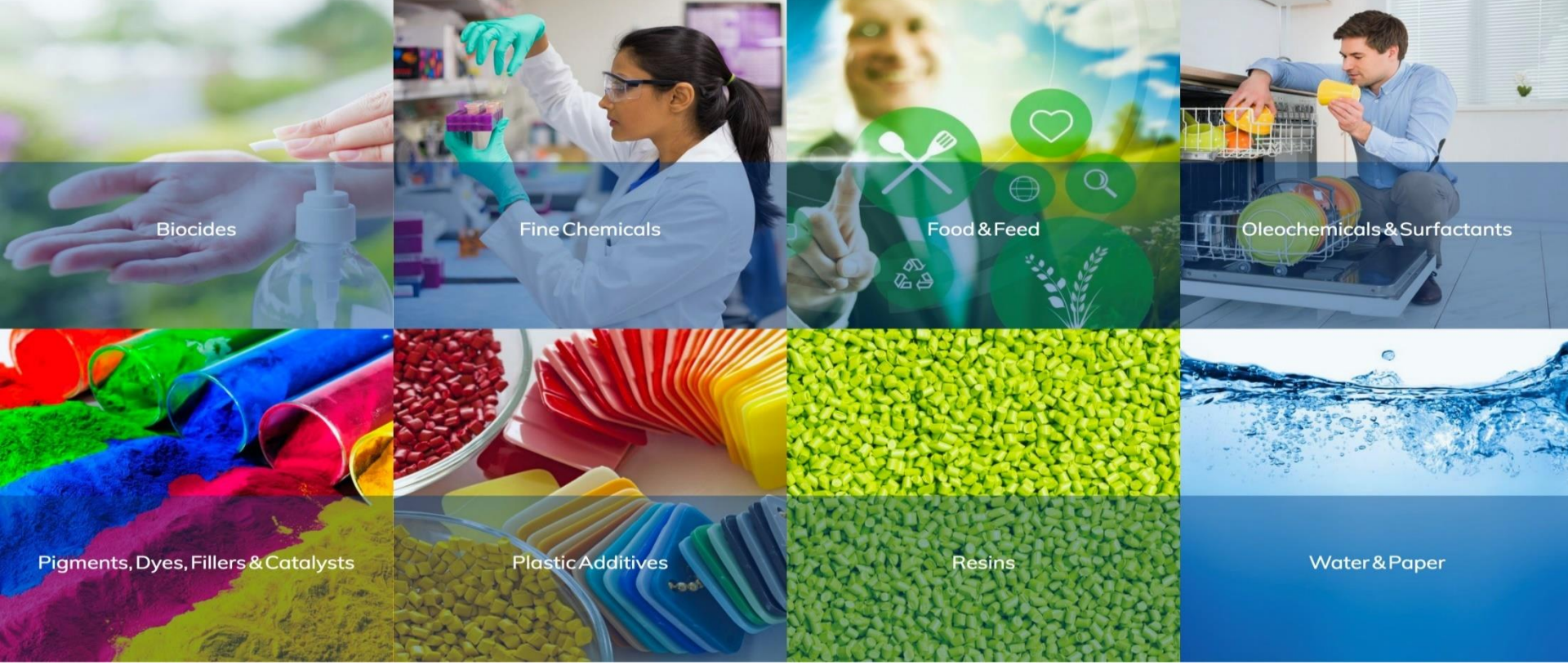

Industry views and experiences on the EU biocides legislation

Workshop - Biocides management in Ukraine

Kiev, 23 November 2017

Flore Cognat
European Biocidal Product Forum
Cefic

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EBPF – European Biocidal Products Forum

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- Sector group of Cefic representing the biocides industry following the regulatory developments of EU biocides legislation
- Recognised stakeholder & observer
- Implementation of the BPR: active substance approval and biocidal product authorisation

EBPF – European Biocidal Products Forum

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CURRENT MEMBERSHIP

- > 60 Members: Active Substance producers & Biocidal Product formulators
- 9 Associate Members - Industry sector groups, downstream user associations and task forces
- 12 National Chemical Federations

https://specialty-chemicals.eu/ebpf/

Agenda

1. Making of & scope of BPR
2. BPR Challenges
3. Biocides and innovation
4. Concluding remarks – lessons learned

Biocidal Product Regulation

In Europe, covers the making available on the market and use of biocidal active substances, biocidal products and treated articles containing biocidal products

The Regulation specifies that:

- Firstly, the **active substance (AS)** must be approved at the European level for a **Product Type (PT)**

- Secondly, the **biocidal product (BP)**, for the **specific use**, is authorised in each European country where it will be placed on the market

Product Types under BPR

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Disinfectants

- PT 1 – Human hygiene
- PT 2 – Disinfectants not intended for direct application to humans or animals
- PT 3 – Veterinary hygiene
- PT 4 – Food and Feed Area
- PT 5 – Drinking Water

Preservatives

- PT 6 – For products during storage
- PT 7 – Film
- PT 8 – Wood
- PT 9 – Fibre, leather, rubber, polymerised materials
- PT 10 – Construction materials
- PT 11 – Liquid-cooling and processing systems
- PT 12 – Slimicides
- PT 13 – Working or cutting fluids

Pest control

- PT 14 – Rodenticides
- PT 15 – Avicides
- PT 16 – Molluscicides
- PT 17 – Piscicides
- PT 18 – Insecticides
- PT 19 – Repellents and attractants
- PT 20 – Other vertebrates

Other

- PT 21 – Antifouling products
- PT 22 – Embalming and taxidermist fluids

The need to regulate biocides in EU

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Main goal: Approval of Active Substances

1998 - Directive (BPD) addressed the need to regulate the biocides market

2002 – Confirmation of participation

2004 – 1st wave of dossiers submitted

2009 – 1st approvals

2010 – 1st extension of the Review Programme for Actives

2012 – Regulation (BPR) adopted to correct gaps and streamline processes

2013 – European Chemicals Agency (ECHA) takes over running of Review Programme

=> Aim of making 50 Active Substance/Product Type decisions per year

2024 – Review Programme to be completed

How existing active substances were identified?

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Main goal of initial EU legislation BPD: Approval of AS

- 1st step: Implement Review Programme intended to identify existing AS and determine those to be evaluated with a view to their approval (Regulation (EC) 1896/2000 of 7 September 2000 on the first phase of the programme)
- Existing active substances defined as those on the market before 14 May 2000 and identified based on a notification procedure
- Products containing existing AS allowed on the market.
- For those not identified by 28 March 2002, no phase-out period.

Review Programme of AS

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Priority list of AS/PT combinations => Market distortion in the PTs

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	31/09/2023

Status of review programme

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Number of AS/PT decisions:

>190

ECHA effect – AS/PT decisions since 1st September 2013:

130

Number of AS/PT decisions still to take (approx)

400

Review programme

- 240 existing AS supported for one or more PT = approx. 620 dossiers
- Number of approval or non-approval decisions = 220
- Number of approved AS/PT combinations: >190
- Status of review programme: 36% complete as of Sep. 2017 (after 13 years of BPD/BPR)

Who in the Supply Chain has obligations?

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- **'making available on the market'** means any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge
- **'placing on the market'** means the first making available on the market of a biocidal product or of a treated article

⇒ Company placing on the market has obligation under BPR

⇒ In a single supply chain of an individual product, only one authorisation holder is needed

Article 95: Aim and principles

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Purpose: Recitals 8 & 58 of the BPR	Results: Article 95(2) of the BPR
"To ensure the equal treatment of persons placing active substances on the market" "A level playing field […] on the market for existing active substances"	"As of 1 September 2015, a biocidal product consisting of, containing or generating a relevant substance, included in the list referred to in paragraph 1, shall not be made available on the market unless **either the substance supplier or the product supplier is included in the list** referred to in paragraph 1 for the product-type(s) to which the product belongs"
• "reducing unnecessary tests and costs to the minimum" • "avoiding the establishment of monopolies" • "sustaining free competition between economic operators" • "equitable compensation of the costs borne by data owners"	

Article 95 listing

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Active Substance Manufacturer or Importer	Biocidal Product Manufacturer or Importer	Article 95 compliance
+	-	☺
-	+	☺
-	-	☹

Routes to Article 95 listing

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- Review Programme Participants

- Automatically included

- Alternative suppliers

✓ Build full Annex II dossier with own data

✓ Build part of Annex II dossier + buy LoA to a selection of studies

✓ Buy access to complete dossier in review programme

BPR - Challenges

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- High regulatory cost
- Small market
- Evolving legislation & guidance
- No holistic approach per product-type
- No socio-economic analysis

=> High legal uncertainty associated with **high business risk**

High Regulatory Cost

Partially due to EU complexity, number of markets and national requirements:

- Active substance: at least a few million EUR
- Biocidal product: 250,000 – 500,000 EUR or more

Small Market

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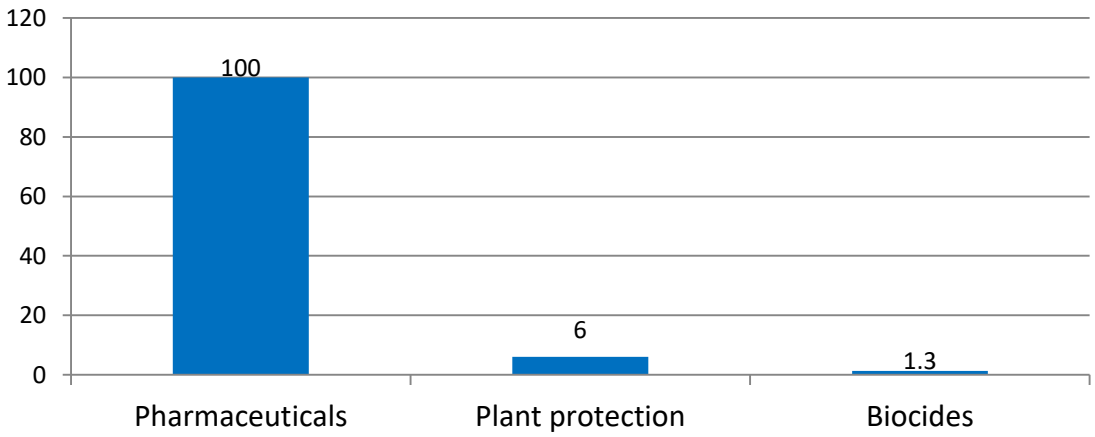
- Biocides is a relatively small market:



- Multiple sectors: disinfectants, preservatives, insecticides, …
- Fragmented market: actives, products, applicators / mosaic of SMEs and bigger companies
- Targeted market for a new active is generally < 50 millions
- Data requirement is not tonnage-related as for REACH

Evolving legislation & guidance

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- BPD (Risk based) >< BPR (add Hazard)
- Direct link between BPR and C&L
- Endocrine Disruptors criteria
- Evolving guidance in terms of Risk Assessments:
  additional worst-case scenarios or aggregated exposure
  - Over 100 Finalised CA documents since 1 September 2013
  - Countless guidance/recommendations – since Sept 2013 and many still under discussions and development

Holistic approach would help

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- Ensures keeping sufficient alternatives on the market
- Currently, each A.S. is being evaluated independently

Example: In can preservatives - PT6 substances

- 50 % of sensitising AS are in this group
- Deadline for PT 6 review is 2020
- By 2020 the choice for PT6 may be considerably smaller
- If some groups of substances are removed or significant restrictions will be set in the approval – not many alternatives

Socio-Economic Analysis would help

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- No detailed and targeted socio-economic considerations during an active substance approval process
- **ZERO** risk is THE criterion for Biocide approvals
- Sustainable use of chemicals: Biocide is part of the solution
- The BPR has to ensure that these benefits are not jeopardised

BPR - challenges for Downstream Users

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- BPR impacts the DUs Industries
- Unlike REACH, no opportunity to make their own Chemical Safety Assessment and be legally involved in the BPR review programme
- DUs are also impacted by other provisions of the BPR (treated articles)
- Uncertainty that their need will be properly covered by Biocide active substances and products suppliers

Place for Improvement

- Industry is aware that the political trend is to reduce quantities of Biocides → But need to consider **socio-economic benefits of biocides**
- **Holistic approach** <> current case by case assessment
- Need for the Biocide Industry to develop **new formulations** to reduce exposure to Human and Environment (**sustainable use**)
- Over-conservative, worst-case, precautionary assessments => **More realistic exposure scenarios**

Need for innovation

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Innovation for life

- Protects public health by keeping a hygienic environment
- Prevent food- and water-borne infection and poisoning
- Prevent human and animal diseases

Innovation for environment

- Preserve available resources and natural material
- Durability of products and reduction of waste
- Reduction of CO2 emission, energy efficiency
- Protect water quality

Regulatory hurdles to innovation

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Tiny number of new AS submitted under BPR

- Development costs versus the time for return on investment
- Complexity, administrative and regulatory burden
- R&D budget swallowed to maintain existing substances and/or products
- Regulatory uncertainty
- Market freeze – largely process related:
    - Process not adapted for changes in the market
    - Often triggered by the transitional period

Allow for innovation

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Industry wish

- Decrease time to market
- Remove process-related hurdles
- Assure regulatory stability

REFIT Proposals

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- REFIT platform
  - Operational since January 2016
  - Chair: COM First Vice President Timmermans
  - Mandate: Advise COM on how to make existing legislation more efficient and effective

- EBPF Proposals to be reviewed in January 2018
  - Streamline the evaluation of biocidal products at active substance level when the BP data is described and evaluated at active substance level
  - Labelling of treated articles vs CLP: only refer to the CLP classification of the substance and the defined SCLs.

Lessons learnt from EU BPR

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- Difficulty to have a clear vision of the future of the Biocide market
- All the actors of the supply chain will be impacted
- Number of products will decrease
- Fewer variability in terms of products
- No innovation in terms of new active substances
- Innovation will be related to new product formulations

Food for thought

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- Prioritise, but be aware of potential market distortions
  - => Consider a step-wise approach where the first target should be the active substance approval
- Transparency and dialogue between evaluator-applicant
- Early identification of gaps in the dossier, especially for requesting new studies
- Hazard versus risk :
  - Linking exclusion and substitution criteria exclusively to hazard properties of the substance (no risk assessment) eliminates from the market valuable substances and products where risk assessment shows they can be safely used. **ZERO** risk should be read as acceptable risk.
- Data requirements – 'international' data should be accepted
- Dialogue with Industry is essential, including downstream users and understanding of the societal needs
- Be mindful of the administrative burdens and expert resources needed by both the authorities and industry

Thank you for your attention

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