# WHAT TO EXPECT FROM ENFORCEMENT

Biocides Stakeholders' Day 26-27 September 2017

Francesca RAVAIOLI, BPR-SG Vice-Chair Ministry of Health – Italy General Directorate on medical devices and pharmaceutical service





## Key issues from stakeholders' day 2016

- Enforcement essential for:
  - Citizens: public health
  - Environment and sustainable use
  - Companies: fair competition
- Compliance and enforcement:
  - a shared responsibility
- Non-compliance from unintentional to deliberate
- Need harmonization and proportionality
- Treated articles a big challenge
- Biocides enforcement group ⇒ BPRS



## Forum BPR Subgroup (BPRS)

- In February 2017, EU COM officially handed over to **ECHA** (according art 76 ( $\ell$ ) BPR) the coordination of MSs' enforcement authorities and control activities on biocidal products
- ECHA established a new body <u>under the FORUM</u>:
  BPR Subgroup of the Forum for Exchange of information on Enforcement
- All the BPRS members have been appointed via the Permanent Representations
- Election of the BPRS <u>Chair</u>: Eugen ANWANDER (AT) & <u>Vice Chairs</u>: Dominik PISAREK (PL) & Francesca RAVAIOLI (IT) <u>EU COM representative</u>: Martinus NAGTZAAM
- The ECHA Forum Secretariat organized the meetings of the BPRS at ECHA: three meetings a year ~ March, June and November



#### **BPRS** identity

- BPRS has been established as a subgroup of the FORUM:
  - firm commitment to seek synergies and work in close coordination with the Forum for REACH, CLP and PIC
    - in particular work on common activities & joint outputs (back-to-back meetings)
- Strong link with European Commission
- Purpose of the group is to share experience, create synergies, identify tools for information exchange



#### **BPRS** tasks

[REACH Reg. art 77 (4)]

#### The Forum shall undertake the following tasks:

- (a) spreading good practice and highlighting problems at Community level;
- (b) proposing, coordinating and evaluating harmonised enforcement projects and joint inspections;
- (c) coordinating exchange of inspectors;
- (d) identifying enforcement strategies, as well as best practice in enforcement;
- (e) developing working methods and tools of use to local inspectors;
- (f) developing an electronic information exchange procedure;
- (g) liaising with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations;



#### **Enforcement process**





#### **BPRS-1** and -2 key results

- Working Group on "Prioritization of the BPR enforcement projects"
- Join the Forum Task Force on 'Best Practice Documents' to develop the BPR Essential requirements for enforcement
- Join the Forum WG REACH-EN-FORCE-6 to implement a project focused on the 'Classification and Labelling of biocidal products'
- Set the BPRS priorities by revising the Forum <u>Multiannual Work</u>
  <u>Programme 2014-2018</u> to include BPRS priorities
- Take over the Forum WG 'Implementation of Portal Dashboard for biocides' allowing inspectors access to data submitted to ECHA
- Revise the Forum <u>Rules of Procedure</u>



### Priorities for BPR enforcement

- BPRS WG "Prioritisation of the BPR enforcement projects"
- The WG is working on defining the scope of the first BPRS project
- a) Defining clear policy objectives and priorities
- b) Creating the necessary organization in order to be able to achieve effective, efficient, transparent and systematic enforcement of the Regulations.
- c) Performing actual enforcement measures, including compliance promotion, compliance enforcement
- d) Development and implementation of procedures for periodic progress monitoring and measurement
- e) Development and implementation of procedures for review, evaluation and update of the enforcement strategy, based on the monitoring procedures.



#### **Training for Trainers 2018**

Forum WG "Training for enforcement trainers"

 BPRS is considering to organise training for trainers who will train the BPR inspectors. The WG is defining the scope of such training, which may take place already in 2018.



### Implementation of PD-NEA

- BPRS WG on "Implementation of PD BPR"
- Objective:
  - Support the implementation of the PD BPR allowing inspectors access to data submitted to ECHA
  - Future timelines for expanding PD-NEA will be communicated in 2018
- Priority was given to the ECHA biocides dissemination project



#### **Next steps**

- Prioritisation of the next BPR enforcement project
- Update on the preparation of REF-6 & best practice documents
- Multiannual Work Programme BPRS activities 2017-2018
- Update on IT tools for BPR NEAs
- EU Commission Report in accordance with Article 65(3) of the BPR

# THANK YOU FOR YOUR ATTENTION

### ANY QUESTIONS?

Francesca RAVAIOLI, BPR SG Vice-Chair f.ravaioli@sanita.it

