Update on the collaborative approach

Agenda point 18 AOB

45th Management Board meeting
30 - 31 March 2017, Helsinki

Leena Ylä-Mononen
Director of Evaluation
European Chemicals Agency

Background

- Assessment of groups of substances is one of the major challenges starting from this year
- It requires adaptations of the traditional approach applied to individual substances
- It is an opportunity for testing new forms of collaboration between ECHA, MSCAs and registrants: the *collaborative approach*

From the proposal to expressions of interest

- Proposal at CAs Directors' meeting on 17 November 2016
- Discussion at Management Board on 13-14 December 2016
- ECHA invited MSCAs to volunteer to pilot projects (letter 22 Dec 2016)
- Interest expressed by:
  - **France**
  - **Germany**
  - **The Netherlands**
  - **UK**
- As observers
  - Ireland
  - Lithuania
  - Sweden
  - Bulgaria
  - Possibly some other MSCAs joining
- Preliminary contacts with registrants' associations, i.a. CEFIC, Eurometaux

Discussion in ECHA WS on the implementation of the Regulatory Strategy (28 Feb – 1 March)

- Workshop with 18 MSCAs, COM services, industry and NGO stakeholders
- Key topic: Role of grouping in addressing substances for further action, including collaborative approach
- General agreement on the need of addressing substances in groups
- Need to be clear and transparent what is the role of the informal interactions vs. the official evaluation processes

Discussion in:
MSCAs workshop on practicalities of the grouping approach (1 March)

Basic principles of the collaborative approach (COLLA) discussed

- COLLA explores the best way to apply our regulatory processes when addressing substances by groups
- Review of relevant experience from similar approaches
- Links with ongoing activities (manual screening, ongoing or planned evaluations / RMM dossier preparations) clarified

Preparation of the pilots

- Outline of practical implementation pilots of collaborative approach
- Key aspects to consider when choosing the pilot groups – relevance and feasibility
- Discussion on the candidate groups identified by ECHA or by MSCAs

CARACAL 22-23 March

- CARACAL (for the first time) discussed and endorsed the proposal for the pilots,
- CARACAL emphasised
  - the purpose of acceleration of getting adequate data on the (groups of) substances
  - the importance of boundaries, i.e. the approach shall not interfere with or delay regulatory processes
  - the need to review the learnings of the pilots after the one year period.
- The selected groups have been communicated in the open session

Confirmation of groups of substances by MSs

Germany:

- **Antimony compounds**, 8 registered substances
- **Polyol acrylates**, 7 registered substances

UK (Sweden):

- **EDTA derivatives group**. UK interested in a subgroup of the 21 substances. SE will be "observer" and will also screen substances not covered by UK

France:

- **Substituted diphenylamines**, 8 registered substances

NL:

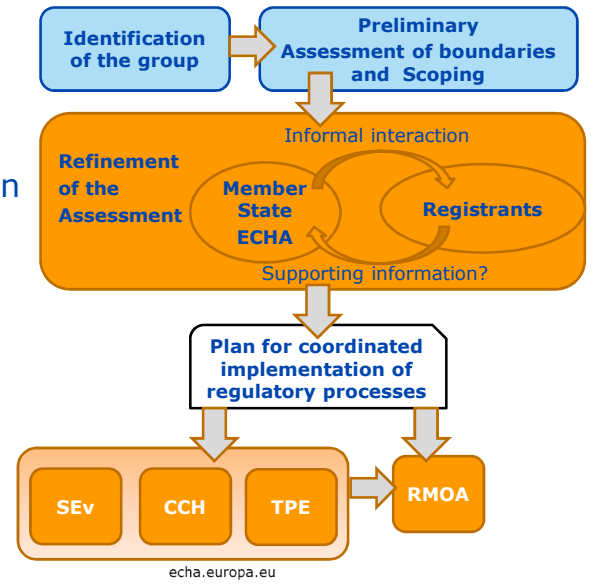
- Selection of group postponed to beginning of May, but ready to start contributing to the concept development and organisation.

Ireland, Lithuania and Bulgaria as observers: which groups to be decided.

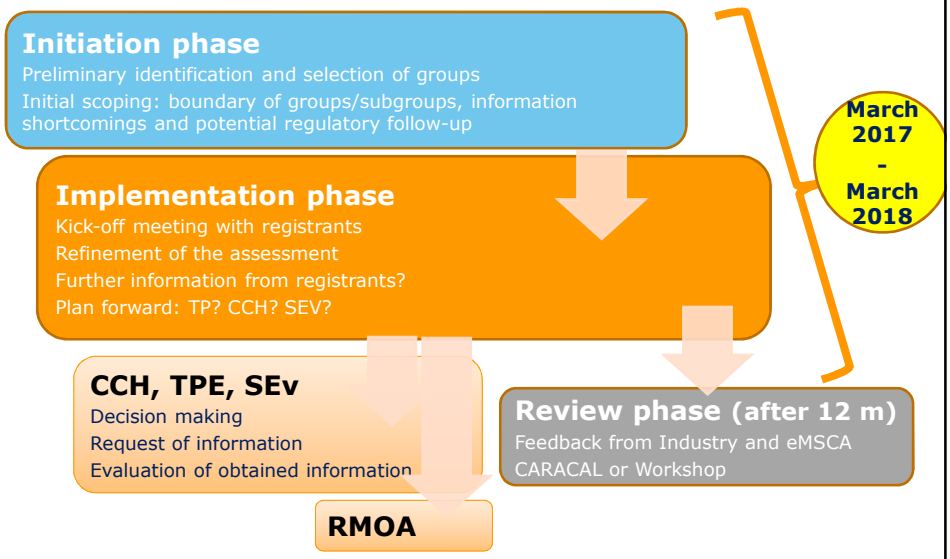
Collaborative approach

Initiation phase

Implementation phase



Phases of pilots and time schedule



State of play and next steps

Positive start:

- Critical number of volunteering MSCAs
- General interest to experiment and learn

Key challenges:

- Resources
- Timing
- Link to all other ongoing work and priorities

Next steps:

- Completion of groups allocation (e.g. NL, observers)
- ECHA indicates contact group manager and establishes supporting group
- MS starts performing manual screening (template provided)
- ECHA facilitates preliminary contacts with registrants
- By end of initiation phase: kick off- meeting MSs, ECHA, Registrants

Action requested

- The Management Board is invited to take note of the current status and comment as appropriate.

Background and further information