Opportunities for companies under the new Biocidal Products Regulation

Raf Bruyndonckx
Cefic – European Biocidal Products Forum

Biocides Stakeholders' Day
25 June 2013
European Chemicals Agency

cefic sector group

Overview

- Aim of the new BPR
- Opportunities offered by the new BPR
- Conclusion and outlook

New regulation on biocides

- **Shared Aim (all stakeholders):**
  - identify and undertake efforts to improve the regulation of biocidal products
- **Industry seeking efforts to identify and realise:**
  - Clarity, Predictability, Consistency, Efficiency in process
  - Measures to reduce administrative burden and time to market
  - Harmonisation in implementation and application

Opportunities offered by the BPR

Simplification and Streamlining

- Procedures & Authorisation options
- **Mutual Recognition of authorisations -** *in parallel or in sequence*
- **Union Authorisation**
- **Biocidal Product Family**
- **Same Biocidal Products**
- **Simplified Authorisation Procedure**
- **Changes to authorised products**

Union Authorisation

Objective: Facilitate access to the entire EU market

Opportunities:

- "One-stop shop" for companies to the EU market
- Address all concerns at once
- Widely applicable
- **But**:
  - Phased approach, high fees

Biocidal Product Family

Objective: Facilitate authorisation of closely-related products

- One authorisation for a group of biocidal products containing the same active substance(s) with similar uses
- Composition variations or replacement of non-active substances
- Individual products are defined
- Improvement on frame formulation concept

Biocidal Product Family

Opportunities:

- Possibility to change composition without new application and new authorisation (within permitted ranges)
- Easier to quickly comply with market demands
- Saves time and resources
- **But**:
    - All products need to have the same classification

2011 Industry survey

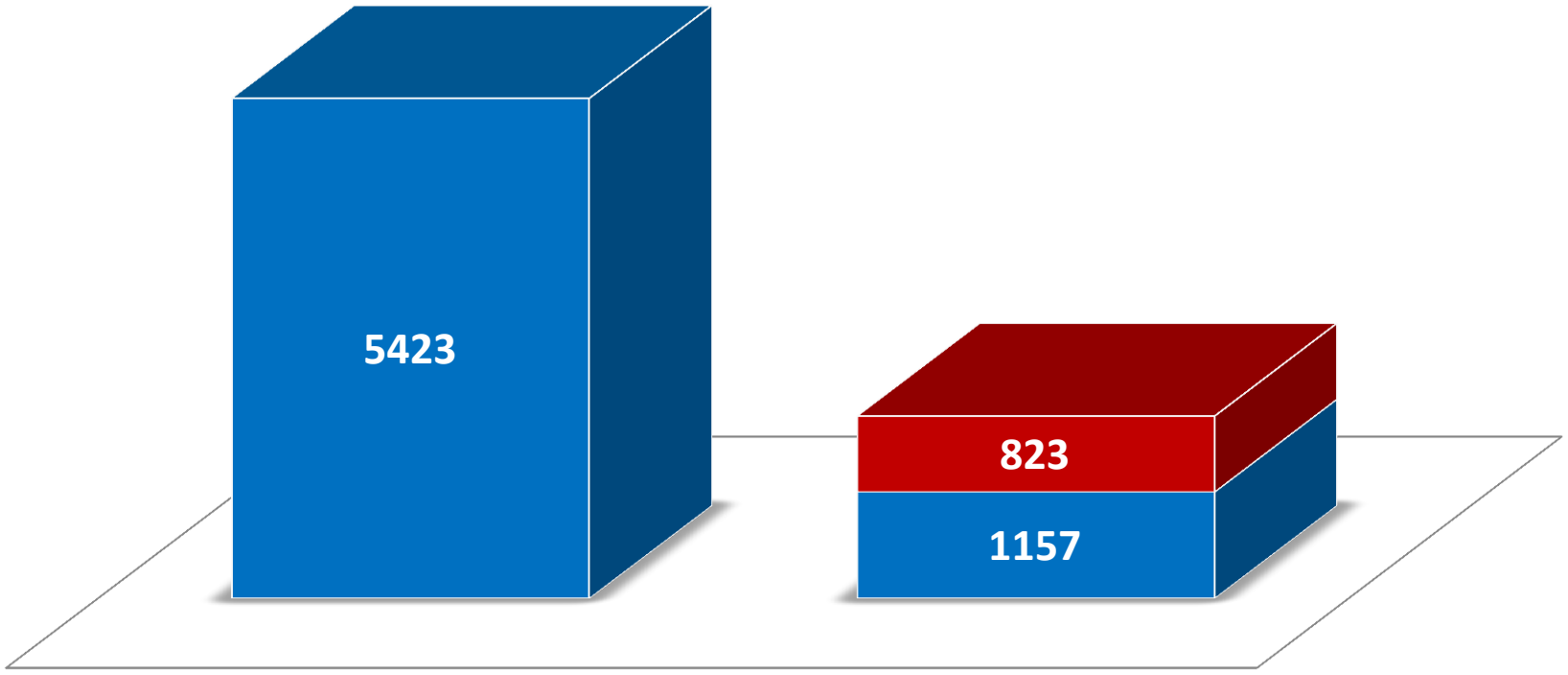
Objective: Assess impact of Union Authorisation and the Biocidal Product Family concept

- Joint exercise A.I.S.E – EBPF
- Questions about portfolio, intentions, expectations
- Approx. 90 companies, 8000 products, all PTs
- Contribution to the BPR second reading

Biocidal product family

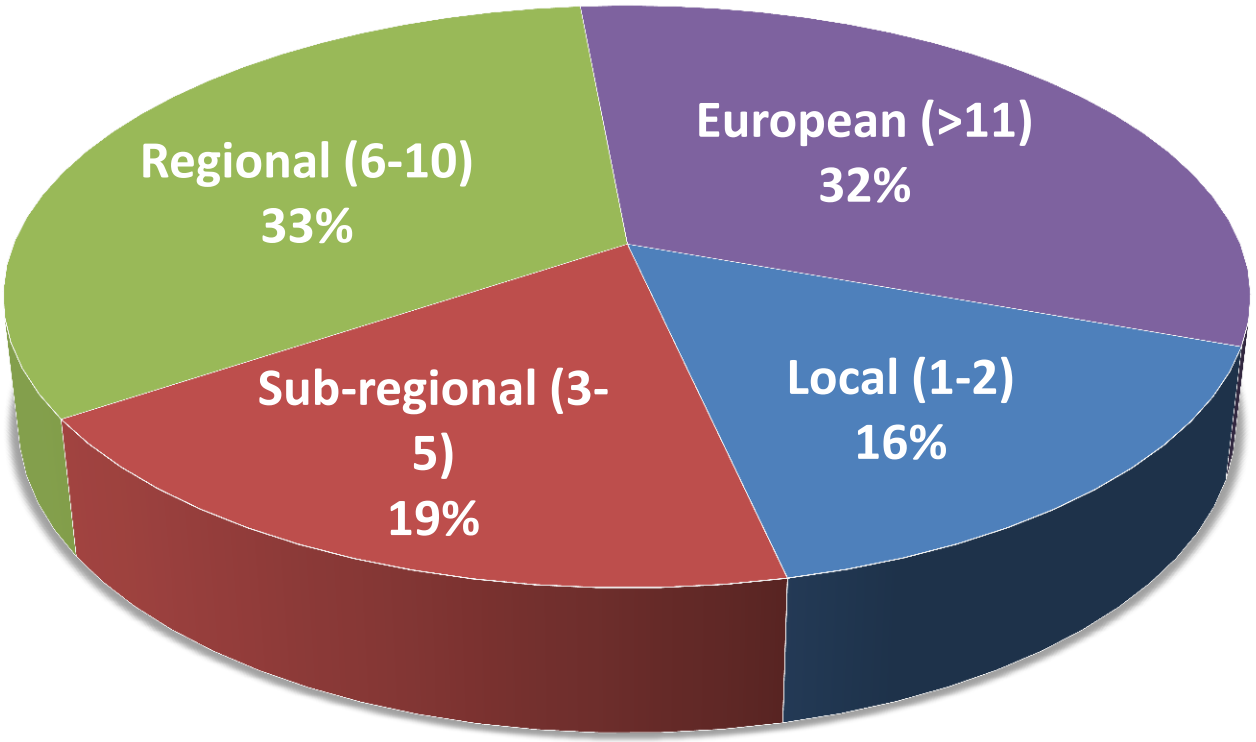
71% of products could be grouped in families

(1980 dossiers)



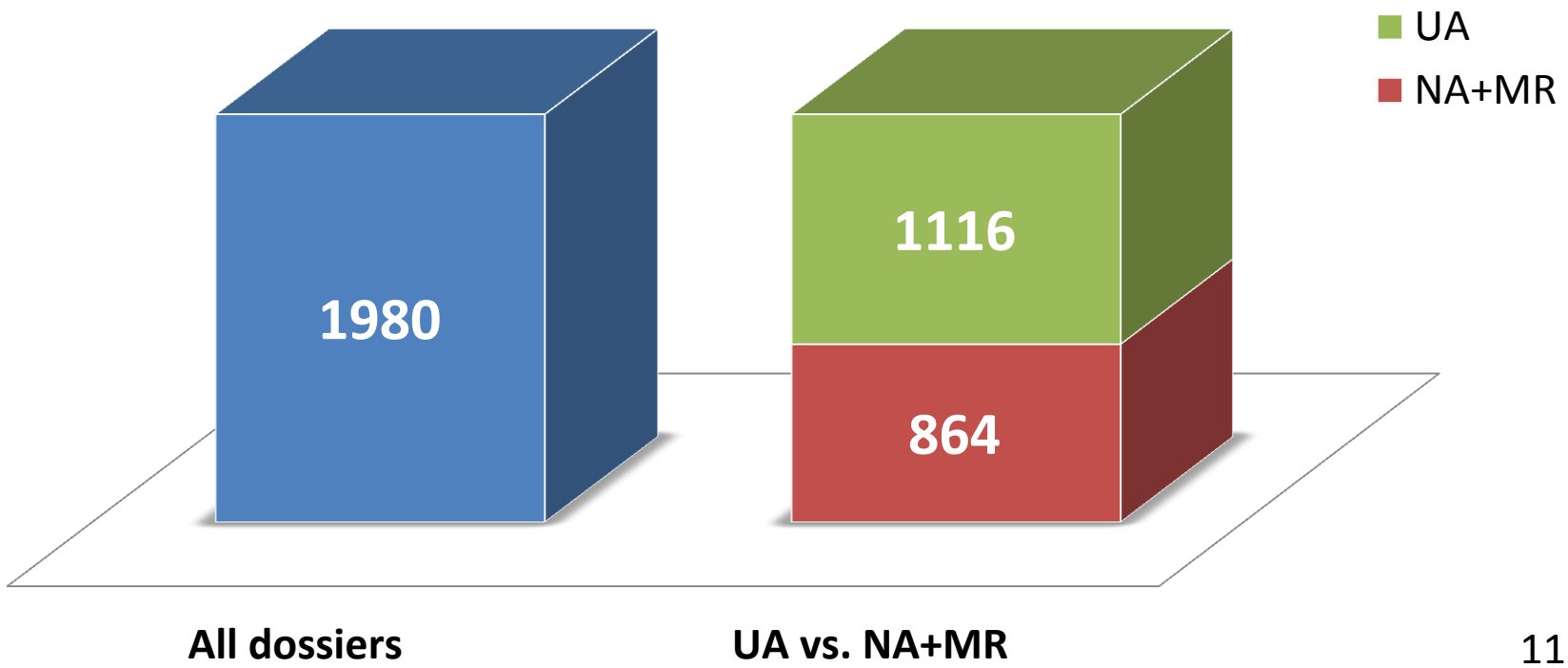
Market size

% of dossiers in different MS bands



Union Authorisation

56% of dossiers for Union authorisation



Same biocidal product authorisation

Objective: facilitate the easy authorisation of an existing product by a second company

- Regulation EU 414/2013, based on Art 17(7) of BPR
- Establishes the system of derived/duplicate authorisations, currently in place under many national systems
- Allows companies easy entry into the market based on existing authorisation of the same product
- “Mutual recognition between companies”

Same biocidal product authorisation

Opportunities:

- Companies can complement their portfolio and service with biocidal product without the heavy regulatory burden
- Focus of operation remains on providing best solutions

Simplified authorisation procedure

Objective : facilitate the marketing of products with lower concern – better profile with regard to HH and ENV

- For products with:
  - Active substances listed on (new) Annex I
  - Do not contain substances of concern, nor nanomaterial
  - Sufficient efficacy
  - No need to wear PPE

Simplified authorisation procedure

Opportunities:

- Faster process: evaluation within 90 days
- No requirement for Letter of Access to active substance dossier
- Once authorised in one Member State, notification to other Member States is sufficient
- **But**:
  - Concrete data requirements remain unclear

Conclusion and outlook

- The EU biocides regulatory scheme – BPD – places a heavy burden on industry and authorities
- The BPR introduces new opportunities and challenges
- A pragmatic use of the biocidal product family concept remains the best opportunity to decrease the regulatory burden
- Union Authorisation offers promise of streamlining and speed to market but there may be some constraints over its applicability

Conclusion and outlook

- Implementation is key
- There remains much work to be done in terms of providing guidance and clarity of processes in new areas
- Pragmatism and practical considerations need to prevail
- Continued dialogue among all stakeholders

Thank you for your attention

Raf Bruyndonckx
+32 2 676 7366
rbr@cefic.be