REACHing the 2020 goals

Break-out group 4

Regulatory Risk Management (2)

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Risk Management Option

- Policy steer is needed, but no high expectation that it would be achievable in the short term
- Scope of RMOA as currently practiced is agreed (i.e. wider than REACH only)

- Earlier agreement that an early "impression" of socio-economic consequences (both costs and benefits) should be looked at is still valid, but further discussion on the nature and depth of analysis is needed, recognising the potential information assymetries resulting from the fact that this is a voluntary process. Both consequences of action and of inaction should be looked at; this can include costs if desired.

RiME should assess current practice in reflecting socio-economic consequences in RMOAs and suggest any necessary adaptation.

Risk Management Option

- Key deciding factors in RMOAs should be made more explicit, and discussion should be initiated on the type of information needed for decision-making. These should then be communicated to stakeholders allowing them to feed the decision making process. This could increase transparency on decision making as well as clarifying information gaps

  First analysis to be made by RiME, and then brought to CARACAL as appropriate

Completion of SVHC Roadmap

- The machinery is in place. Tools and coordination mechanisms are sufficient and should be used

- We need better information on uses in order to focus on substances that matter and have highest and most efficient impact of regulatory action. Recommendations from groups on themes 1 and 2 should support improving the situation in this respect.

- We should be clearer on what we want to see for substances in PACT.

  - *MSs who are initiating the development of an RMOA should clarify towards stakeholders that they are seeking for information, including any specific types of data.*

  - *ECHA and MSs to look at practical implementation.*

Upstream Applications for Authorisation (1/2)

- We have to deal with them, they are there on purpose.

- For upstream applications but equally for the others, *ECHA should clarify to applicants (and consultants) what information (nature and quality) is expected*, so that
  - the circumstances of potential rejection can be clarified, and
  - RAC/SEAC efficient opinion-making is supported.

  Where are the limits? These could be different for upstream and other applications.

  Implementing act? Update guidance? Instructions? Check list?

Upstream Applications for Authorisation (2/2)

- *Further discussion is needed amongst authorities on what is the most effective way of achieving safe use: requiring detailed use descriptions for DUs in upstream applications, or setting additional operational conditions in the decisions?*

Restriction (1/2)

- *To consider using restrictions for a wider range of issues. E.g. MSs could consider restrictions for uses advised against.*

- Restrictions can also have an impact on safer use of chemicals outside the EU (e.g. through substances in articles).

- The scope of restriction can include preventive action. Grouping from hazard or use perspective? Including alternatives from the start to avoid regrettable substitution (e.g. D4/D5)?

Restriction (2/2)

- Burden to gather information on costs and impacts for developing RES proposals is still perceived to be high.

- Are we prepared to accept a different level of evidence for introducing restrictions
  - e.g. on Annex XIV substances in articles?
  - for "obvious" cases (e.g. sensitizers in tattoo inks)?
  - can we accept that missing information in Annex XV dossier (after making genuine effort) is expected to come later in the process (e.g. public consultation)?

What policy steer would be needed?

Substances in articles

- *A workshop between MSs, COM, ECHA and stakeholders is recommended to agree on means to ensure better compliance and understanding of SiA.*
  Issues for consideration could include:
  - develop complementary means to get information on substances in articles
  - more enforcement (NEAs)
  - cooperation with non-EU countries
  - focus on key sectors (e.g. children articles)
  - information campaigns on 0.1%
  - common format for reporting uses in articles in supply chains

- This discussion should feed the policy discussion on the interrelationship between REACH and the circular economy