Assessing endocrine disrupting properties

Where we are

Klaus Berend
DG Health and Food Safety
European Commission

Biocides Day, Helsinki, Finland
29 October 2019

Health and Food Safety

European Commission

Development of the Criteria

- Public consultation
- Impact assessment
- Meetings with stakeholders (roundtables, conference)
- Expert group – Standing Committee
- Commission Delegated Regulation (EU) 2017/2100

Scientific criteria for EDs

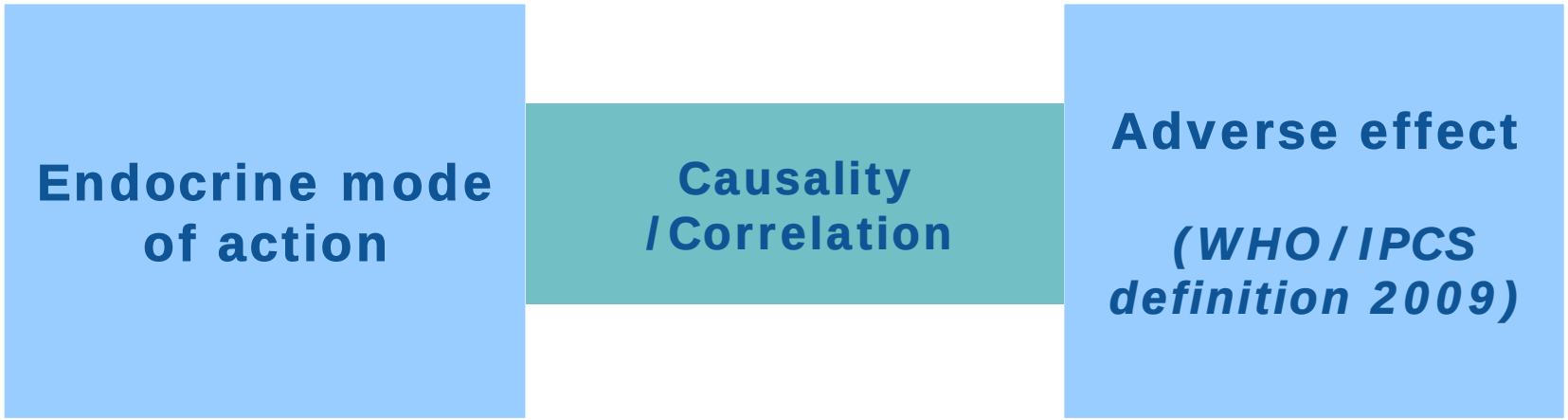
- **Biocides:**
  applicable from 7 of June 2018
  Commission Delegated Regulation (EU) 2017/2100 of 4 Sept. 2017

- **Pesticides (plant protection products):**
  applicable from 10 November 2018
  Commission Regulation (EU) 2018/605 of 19 April 2018

European Commission

Scientific criteria for EDs

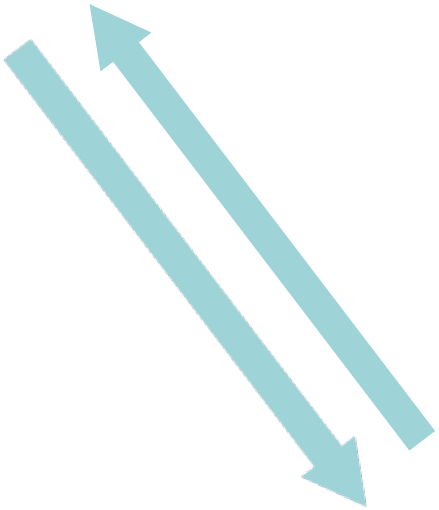
- protect human health and the environment
- are harmonised for BPs and PPPs
- based on the 3 elements of the 2002 WHO/IPCS definition of an ED



European Commission

Information requirements - biocides

Joint EFSA-ECHA technical guidance



Update of Annex II and III to the BPR

Discussions in expert group

Delegated Regulation amending Annexes II and III

General objectives update Annexes II and III of the BPR

- Propose an aligned approach for reproductive testing under REACH, BPR and possible PPPR
- Give better considerations to animal welfare

State of play activities 2019:

- Meetings between ECHA, EFSA, JRC, DG ENV, DG GROW and DG SANTE
- Inputs from participants of experts of CA meeting (expert group: Member States and observers)

European Commission

State of play CA notes

- ✓ **“On- going procedures active substances”: agreed in March 2018 CA meeting**
  CA-March18-Doc.7.3a-final- EDs- active substances under assessment.docx
- ✓ **“Already authorised and on- going procedures biocidal products”: agreed in March 2018 CA meeting**
  CA-March18-Doc.7.3b-final- EDs- biocidal products.docx
- ✓ **“Approved active substances”: agreed in September 2018 CA meeting**
- ✓ /CircaBC/SANTE/BPR - Public/Library/documents_finalised/CA-September18.Doc.7.5.a-final EDs approved active substances.docx

European Commission

On-going procedures active substance (I)

1. If assessment report submitted before 1 September 2013:

ED properties have to be assessed based on the information already provided, but the opportunity is given to the applicant to submit additional information if considered necessary by the eCA.

No conclusion might be possible because of lack of information.

2. If assessment report submitted after 1 September 2013:

The applicant has the obligation to submit requested information on ED properties, and a conclusion is required

European Commission

On-going procedures active substance (II)

ED criteria apply to all procedures, including for active substances dossiers:

- *Under peer review*
- *ECHA opinion is submitted to the Commission*

European Commission

Applying ED criteria (type of chemicals)

Biocidal active substances

Active substance

Biocidal products

Active substance

Non-active substances

Substances of concern

Other non-active substances

Health and Food Safety

European Commission

What is an active substance with ED properties?

1. **Scientific criteria according to Regulation (EU) No 2017/2100**

2. **Article 57(f) and 59(1) of REACH**

European Commission

Approved active substances

Examining ED properties of an approved active substance can happen:

- *During regular renewal process or*
- *Triggering an earlier review (Article 15 of the BPR)*

Health and Food Safety

Article 15 – BPR: review of approved biocidal active substances

1. EC considers that there are significant indications that the approval conditions are no longer met

3 months

2. EC makes publicly it is carrying out a review of a biocidal active substance and provides opportunity to make comments and provide information

270 days

3. ECHA prepares opinion and submits it to EC

Article 15 – BPR: Review of approved biocidal active substances

60 days

4. Public consultation on derogation to the exclusion criteria (if the active substance meets exclusion criteria)

5. The Standing Committee on Biocidal Products discusses the possibilities on derogation to the exclusion criteria and a draft implementing regulation

6. The Standing Committee on Biocidal Products delivers an opinion on the implementing regulation

Outcome
No need to amend approval, or
Implementing regulation amending the conditions of approval or cancelling approval

European Commission

Intention to trigger early review for 3 approved biocidal active substances

Zineb, iodine and PVP iodine

'Significant indications' based on screening study performed during the impact assessment accompanying the draft acts setting ED criteria

Health and Food Safety

European Commission

Biocidal products (I)

1. When assessment phase is closed, no additional information will be be asked
2. If waiting for the outcome of assessment is incompatible with the legal deadline: process will be concluded at the post-authorisation stage

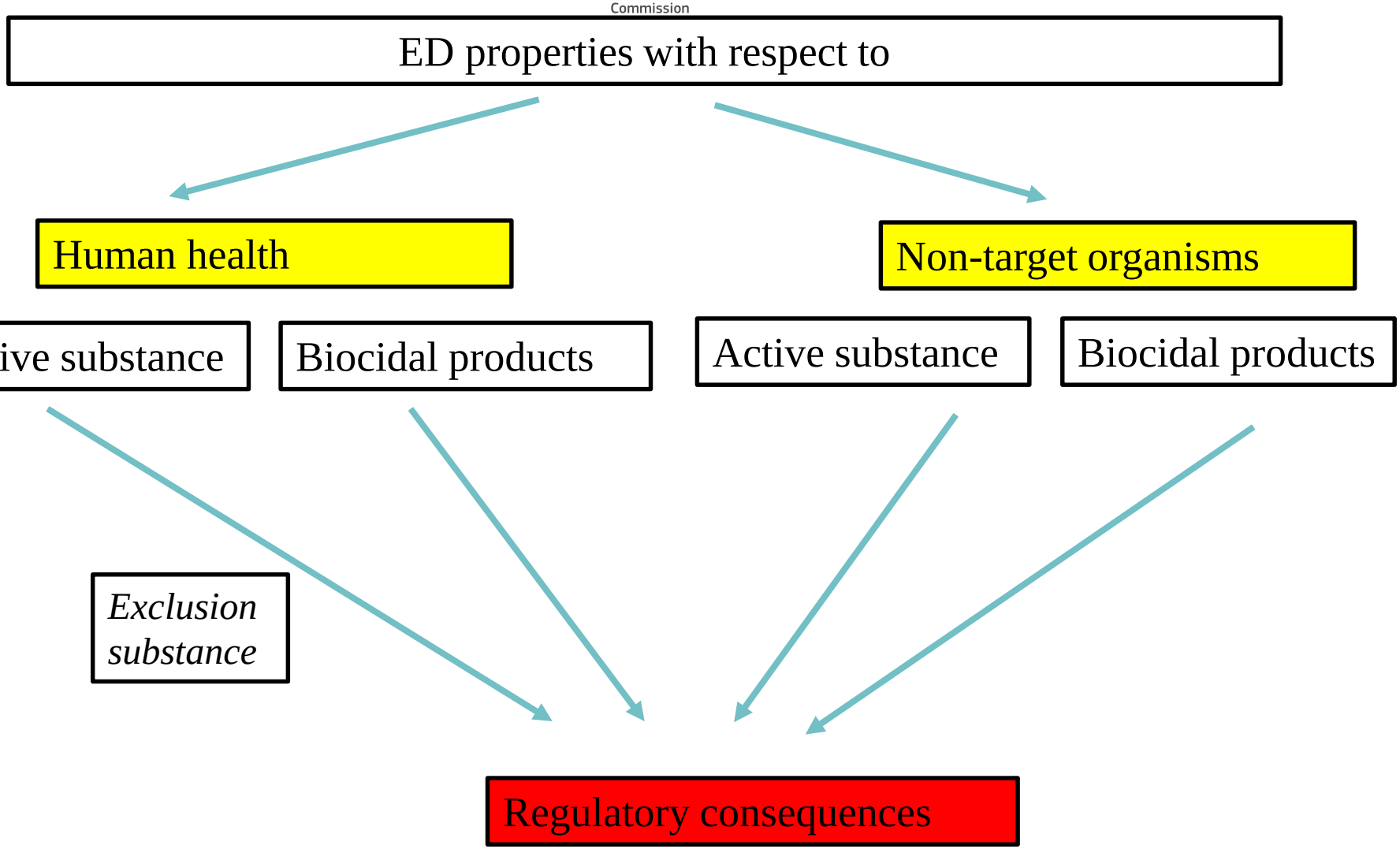
European Commission

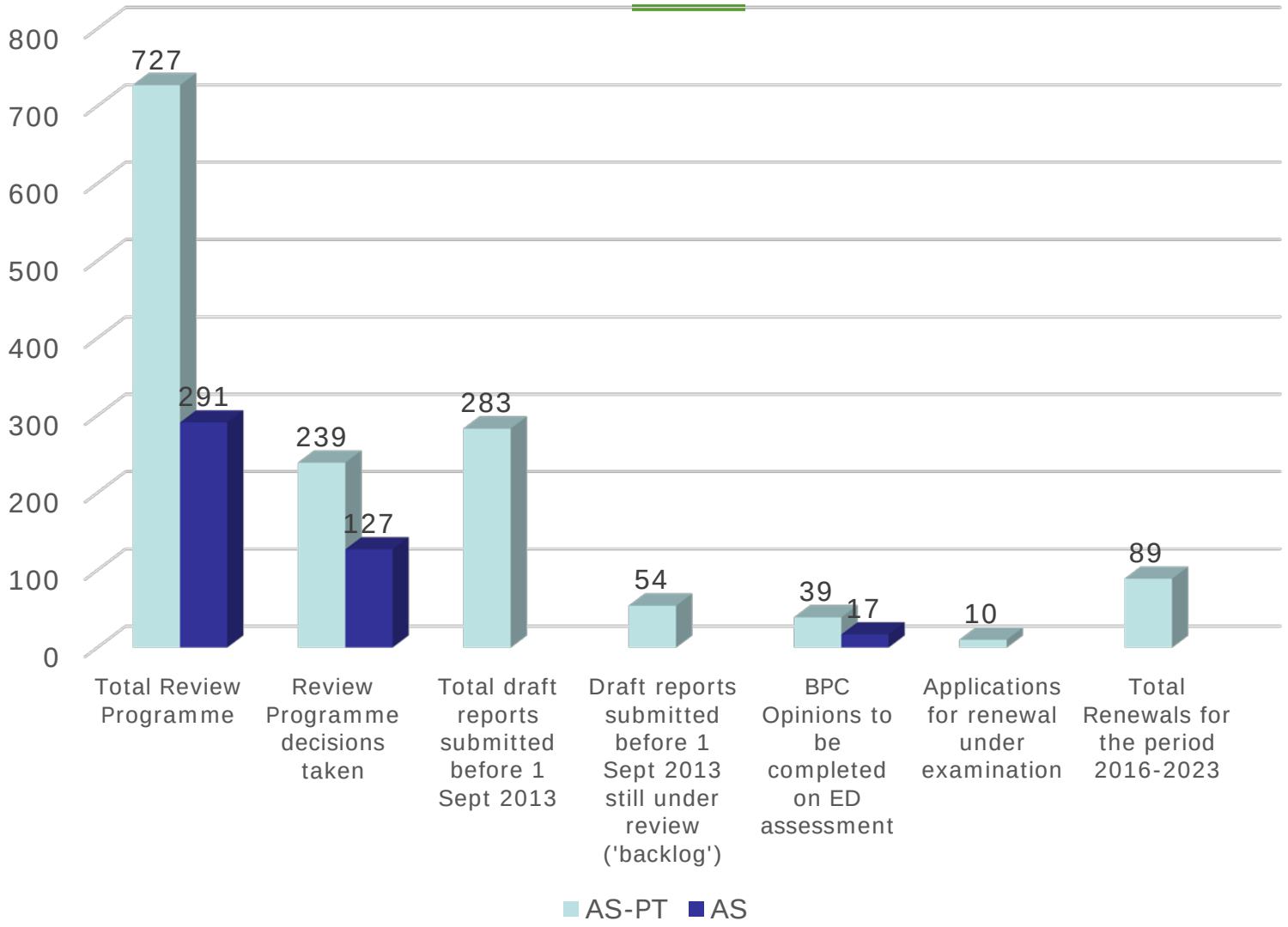
Biocidal products (II)

Already authorised products:

- Article 48(1)(a) of BPR if conditions in Article 19 are no longer satisfied,
- At renewal of biocidal product authorisation evaluating body shall assess ED properties

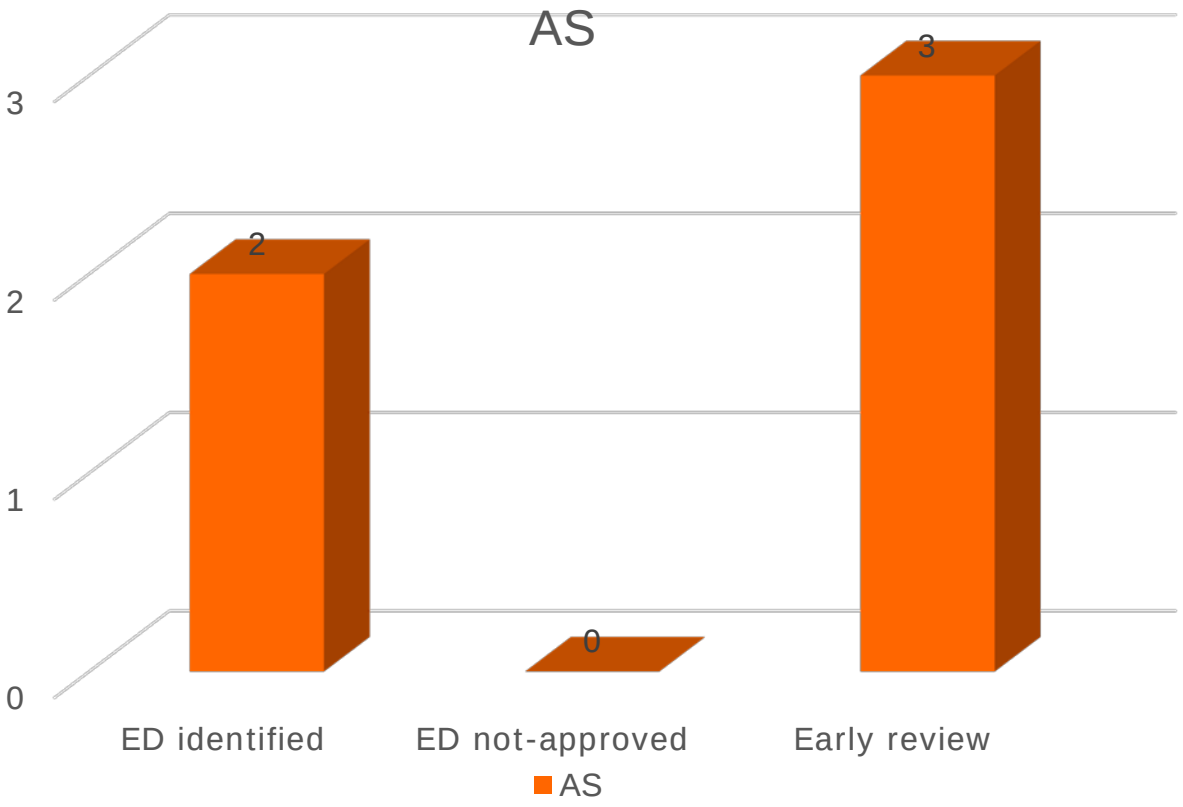
Member States decide whether the ED criteria apply for biocidal products made available and used during the transitional measures


ED properties with respect to
Human health
Non-target organisms
Active substance
Biocidal products
Active substance
Biocidal products
Exclusion substance
Regulatory consequences


800
700
600
500
400
300
200
100
0
727
291
239
127
283
54
39
17
10
89
Total Review Programme
Review Programme decisions taken
Total draft reports submitted before 1 Sept 2013
Draft reports submitted before 1 Sept 2013 still under review ('backlog')
BPC Opinions to be completed on ED assessment
Applications for renewal under examination
Total Renewals for the period 2016-2023
AS-PT
AS

European Commission

Since June 2018:



Health and Food Safety

European Commission

Challenges

- Generating data (costs, time, lab facilities)
- Expertise, human resources
- Concluding on ED properties (scientific uncertainty, OECD tests)

European Commission

Other "ED-news"

- *Science & Horizon 2020*
  - Horizon 2020 topic **'New testing and screening methods to identify endocrine disrupting chemicals'** has been evaluated and project is selected.

- *Commission Communication - Towards a comprehensive EU framework on endocrine disruptors (COM 2018 734, 7 Nov 2018)*

European Commission

Towards a comprehensive EU framework on endocrine disruptors

Taking forward the EU's policy on EDs*; significant progress achieved in the past 20 years but more is needed*

Launch of a cross-cutting Fitness Check *(including public consultation)*

- First time for cross-cutting look at how different legislation deals with endocrine disruptors
- will build on scientific evidence and data collected through finalised/on-ongoing evaluations (e.g. food contact materials, fitness check on chemicals legislation, etc.)

European Commission

Towards a comprehensive EU framework on endocrine disruptors

Most up-to-date science; commitment to invest in research:

- fill knowledge gaps for ED
- Several relevant research strands under Horizon Europe

Inclusive

- First Annual Forum on 8 November 2019
- Commitment to step up international work (OECD, international system for classification of chemicals)
- Launch of a web portal on ED
- Encourage Member States to develop specific information and educational campaigns

European Commission

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

Health and Food Safety