
I.1- **Review programme**

November 2017: 37% of decisions adopted



I.1- **Review programme**

November 2017: 228 AS/PT combinations



I.1- **Review programme**

- Concerns: achievement of the 2024 objective?

→ Key issue to achieve the objectives of the BPR:

1.- protecting Human health and Environment:

- → Non-approved AS out of the market
- → New/stricter conditions for approved AS
- → Product authorisation according to the BPR: safety & efficacy demonstrated; comparative assessment (substitution), etc…

2.- sustainable use of biocides

→ **On-going discussions in the CA meeting**

I.2 - **Deadline 1/9/2016**

- Under Article 93 of the BPR: Deadline for applications for AS which were not under the scope of the BPD but came in the scope of the BPR (e.g. some in situ without precursors, free radicals, some substances in food contact materials)
- Under Article 94 of the BPR: Deadline for new applications for AS in (imported) treated articles. Treated articles contains AS under assessment on 1st September 2016 can continue to be placed on the EU market.

→ **Some applications have been submitted to ECHA and evaluating Member States**

→ **Relevant lists published on ECHA website:**

Art 93: https://echa.europa.eu/regulations/biocidal-products-regulation/in-situ-generated-active-substances/article-93-transitional-measure

Art 94: https://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles

I.3 - **Renewal of approvals** *(CA-July17-Doc.5.3 – Final)*

1. Coordination of the renewal process
2. Original participants, article 95 suppliers and other prospective applicants for the same AS/PT combinations
3. Finding the evaluating competent authority for the renewal
4. Setting the deadline for submission of the application for renewal when the AS is approved, or assessed for several PTs
5. Timing for the submission of applications
6. Guidance on the content of applications for renewal
7. Assessment phase of the applications for renewal.
8. **Substances meeting the exclusion criteria**

I.4 – **Relevance of public consultations**

- Critical step to achieve the substitution objective
- Key source of information on alternatives for:
  - the BPC opinion on the approval of the AS
  - the comparative assessment of biocidal products
- Former discussion in 2016 (CA-May16-Doc.5.3-Final)

→ Latest consultations still show limited contributions

I.4 – **Relevance of public consultations**

→ Clear need for additional efforts:

- *ECHA*: further clarify which information is expected from contributors, particularly on non-chemical alternatives (e.g. required level of robust evidence showing sufficient efficacy)

- *MSs*: further spread the consultation and ensure that:

- it reaches the key involved sectors (e.g. manufacturers or users of alternatives)

- the available information is made available to ECHA

Link to ECHA's public consultations:

During BPC review, on substitution: https://echa.europa.eu/public-consultation-on-potential-candidates-for-substitution

In addition, for AS under exclusion, gathering information on derogation to exclusion: Fohttps://echa.europa.eu/derogation-to-the-exclusion-criteria-current-consultations

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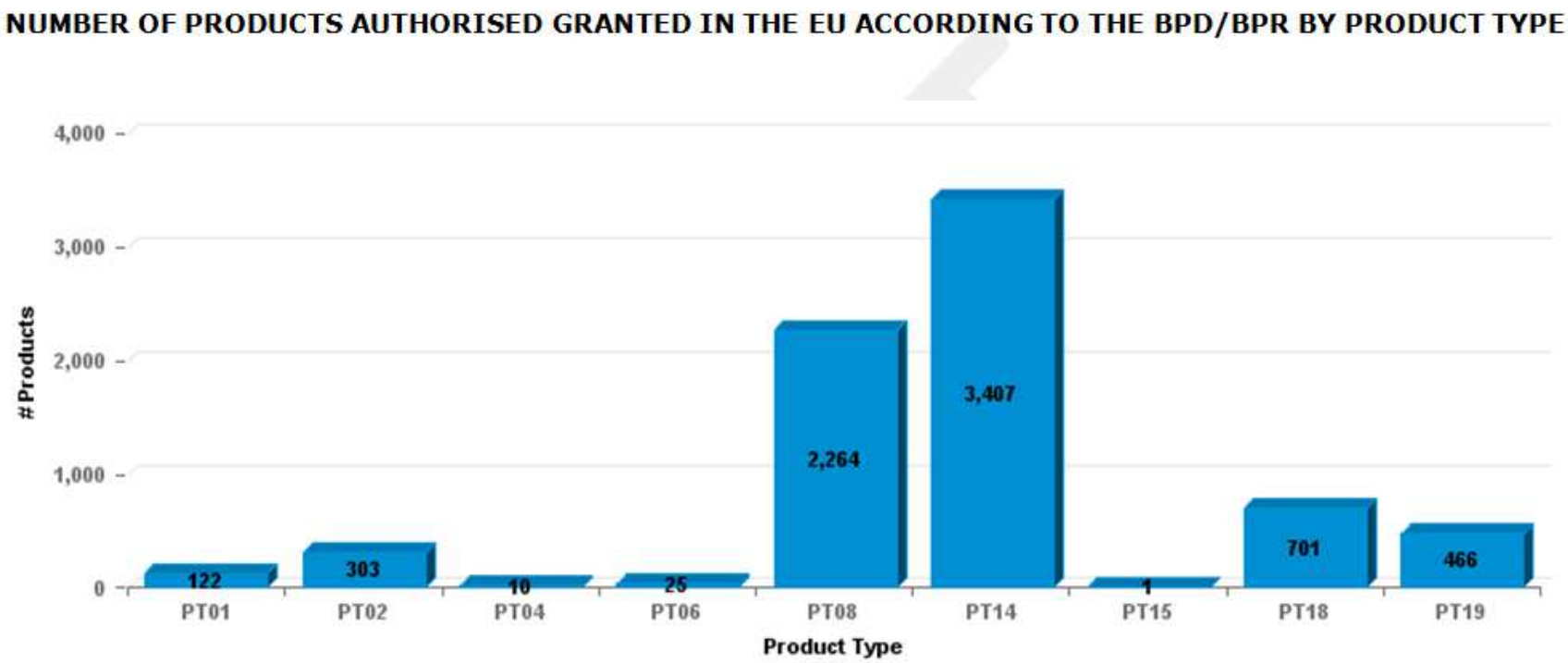
II- Product authorisation

7,273 products authorised under the BPD/BPR

(CA-Nov17-Doc.4.5 - executive report on product authorisation)



II.1 - **Action list to minimise delays**

Discussion & diagnosis (64th CA & CG-18)

- Need for immediate actions on account of the prospect on future workload:

→ Number of AS approvals will increase (up to 50/year)

→ Number of applications for PA submitted to MSs could be 3 fold than now!!

Conclusion: multifactorial problem, with actions to be taken at the EU and MS level

II.1 - **Action list to minimise delays**

1. **ECHA**: continue improving R4BP and SPC editor
2. **ECHA/COM/MSs**: continue efforts to develop guidance
3. **BPC**: "Horizon scanning" approach: flag the needs to be addressed by WGs, if possible, before the date of approval; work according to priority lists.
4. ✓ **refMSs**: early identification of any emerging issue and to refer it to the relevant EU fora
5. **ECHA/MSs**: ensure assistance in WGs to product authorisation issues
6. ✓ **ECHA/COM**: monitor delays, particularly in refMSs
7. ✓ **CG**: to agree and implement appropriate steps in the MR phase
8. ✓ **cMSs**: if no referral is sent to CG just after the MR phase, the SPC shall be deemed as agreed and the NA phase shall start
9. ✓ **CG**: referrals are not accepted if not informed by day 90 (amend RoP/WP)

II.1 - **Action list to minimise delays**

4. **refMSs**: early identification of any emerging issue and to refer it to the relevant EU fora

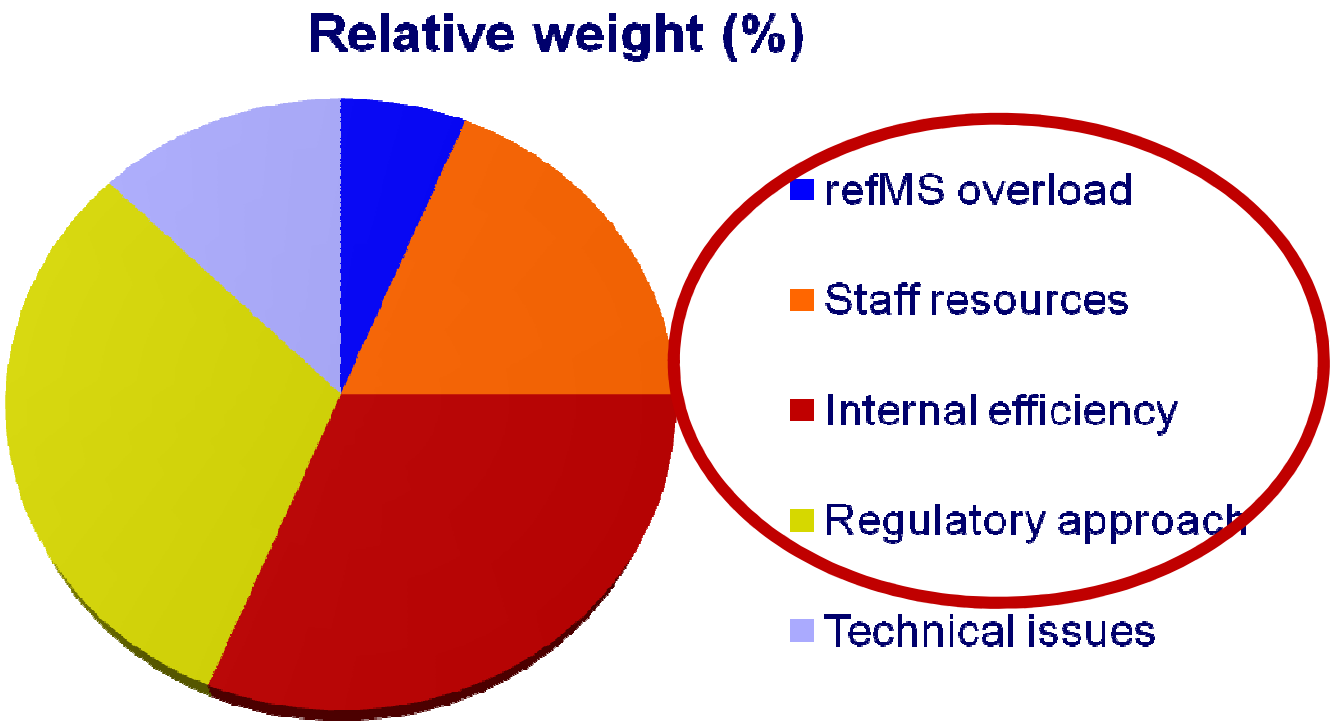
- e-Consultations within the CG and/or WGs
- CA-July17-Doc.4.2 - Final - Handling the stop of the clock

7. **CG**: to agree and implement appropriate steps in the MR phase

- 60+30 → 40+14+20+10+6
- Already agreed for MR-P and MR-S (*adapted*)
- Applicable to any MR phase starting as from 01/01/2018
- Also applicable to changes and renewals in MR products

Delays in PA: Multifactorial problem:

→ Relative weight of each factor might be MS-specific



Dummy example

II.2 - **CG role & achievements**

- Key role for a harmonised & efficient product authorisation
- Preventive approach: agreeing on harmonised ways forward or guidance in order to avoid MR disagreements
- High agreement reaching rate: 100% in 2016; 91% in 2017

  → earlier discussion within the MR phase

  → Key role of Chair, CG SECR & CG members (best endeavours to reach an agreement)
- Record of agreements publicly available
- *Ad hoc* WPs: comparative assessment, SPC AVKs, BPF, etc...

II.3 - **Experience with the BPF concept**

→ Main issue: right balance both for applicants and CAs between "flexibility" and "complexity"

- Workshop organised by Industry on 10 March 2014:

The group has identified a number of further recommendations:

- Meta-SPC approach provides opportunities but some flexibility will be needed
- It is important to hold a pre-meeting with Evaluating MS to clarify different aspects and limitations of the proposed families
- Applicants should refrain from creating too complex BPFs.

➲ ***Session 3: Understanding similar levels of efficacy***

This group assumed in its discussions that it is possible to group different PTs within one family. The group concluded that different claims are possible within one family. Moreover

II.3 - **Experience with the BPF concept**

Right balance between "flexibility" and "complexity"

Current situation:

- → Certain degree of flexibility and case by case approach
- → Industry is proposing complex BPFs grouping a high number of “similar” products
- → This may reduce the number of PA procedures for both applicants & CAs
- → But there are clear signals from eCAs that, in the light of experience, applications are too broad and being complex to assess (also connected to delays)

II.3 - **Experience with the BPF concept**

WP in the CG – discussion topics:

a) Further clarification of the concept of similarity applicable to composition, uses and levels of risk and efficacy

b) Definition of limits for setting meta-SPC ranges.

c) Possible limitation on the inclusion of different formulation types in BPF.

d) Grouping of co-formulants.

e) Definition of a BPF/meta-SPC range for physico-chemical parameters.

f) Clarification whether the assessment of BPFs should be based on the BPF or meta-SPC level.

g) Establishment of clear rules for identification of the worst case scenario (maximum risk/minimum efficacy).

h) Application of paragraph 77 of Annex VI to the BPR in relation to BPFs.

i) Revision of the Q&A section and assess whether any points can be integrated in the general guidance.

II.3 - **Experience with the BPF concept**

WP in the CG – discussion topics:

a) Further clarification of the concept of similarity applicable to composition, uses and levels of risk and efficacy

UK CA acting as topic leader

First meeting on 22/11/2017

Follow-up meeting in January 2018

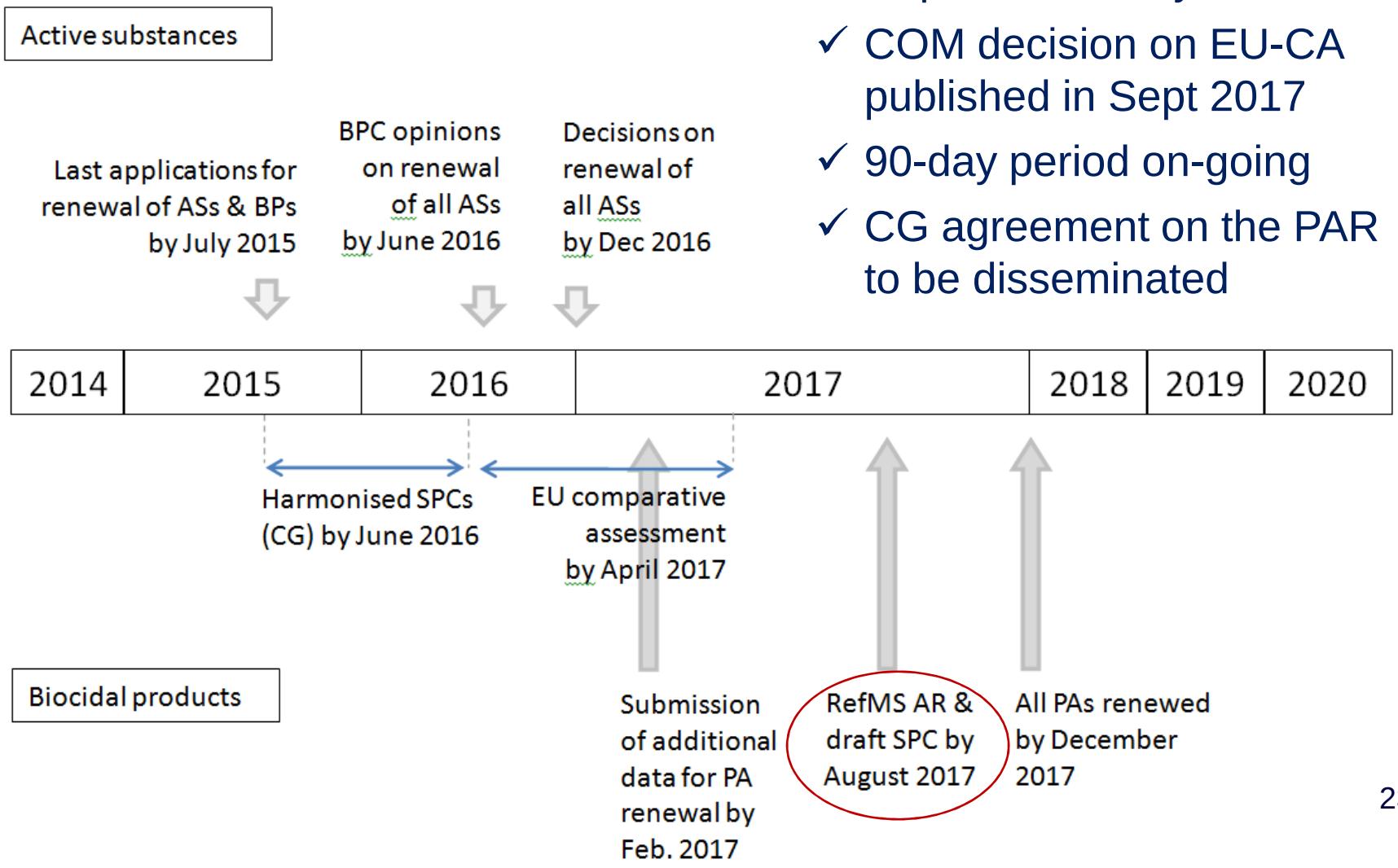
II.4 - **Renewal anticoagulant rodenticides**

State of play

Annex 2: Optimised renewal process of anticoagulant rodenticides.

(CA-Nov14-Doc.5.2.a – Final)

- ✓ IR published July 2017
- ✓ COM decision on EU-CA published in Sept 2017
- ✓ 90-day period on-going
- ✓ CG agreement on the PAR to be disseminated



II.5 - **Union Authorisation**

- Key instrument to achieve the single market
- 70 on-going applications (60 BPFs) + 45 SBP applications
- 9 e-CAs (AT, BE, DE, DK, FI, FR, LV, NL & UK)
- Pre-submission phase: does not mean agreement on the BPF design/structure

→ Need to ensure coordination/consistency between e-CAs (ECHA role) and with NA procedures (CG role)

- Meeting deadlines: a priority for COM (monitoring of e-CAs)
- COM working on internal procedures

II.5 - **Union Authorisation**

Further information in the draft Commission report to EP & Council:

- factual overview of the applications for UA until 1/10/2017 and
- some preliminary conclusions based on the relatively limited experience gained so far

Draft presented at the November CA meeting:

https://circabc.europa.eu/w/browse/a507185f-7707-4499-a511-3533b539907b

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III- Endocrine disruptors

III.1 - State of play

III.2 - Technical guidance

III.3 - Guidance on implementation:

- Active substances

- Biocidal products

III.1- **State of play**

- Delegated act (BP)

→ Last discussion in July CA meeting

→ Adopted by COM on 4 September 2017

→ Council & EP did not oppose during the 2-month scrutiny period (nor did they request an extension of the scrutiny period)

→ Published on 17 November 2017

Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1.)

→ Applicable as from 7 June 2018

III.2- **Technical guidance:**

- Guidance for biocides & PPPs
- Intention to have it available by the date of entry into application
- Joint action by ECHA & EFSA
- First draft almost ready for public consultation
- Workshop on "case studies" (Q1 2018)

III.3- **Guidance on implementation:**

- Active substances:

- First draft introduced in the March CA meeting
  (CA-March17-Doc.7.7)

- ***Biocidal products:***

- First draft introduced in the July CA meeting
  (CA-July17-Doc.7.5.c)

→ On-going discussions in the CA meeting

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IV.1- **Background**

Main pillars in the BPR

Proper implementation & enforcement

Active substance approval	Product Authorisation	Treated articles

IV.1- **Background**

Some implementation priorities for COM

1.- Conclude the review programme by 2024

- Work according to priority lists
- Meet the planned dates for submissions by the eCAs – BPC organisation

2.- Timely product authorisation:

- Improve the key role of the refMS: validation & assessment (stop of the clock & 2-y boundary)
- Improve the MR procedure (SoP agreed by the CG)

IV.1- **Background**

Some enforcement priorities for COM

1.- Products are legally made available on the market and used:

- During the transitional period: products do contain AS that are in the review programme.
- Under the BPR: products are authorised according to the Regulation, labelled and used in compliance with the SPC.
- In both cases, products do contain a source of AS the supplier of which is listed in the Article 95 list.
- Phasing-out periods are respected *(Articles 89 & 52)*

2.- Treated Articles are legally placed on the market:

- As from 1st March 2017, they only contain active substances that are either approved, in the review programme or in Annex I.

IV.2- **“Biocides project” of Directorate F**

- Lead by Unit F3 (similar to a project on PPPs)

- **Fact-finding missions** to a number of MSs in 2017-2018

Objectives: see how MSs are implementing & enforcing the BPR

→ Identify areas for improvement: resources, internal efficiency / organisation, etc...

→ Identify best practice: to be shared with other MSs

In the long term, take informed decisions to improve:

→ Implementation: review programme & product authorisation

→ enforcement (key role of Sub-group biocides Forum)

IV.3- **Biocides Sub-group of Forum**

- Taking over the biocides enforcement group (BEG)

- First meeting on 31 March 2017 (Chair Eugen Anwander - AT)

- Secretariat provided by ECHA; COM observer

- Coordination/cooperation/harmonisation/spreading best practice on enforcement issues

- Follow-up and interaction with the CA meeting: practical consequences on enforcement of policy or regulatory decisions

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V.1 - Raising awareness

- Need to increase awareness in economic operators

- Timely decisions (future applications)

- Notice from the Commission on 13/09/2017 (Q&A document)

(https://ec.europa.eu/health/biocides/biocidal_products_en)

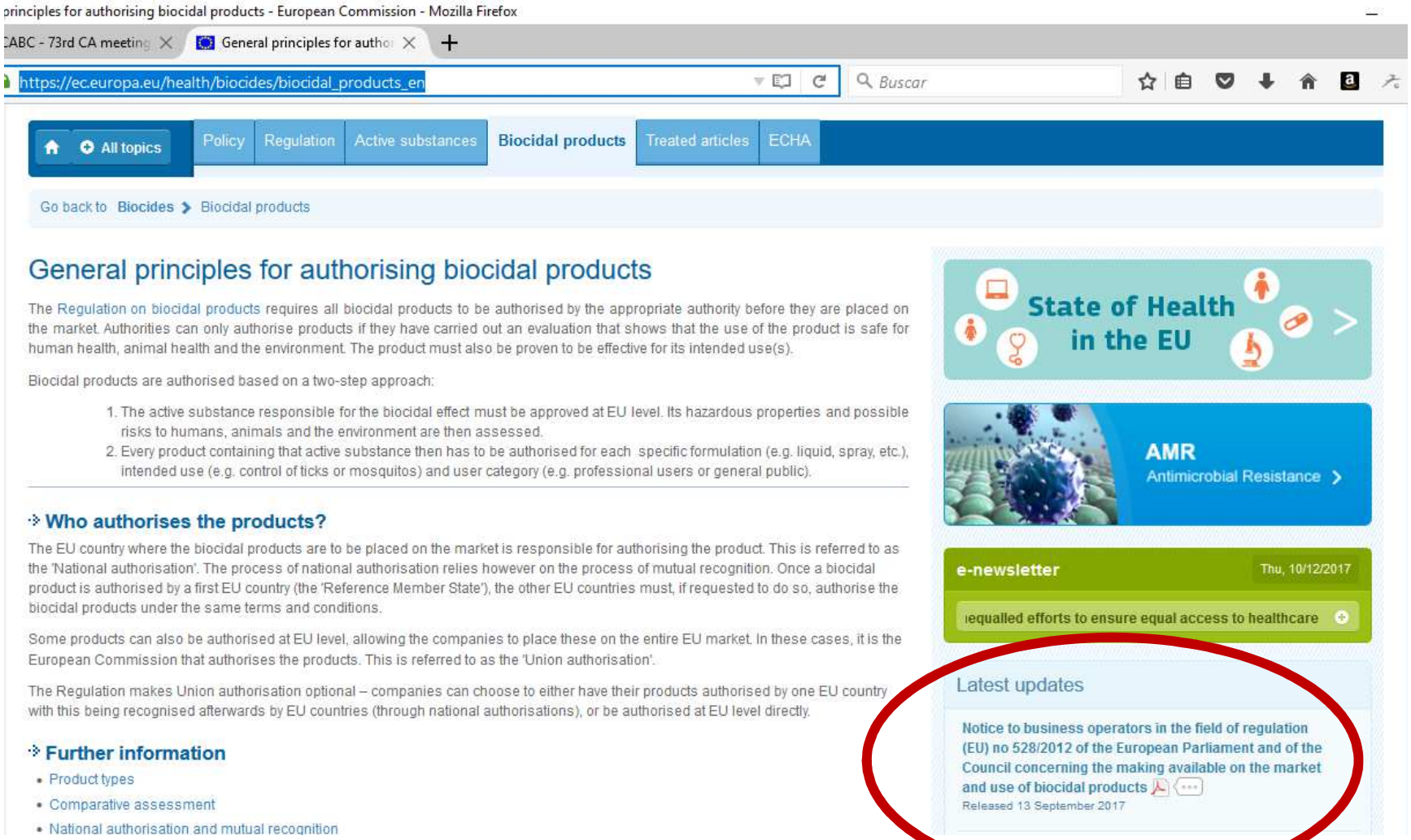
- ECHA webpages for REACH, CLP, PIC & BPR (22/09/2017)

(https://echa.europa.eu/uk-withdrawal-from-the-eu)

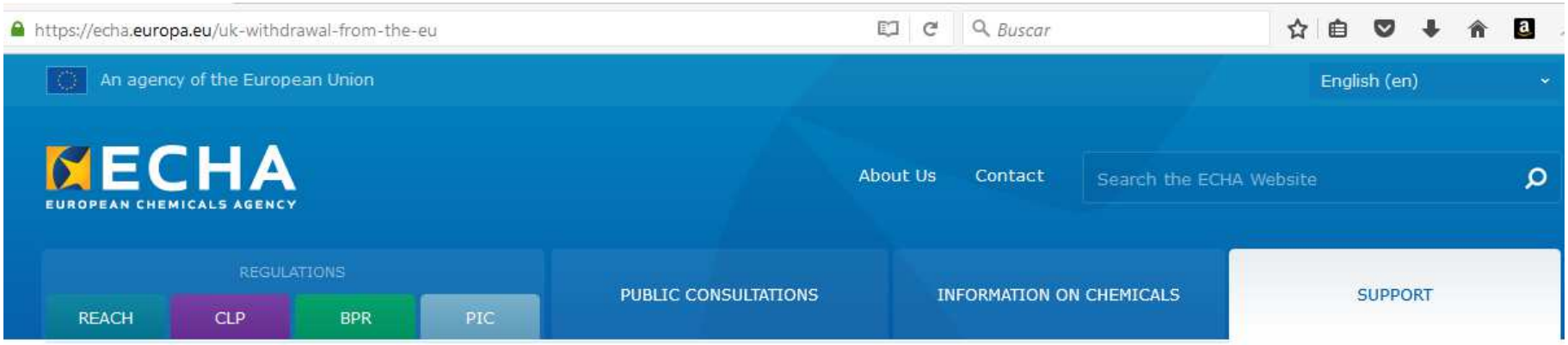
- BPR Q&A section

(https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/topic/theukswithdrawalfromtheeu)

European Commission



European Commission



Support

- Guidance
- Getting started
- Q&As Support
- Testing methods and alternatives
- Webinars
- Dossier Submission Tools
- National Helpdesks
- Practical examples of exposure scenarios
- Small and Medium-sized Enterprises (SMEs)

The UK's withdrawal from the EU

The United Kingdom is withdrawing from the European Union. From 30 March 2019 onwards, the UK will be a "third country" outside the EU. This date can only be changed by mutual agreement between Brussels and London. The withdrawal process is unique and unprecedented.

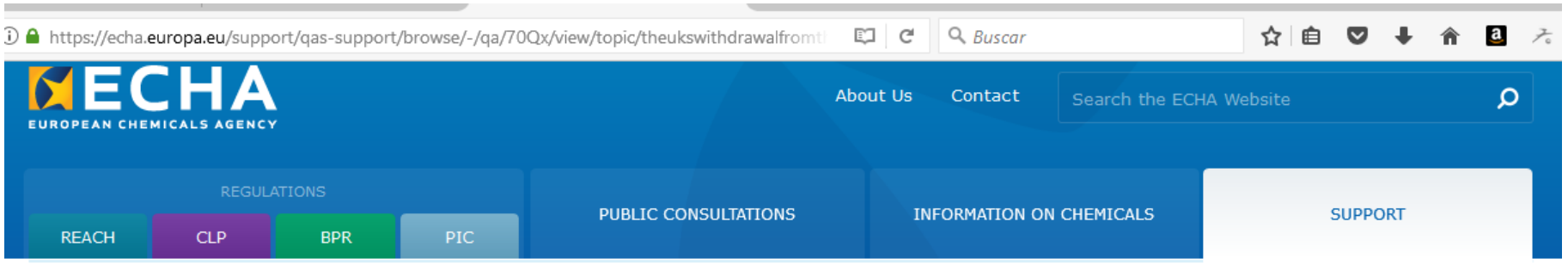
These webpages contain information as it is known to us at the time of its publication. We will continually populate these webpages as developments unfold.

You can find more specific information on various aspects of interest under the sub-headings of these webpages.

The information provided in the section providing "Advice to companies" contains Q&As jointly established with the respective services of the European Commission. The answers contained in these Q&A pairs, in particular, will be regularly updated, as needed. A potential future agreement between the EU and the UK on their future relationship may profoundly alter some of the answers given.

Learn how the UK's withdrawal from the EU may affect you

European Commission



Q&As

Search | Browse by topic

Want to search for the relevant question and answer in your own language? Change the language in the dropdown menu above.

The UKs withdrawal from the EU

BPR

› **I understand that the Commission has also published information on the impact of the UK withdrawal on companies with obligations under the Biocidal Product Regulation (BPR). Where can I find that information?**

› **My UK-based company is the holder of a product authorisation in an EU-27 Member State or of a Union authorisation under the BPR. What effect will the UK withdrawal have on our authorisation?**

V.2- **Work reallocation**

- Discussions COM/ECHA/EU-27/EEA countries/Switzerland

- First discussion 24 November 2017; to be continued…

- Priority to AS in the review programme → amendment of the review programme Regulation

- Renewal of biocidal products (PT 8): BPR allows for free choice by applicants, but some facilitation of the process may help

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VI- Conclusions

VI- Conclusions

- Need to focus on key priorities:
  - Progress in the review programme (objective 2024!)
  - Timely product authorisation
  - Enforcement (level playing field)

- For COM: further efforts on some on-going topics:
  - Setting up the Union authorisation system
  - Article 50 TFEU - UK withdrawal
  - Practical implementation of ED criteria
  - "Biocides project" (fact-finding missions & follow-up)
  - Implementation of the interim approach on MRLs
  - *In situ* (product authorisation)

Thank you for your attention

For further information:

Commission website:

http://ec.europa.eu/health/biocides/policy/index_en.htm

https://circabc.europa.eu/w/browse/e947a950-8032-4df9-a3f0-f61eefd3d81b

(Sante-Biocides@ec.europa.eu)

ECHA website & Helpdesk on Biocides:

http://echa.europa.eu/regulations/biocidal-products-regulation