Europese ontwikkelingen op het gebied van biociden

Ctgb relatiedag, 13 juni 2019, EDE

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EC, DG SANTE, Unit E4 Pesticides and Biocides

Agenda

1. Wat gaat er niet gebeuren?
2. Wat komt er?
    i. Europese Hof
    ii. Meer transparantie
    iii. Actieve stoffen
    iv. Producten
    v. EDs
    vi. Controles
    vii. 2021 rapport
    viii. Niet technische ontwikkelingen

Wat gaat er niet gebeuren?

Rustpauze

Herziening regelgeving (korte termijn)

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Wat gaat er gebeuren

Hof van Justitie van de Europese Unie

T337/18 Laboratoire Pareva PHMB

T734/18 Sumitomo empenthrin

C-592/18 pre-judiciële vragen

Board of Appeal -ECHA

Wat gaat er gebeuren?

Meer transparantie

Permanent Comité

ATDs

Dissemination

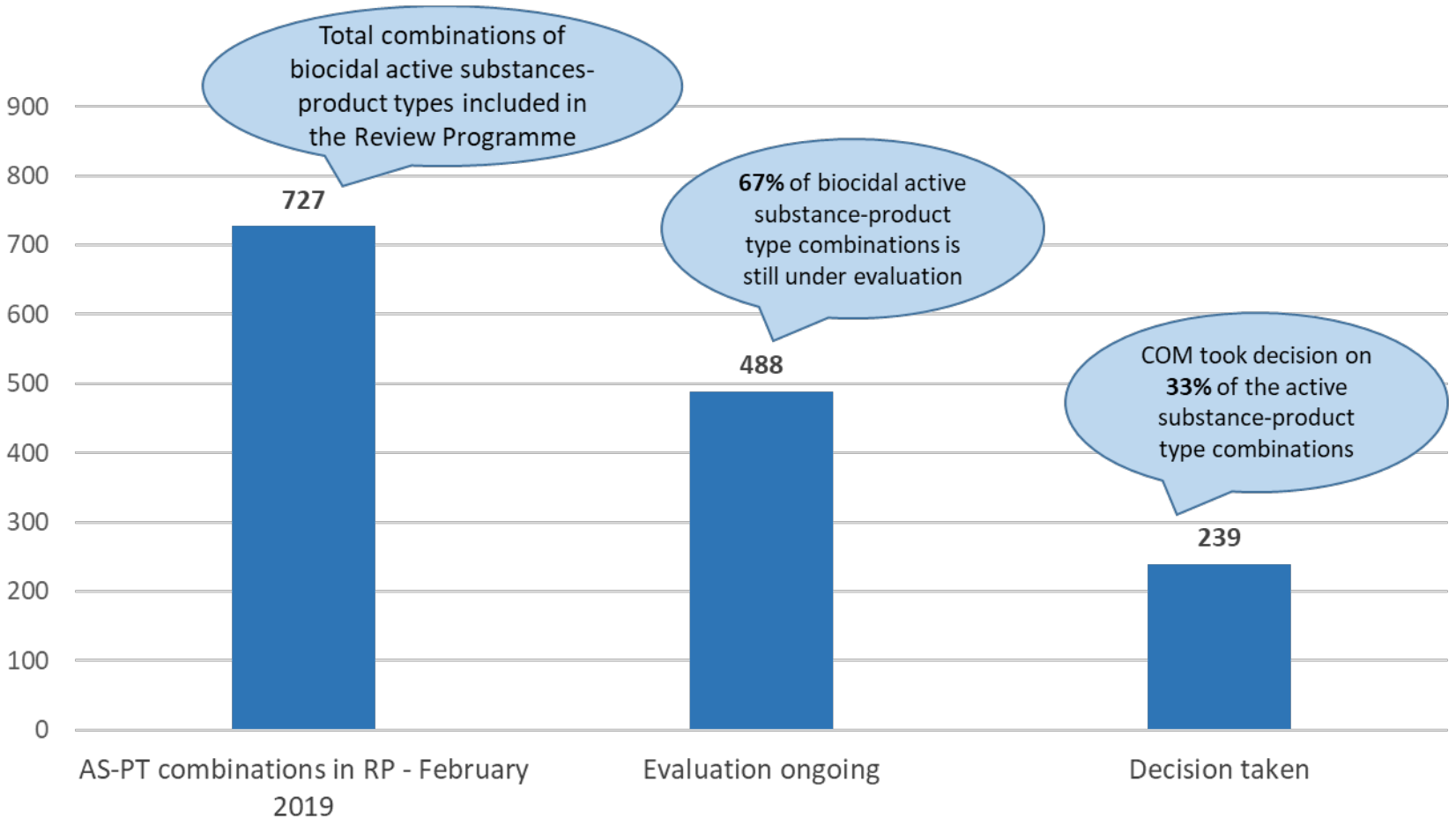
General Food Law

Aarhus

Wat gaat er gebeuren?

Actieve stoffen

Review Programme - state of play



Review Programme – state of play

- Delays in the review programme

- Discussions in 2017-2018 with Member States and stakeholders representatives, agreements on some actions :

CA-March18-Doc.5.1a - Final - Actions for AS review programme.pdf

- ECHA workshop on the review programme on 12-13 February 2019 : further actions under consideration, upcoming discussions in CA meetings

Wat gaat er gebeuren?

Actieve stoffen

Versnelling werkprogramma

Meer besluiten

Innovatie

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Wat gaat er gebeuren?

Producten

Wat gaat er gebeuren?

Producten

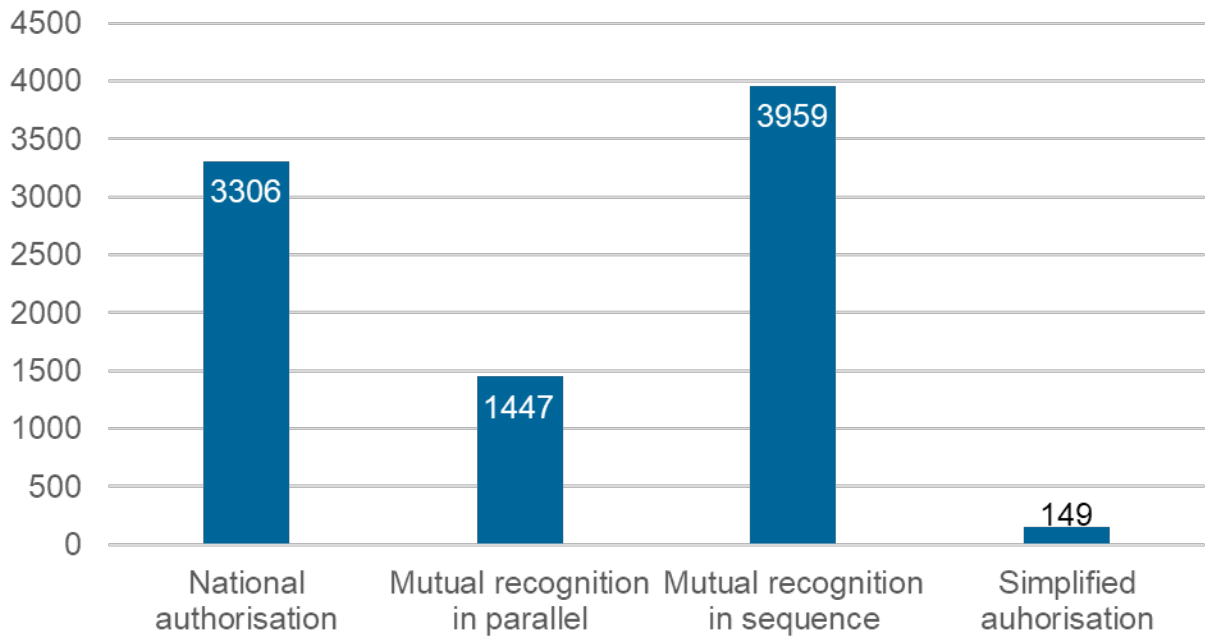
Meer toelatingen

Meer toelatingen van de unie

Meer doorverwijzingen van bezwaren aan de EC?

Product authorisation

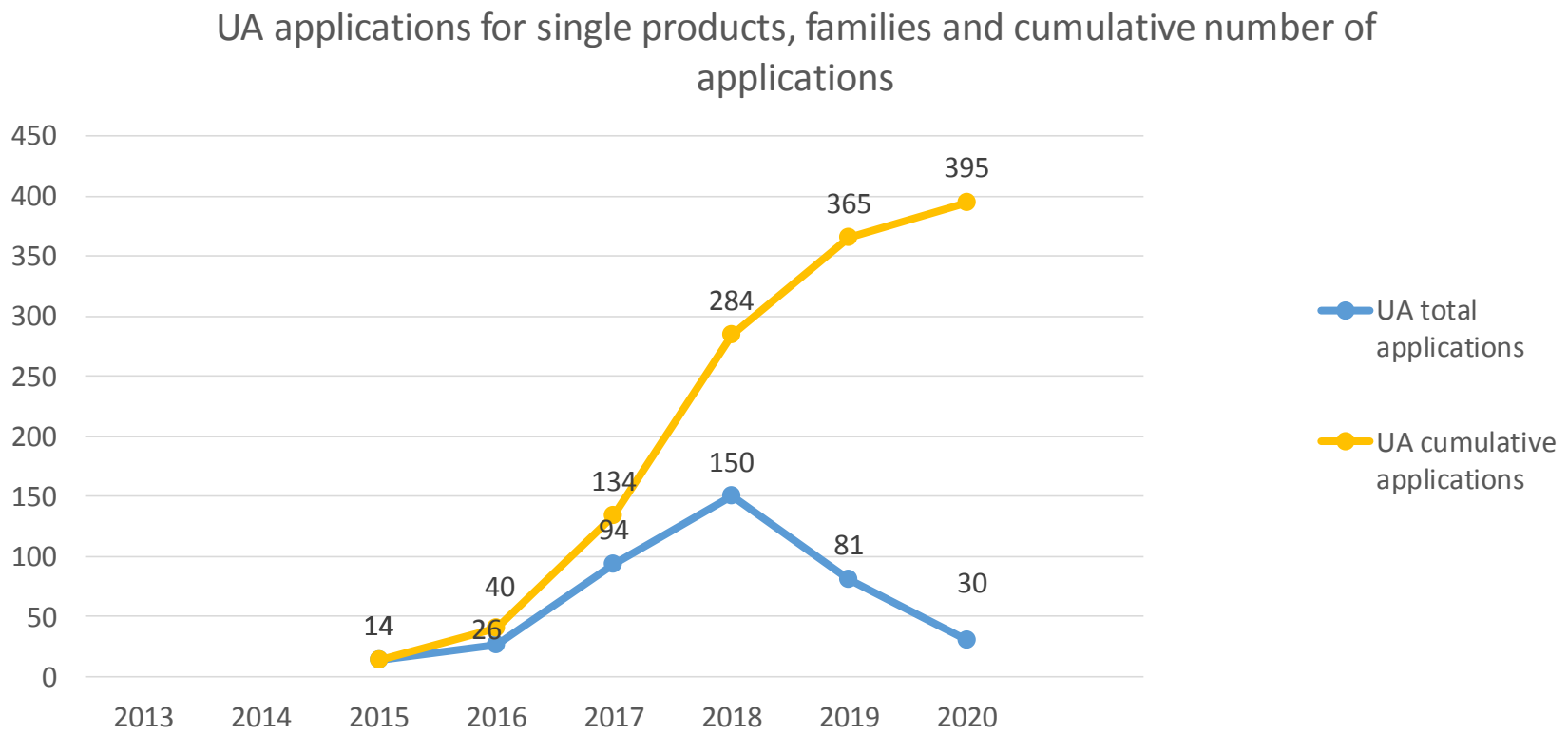
Number of products authorised under BPR



National authorisation and amendments	3306
Mutual recognition in parallel	1447
Mutual recognition in sequence	3959
Simplified authorisation	149
Total	**8861**

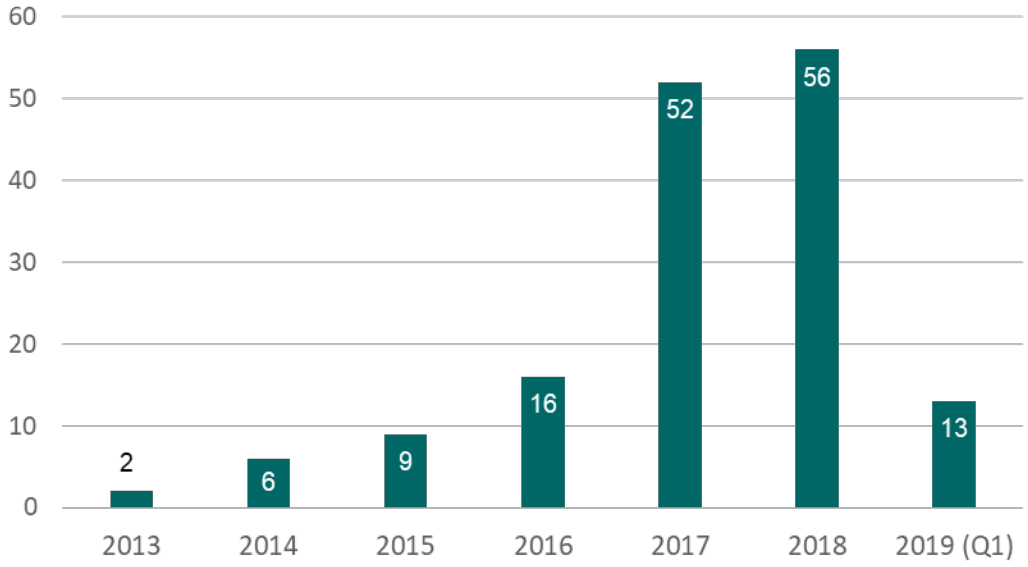
- First Union authorisations granted in 2018: **7** Union authorisations for BPFs >> **48 products** authorised for the entire EU market

Union authorisation



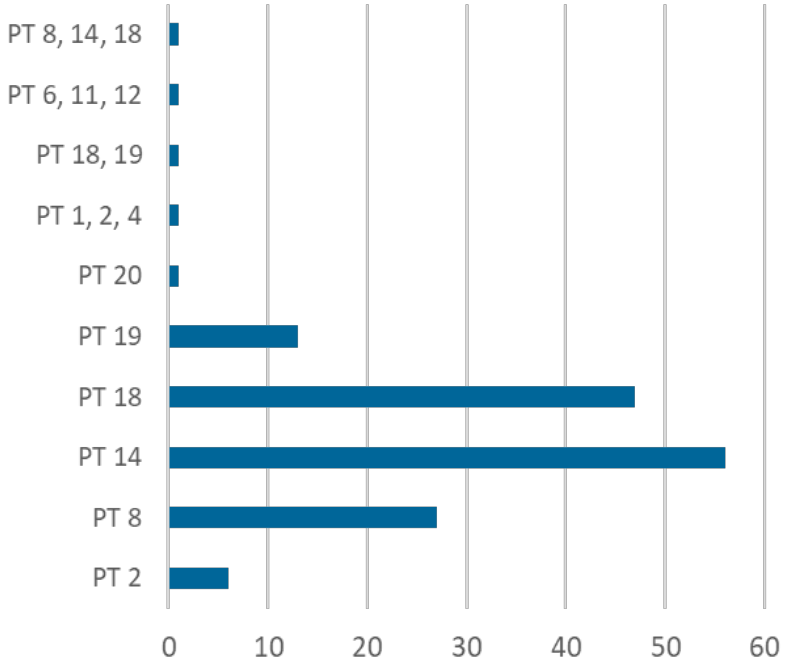
Product authorisations – harmonisation between MSs

Number of referrals submitted to CG



Total number of referrals submitted to CG: **154**

Number of referrals per product-type

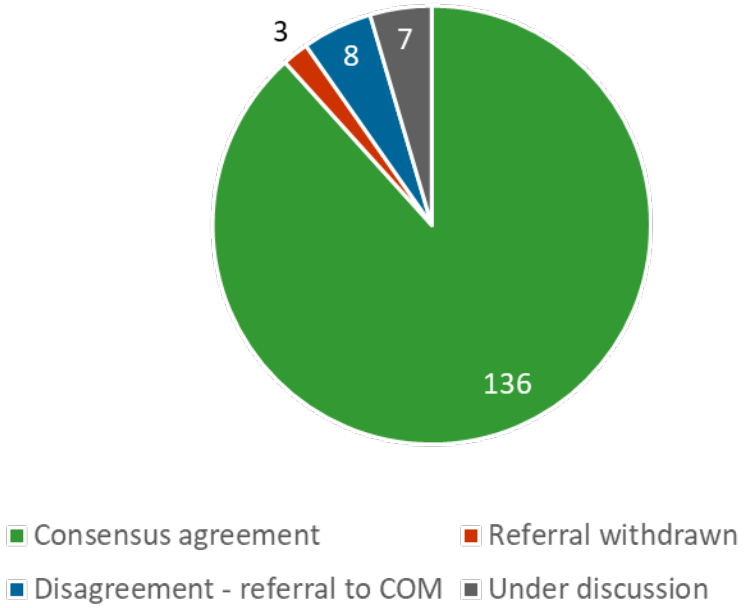


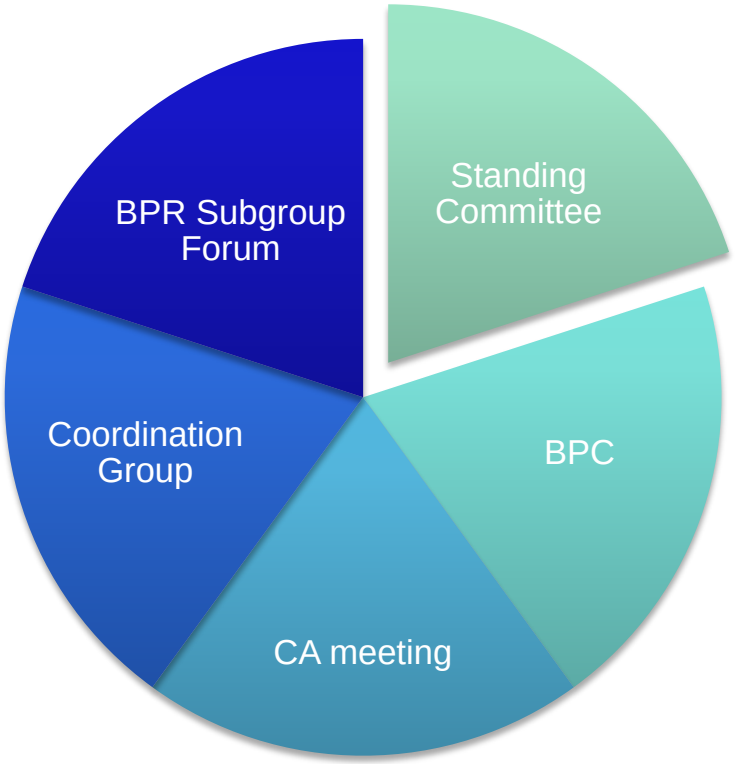
Product authorisations – harmonisation between MSs

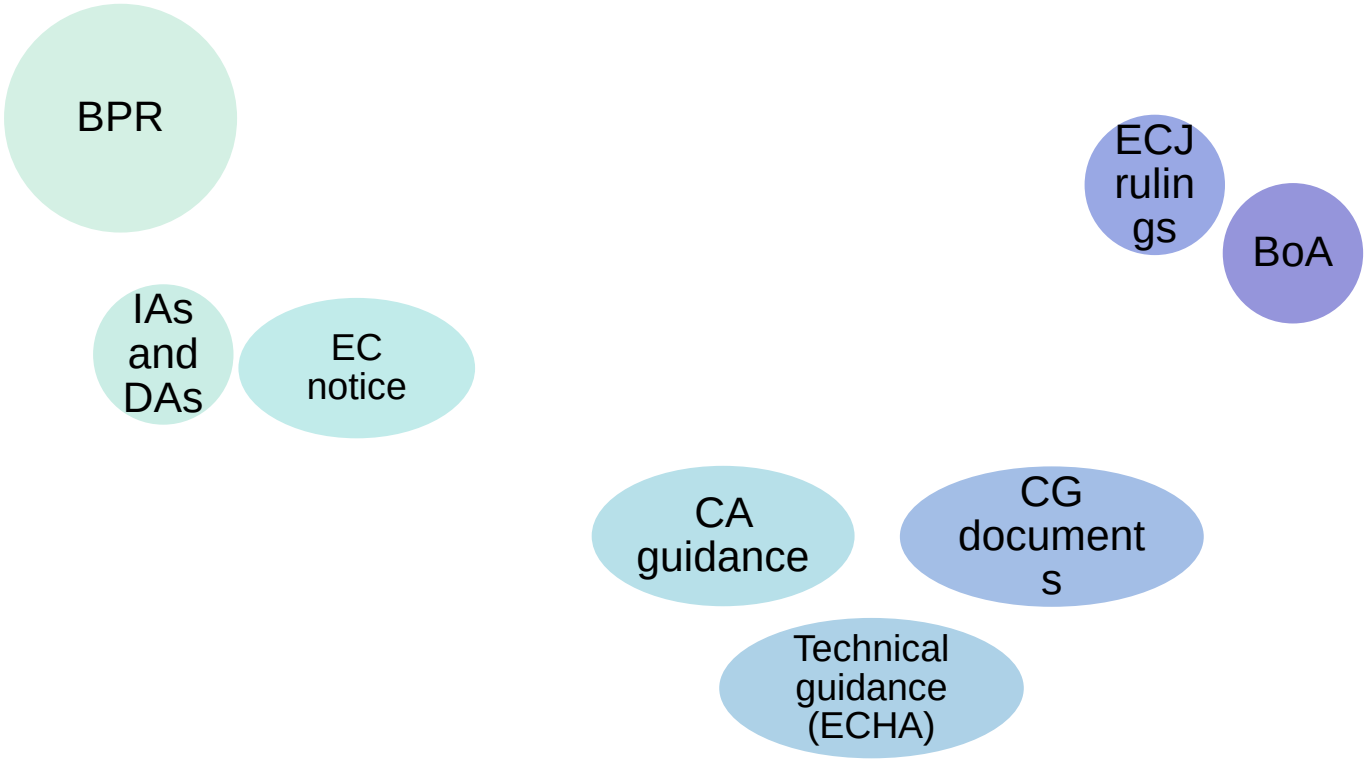
Referrals – agreement rate, disagreements referred to Commission

- high agreement rate (88.3%)
- 5.2% of referrals resulted in disagreement referred to COM

	Number	%
Referrals	154	
Consensus agreement. Product can be authorised through Article 19 or Article 26	**136**	**88.3**
Consensus agreement. Product cannot be authorised through Article 19 or Article 26	0	0
Referral withdrawn	3	1.9
No agreement reached. Disagreement referred to Commission	**8**	**5.2**
Referrals under discussion	7	4.5




Standing Committee
BPC
CA meeting
Coordination Group
BPR Subgroup Forum


BPR
IAs and DAs
EC notice
ECJ rulings
BoA
CA guidance
CG documents
Technical guidance (ECHA)

Example of referral timeline

Applicant submitted an application for the mutual recognition of BPF containing the active substance deltamethrin

On *23 February 2017* Germany referred an objection to the CG

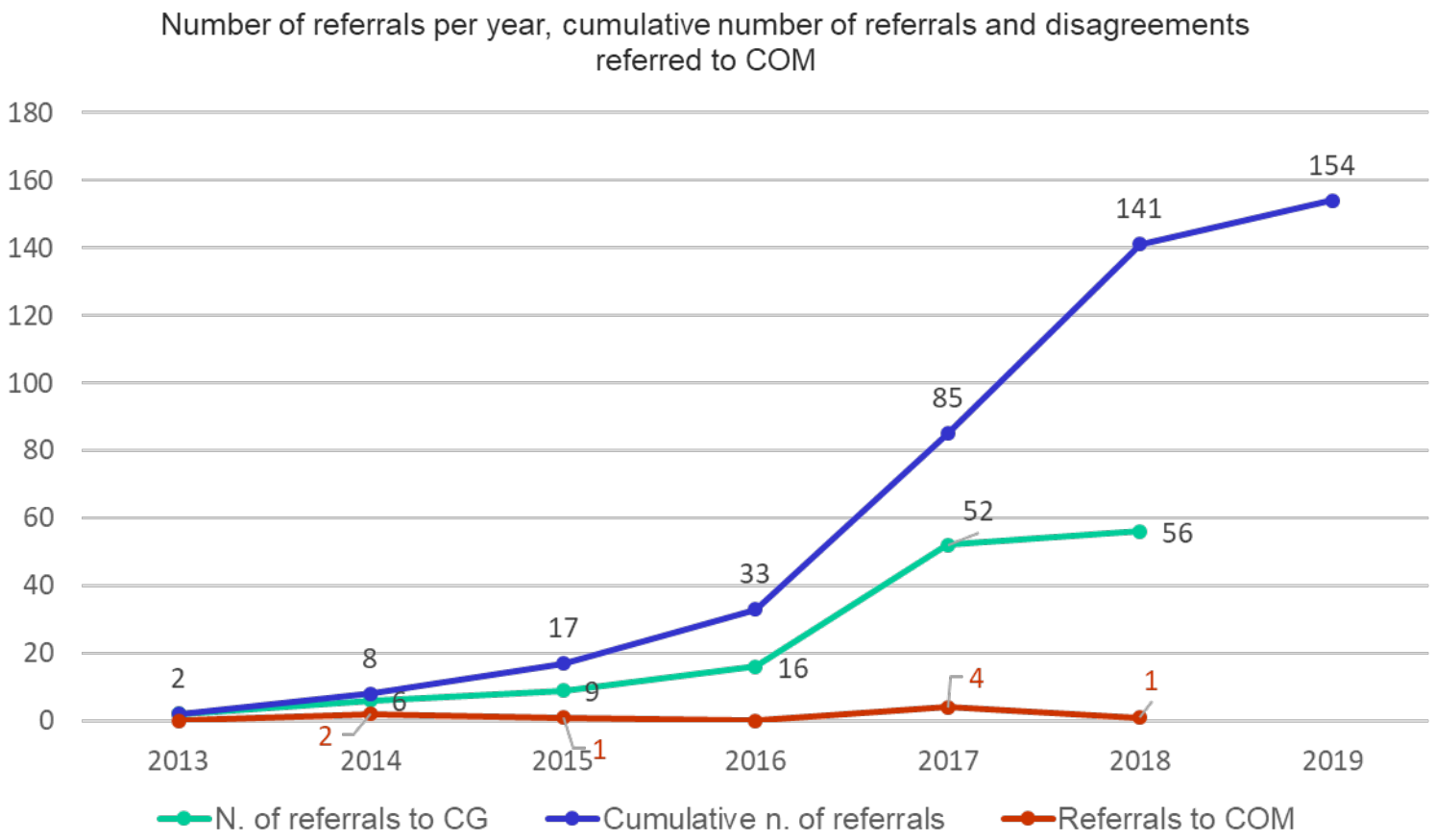
On *14 March 2017* and 10 May 2017 referral was discussed in CG

On *18 May 2017* the unresolved objection referred to the EC

On *30 May 2018* the Standing Committee gave a favourable opinion

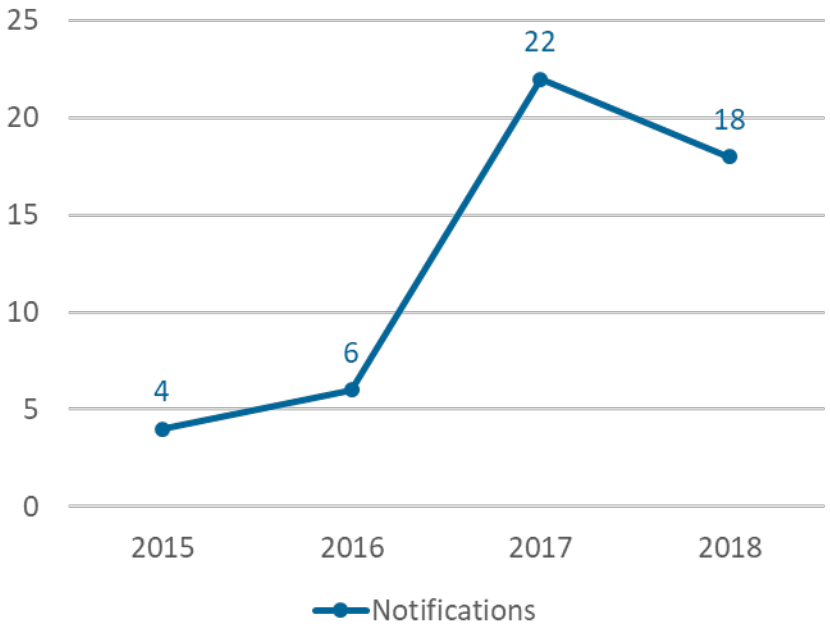
On *28 September 2018* published the Commission Implementing Decision (EU) 2018/1305 in Official Journal

Product authorisations – harmonisation between MSs

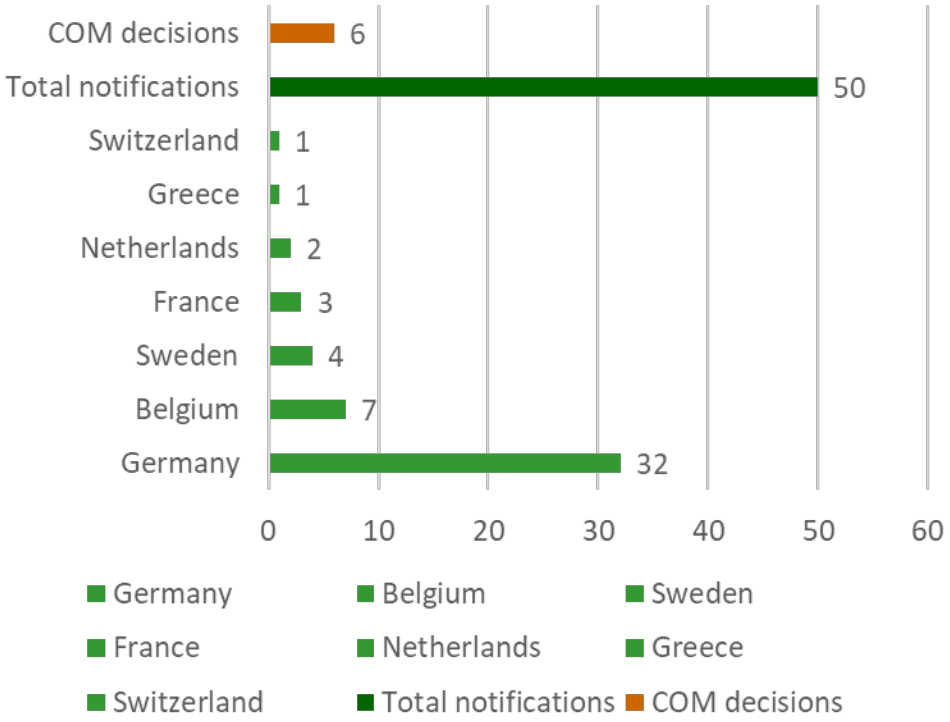


Emergency authorisations

Emergency authorisations notifications per year



Emergency authorisations notifications per Member State and COM decisions on extensions



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Wat gaat er gebeuren?

In situ

BPFs

DBPs

MRLs

Bestuivers

UFI

Wat gaat er gebeuren?

Producten
In situ

-CA-guidance in situ biocidal products July CA meeting

-In situ nitrogen for the preservation of museum objects

Article 55(3) Essentieel voor bescherming van cultureel erfgoed

Wat gaat er gebeuren?

Producten

In situ

BPFs

DBPs

MRLs

Bestuivers

UFI

Application of Unique Formula Identifier for biocidal products

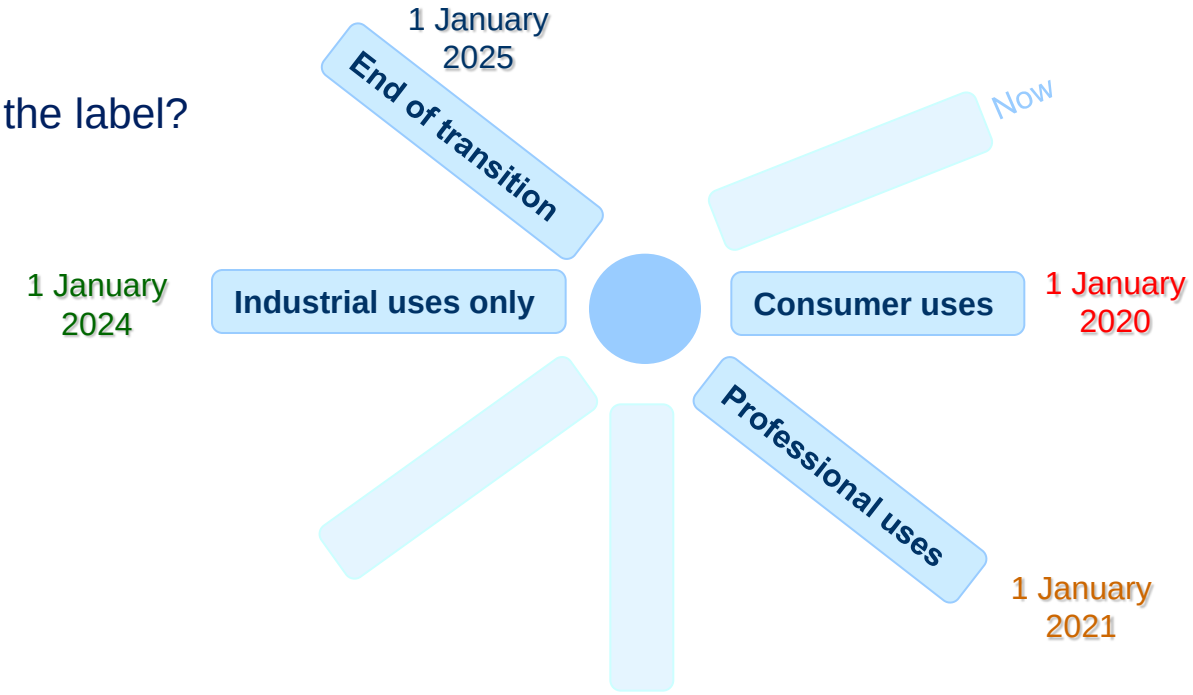
UFI: unambiguous link between a product placed on the market and the information on the specific mixture

rapid and precise identification of the chemical formulation of the product in case of emergencies

Timelines

By when should the UFI be on the label?

Step-wise application



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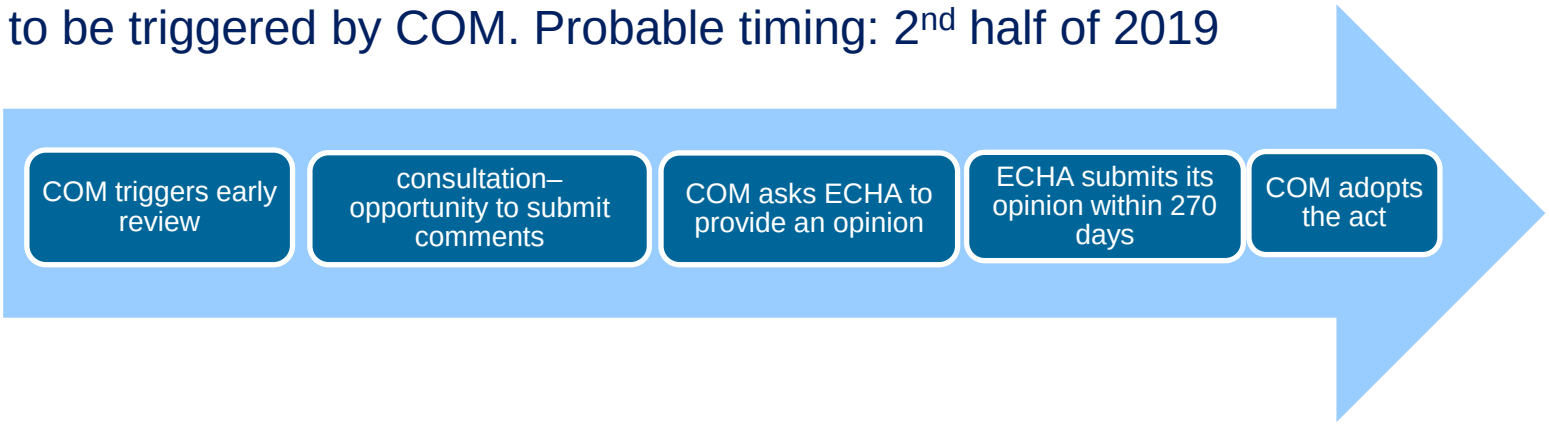
Endocrine disruptors

Status:

- Discussions ongoing with CAs for the update of Annexes II and III to BPR >> expert meeting; draft delegated act to be presented at CA meeting in Sept 2019
- RP and renewals
- Draft CG-document on non-active substances
- Early review of three active substances (iodine, PVP iodine, zineb): process still to be triggered by COM. Probable timing: 2nd half of 2019



Update of information requirements of the BPR

Amendments of Annex II and III to BPR – under discussion in CA meeting.

Main drivers for amendments:

- ED criteria : Entry into force of scientific criteria for assessing the endocrine disrupting potential of substances

- Need to adapt information requirements to technical and scientific progress

✓Reduction of animal testing

✓Better protection of human and animal health

✓Improvement of consistency of BPR Annexes

✓Streamlining of certain requirements for micro-organisms

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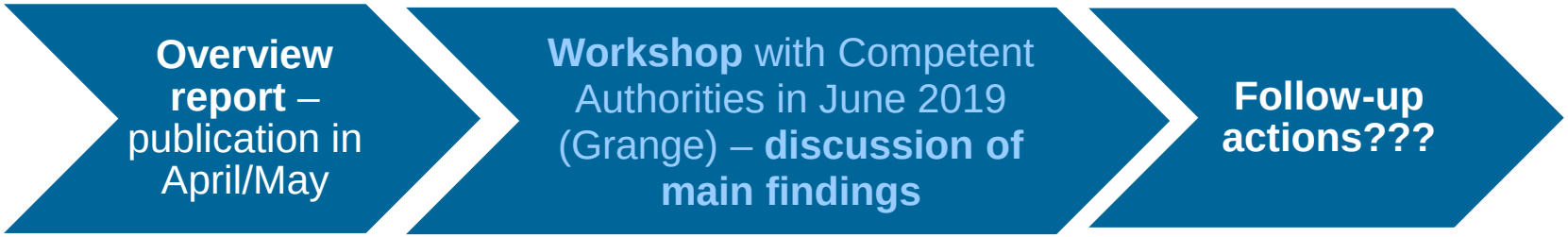
Controls

Fact finding missions in 5 MSs, conducted between November 2017 and June 2018 (HU, DE, ES, BE, NL); workshop next week (19-20 June)



FORUM-BPRS –treated articles

Controls - to ensure a level playing field on the market

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Article 65(3) reporting - background

Art. 65(3) >> Member States to report every five years on the implementation of the BPR – Year 2020

Art. 65(4) >> COM to produce a composite report to the Council and European Parliament, based on MSs reports – Year 2021

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Non-technical developments

Brexit

New EP

New Commission