European Commission

Status of simplification of applications in specific cases

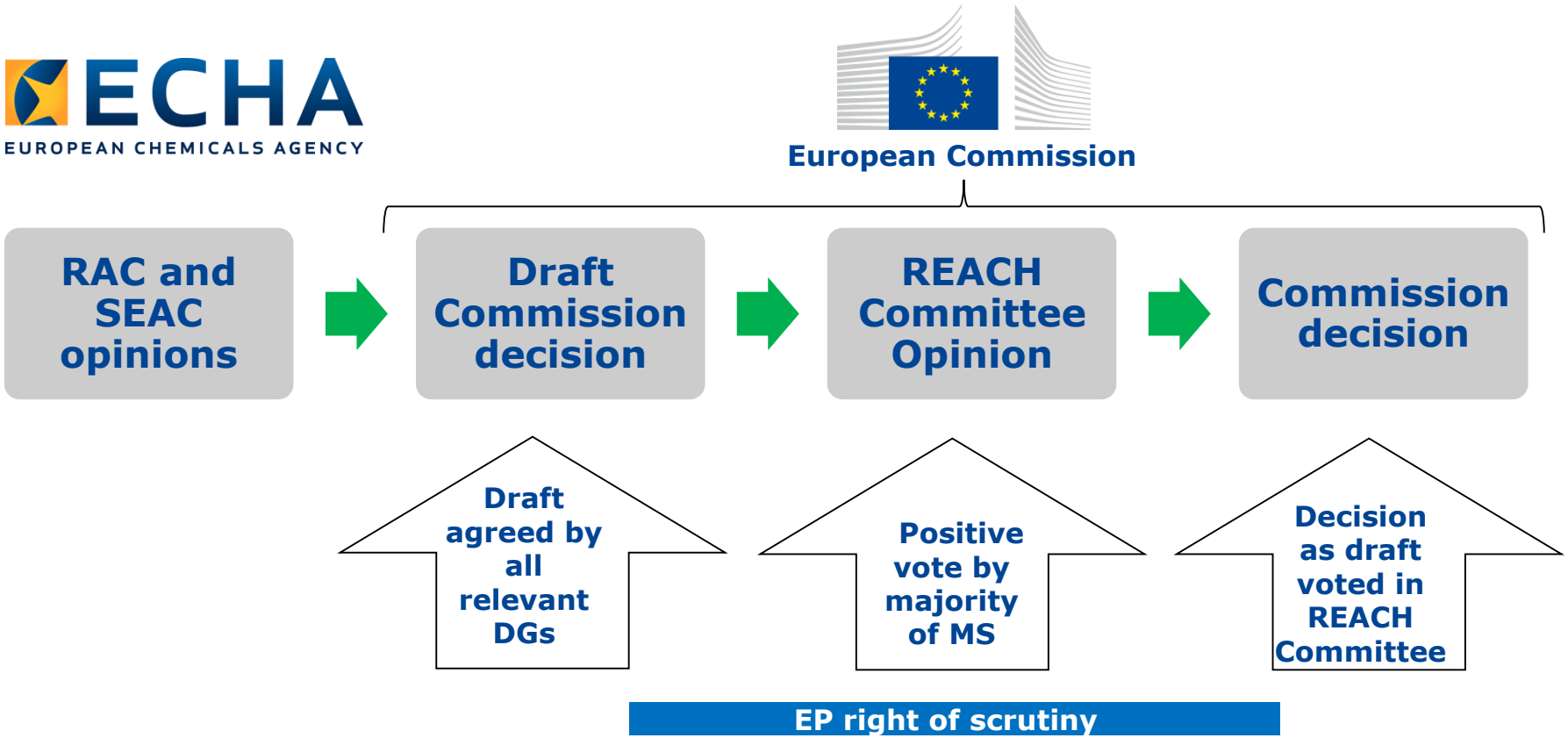
Workshop – Streamlining Applications for Authorisation

Brussels, 17 November, 2015

Anna Borràs
Unit D1 - REACH
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
European Commission

REACH Authorisation: Where are we?

1) The process



REACH Authorisation: Where are we?

2) The Commission's experience so far

- Seven Decisions adopted (DEHP, DBP, diarsenic trioxide)
- Two draft Decisions in final adoption stages (positive opinion in REACH Committee) (trichloroethylene, HBCDD)
- Draft EP Resolution calling on COM to inverse intention of one draft Decision (DEHP)
- 18 applications/opinions pending (DEHP, DBP, lead chromate and lead chromate pigments, trichloroethylene)
- Transparency: draft Decisions publicly available via Comitology Register

REACH Authorisation: Where are we?

- **Each case is different**, often more complex than not: need to address questions along the way, e.g.:
  - Clarification in which cases risks for human health has to be assessed for PBT substances
  - Interface between REACH and other EU legislation (waste legislation, POP Regulation)
  - Changes in the legal entity
  - New evidence subsequent to RAC and SEAC opinions
- **Upstream AfAs** present most challenges:
  - Making a risk assessment that is sufficiently representative of the DUs concerned
  - Defining the use in a sufficiently specific way to be able to clearly identify and assess the potential alternatives

REACH Authorisation: Where are we?

- **Conclusion:**

Preparing and processing an AfA is no easy ride

  - COM's intention (REFIT 2014 and 2015 Communications):
    - to simplify the authorisation process for some specific cases and
    - to increase the predictability of the process
  - AfA Task Force set in place in September 2014 to develop proposals for streamlining and simplifying AfAs.

Paving the way: for applicants, interested parties and authorities

- **Simplifying AfAs in specific cases:**
  - Where risk is expected to be low (low quantities)
  - Where substitution is not feasible (legacy spare parts)
- **Making AfAs fit-for-purpose:**
  - Identifying not only what is needed, but also what is NOT needed in an application
  - First concrete discussions on “process chemicals”
  - Need of additional guidance?
- **Making the fees fit-for-purpose:**
  - Reducing the fees for simplified AfAs
  - Eliminating the additional fee per each additional applicant in joint AfAs
  - Increasing the fee per each additional use

The way ahead

1) AfA simplification for uses in low quantities

- Rationale: too high costs of applying for authorisation compared to potential risk
- Scope:
  - Total maximum 100 kg per applicant p.a. (for all uses) and 100 kg p.a. per user (for all uses and supplies)
  - Excluded uses:
    - uses in mixtures for supply to the general public containing the Annex XIV substance above the Article 56(6) limits
    - incorporation in articles for supply to the general public
- Reduced level of detail required in AoA and SEA (but remaining within the framework of Article 62 REACH)
- Timing: draft to be finalised end of 2015, Implementing Regulation to be adopted in 1st quarter 2016

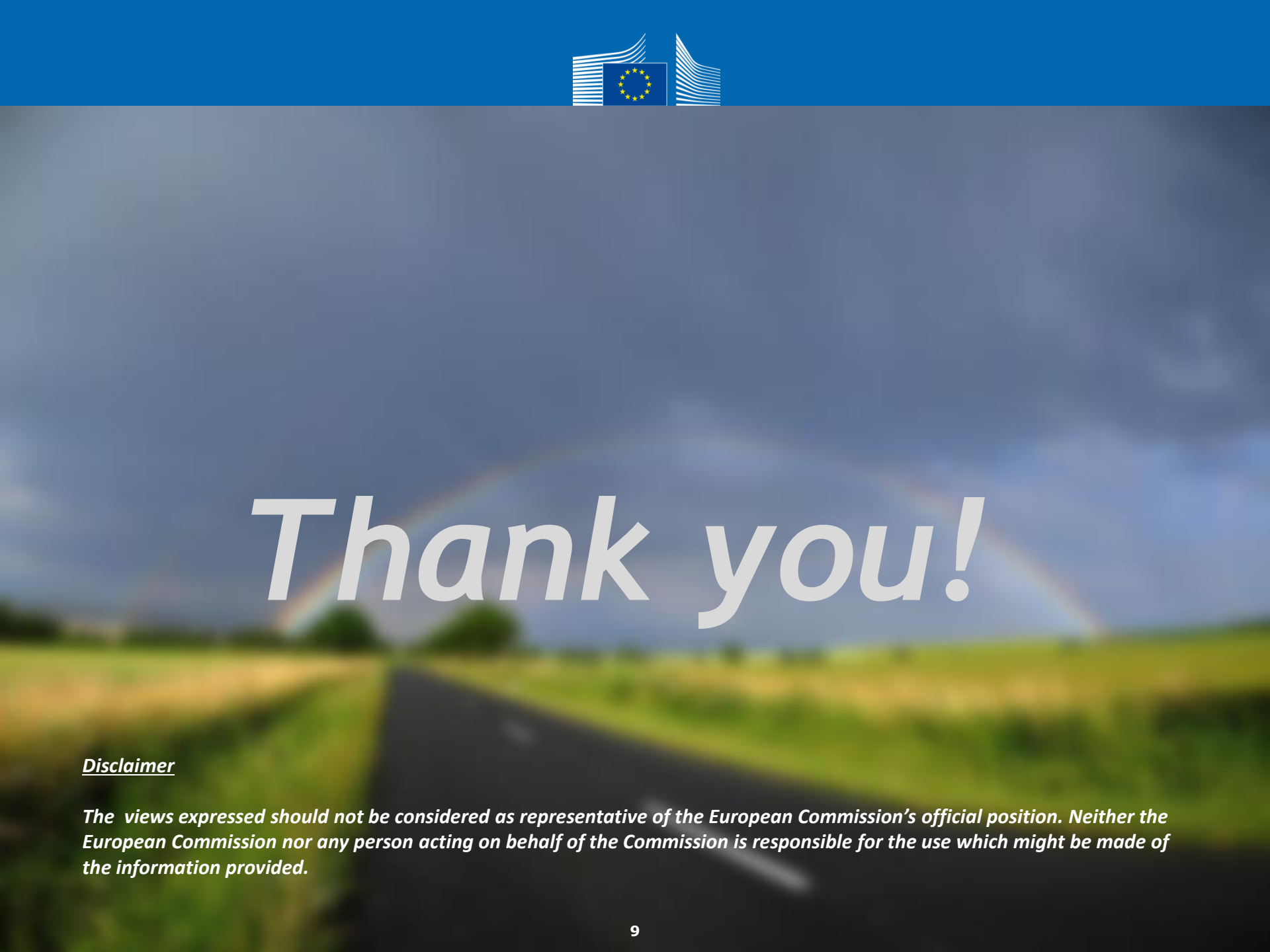
The way ahead

2) AfA simplification for uses in legacy spare parts

- Rationale: technical / economic constraints to substitute substances in legacy spare parts, i.e. intended for articles no longer produced after the sunset date and need to ensure availability of spare parts to prevent early disposal of such articles
- Scope: still under discussion whether to cover mixtures intended for the repair of no longer produced articles
- Timing: two-step approach:
  - one-time extension of LAD/SD for substances concerned (1st quarter 2016)
  - development of a simplified AfA (2016)

3) General streamlining of all cases

What have we learnt from the experience gained in the assessments by RAC and SEAC? Need to reflect it into guidance available to all?



Disclaimer

The views expressed should not be considered as representative of the European Commission's official position. Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the information provided.