FCM & coherence with REACH

Member States' Experts Working Group on FCM of SC-PAFF

3 May 2019

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion and understanding of existing and potential new legislation as well as ongoing activities, but should not in anyway be seen as giving a final interpretation of existing legislation or a proposal of new legislation.

What is REACH?

➡ Regulation (EC) No 1907/2006 of the EP and of the Council of 18 December 2006 concerning:

- Registration
- Evaluation
- Authorisation and Restriction of CHemicals

Preparatory work started in 2001…

… entered into force on 1 June 2007

Aim and scope of REACH

- ☑ ensure a high level of *protection of human health and the environment*
- ☑ reduce animal testing
- ☑ *free circulation of substances on the Internal Market*
- ☑ *enhance competitiveness and innovation*

Registration

Manufacturers and importers must:

- Gather information on their substances and use this knowledge to ensure responsible and well-informed management of the risks these substances may present throughout their life cycle
- Register substances used in quantities above 1 tonne per year.
- Information requirements depend on the tonnage band concerned (1-10t, 10-100t, 100-1000t, 1000t+)

Registration – a staggered process

Evaluation

- Dossier evaluation (ECHA):

  Checking compliance of registration dossiers (5% of dossiers)

  Checking of testing proposals: is animal testing needed? (100% of dossiers >100 tonnes)

- Substance evaluation (Member States):

  Checking whether there is a need for further information on a substance based on initial concerns

Authorisation

***Aim**: Assuring that risks from Substances of Very High Concern (SVHCs) are properly controlled and that SVHCs are progressively replaced by suitable alternative substances/technologies where these are economically and technically viable.*

- *Applies to the use of a substance on its own/in a mixture or to the incorporation of the substance in an article*
- *Imported articles containing SVHCs are not affected*
- *Applies to the use of food contact materials only for environmental hazards*
- *For substances listed in REACH Annex XIV*

Authorisation – how does it work?

Universe of chemical substances

- MS or ECHA (for COM) prepares dossier for SVHC-identification
- Public consultation
- Decision in MSC or REACH Committee

REACH Candidate List (all identified SVHCs)

- Prioritisation: Decision by COM/REACH Committee to move substances forward

Annex XIV: List of substances requiring authorisation

Authorisation – how does it work?

SVHC-identification

- Human health hazards
  - CMR cat. 1A/1B
  - Equivalent level of concern: e.g. endocrine disruption (human health), STOT RE, sensitizers, …
- Hazards to the environment
  - PBT or vPvB (persistent, bioaccumulative, toxic)
  - Equivalent level of concern: e.g. endocrine disruption (environment), …

Food contact material: authorisation required only if identified for hazard to the environment and moved to Annex XIV

Authorisation – how does it work?

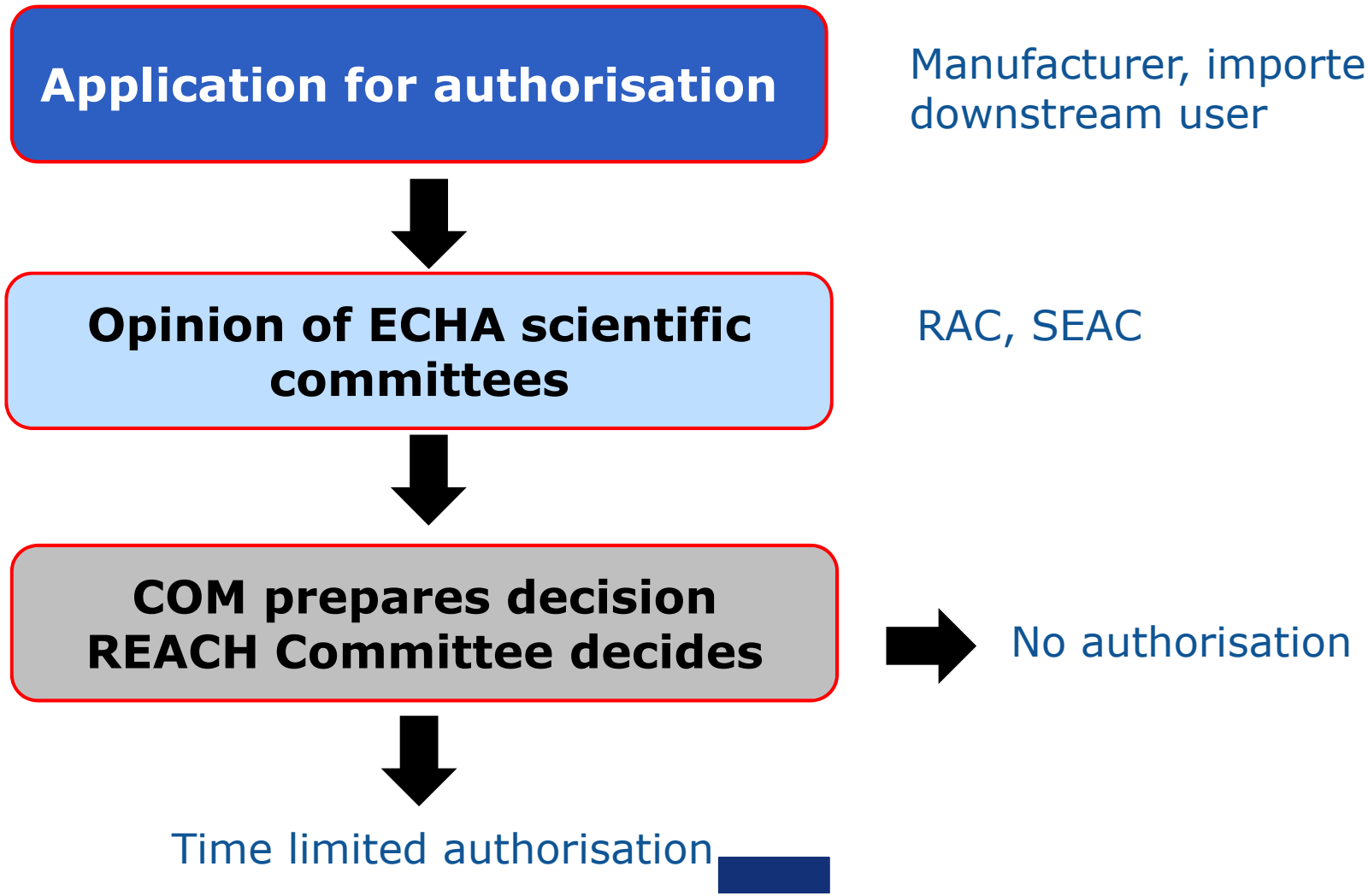
Candidate List (all identified SVHCs)

- Currently 197 substances
- Triggers obligations for suppliers
  - Supplying a safety data sheet
  - Communicating on safe use; response to consumer requests
  - Notifying ECHA if an article contains an SVHC

Authorisation List (REACH Annex XIV)

- Currently 43 substances
- Manufacturer, importer or downstream user need to apply for authorisation for the (further) use of a substance

Authorisation – how does it work?

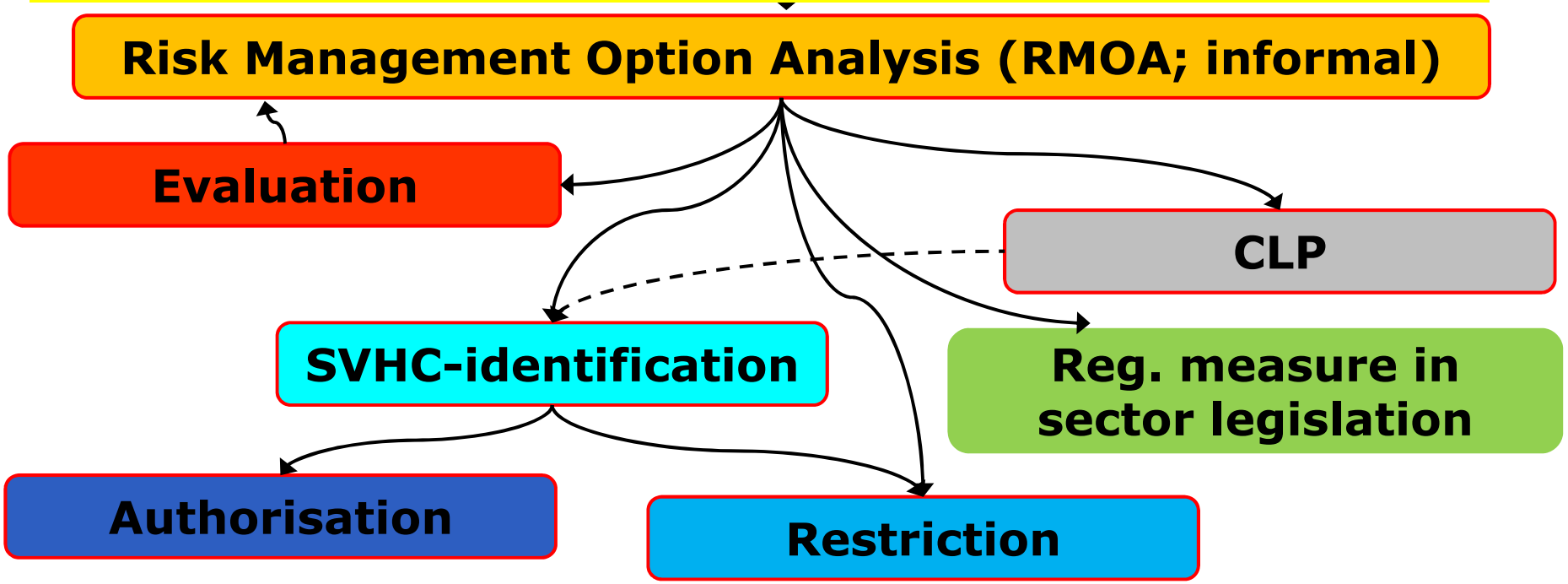


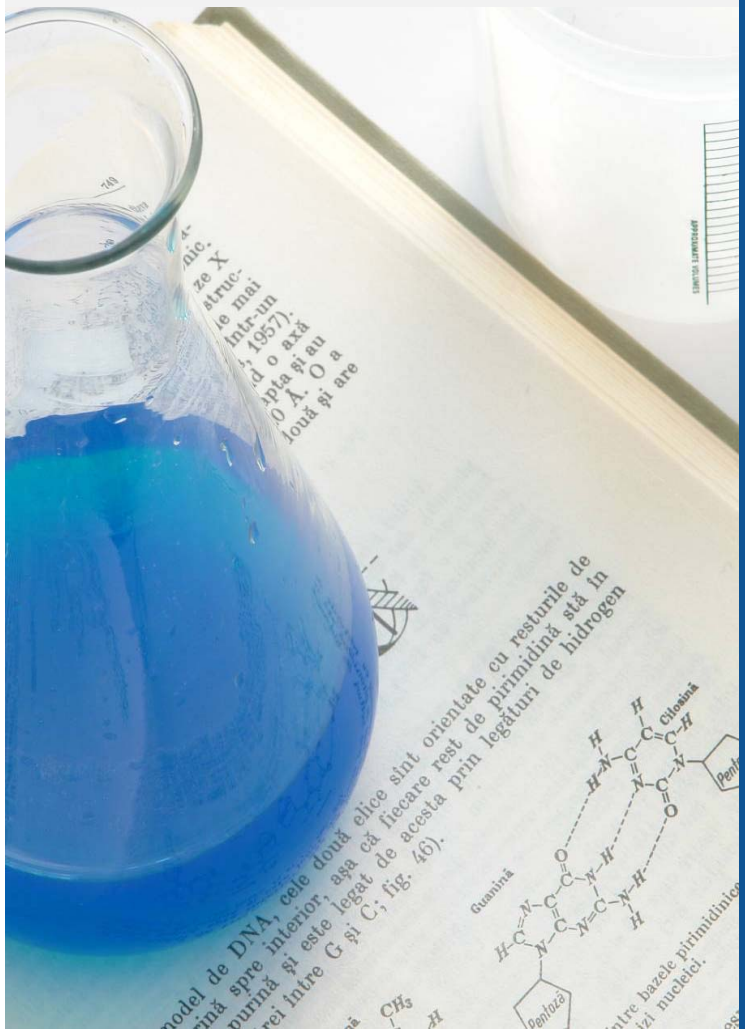
Restriction

Aim:*Control at EU level if risks not adequately controlled.*

- *Limits or ban manufacture, placing on the market or use of a substance (on its own/in mixtures or articles)*
- *Applies to both domestic production and imports*
- *Applies to the use of food contact materials (unless exemption included in restriction)*
- *Restrictions are listed in REACH Annex XVII*

Consider use in FCM early on – during RMOA!!





Thank you!

Further information:

- **https://ec.europa.eu/growth/sectors/chemicals/reach_en**
- **echa.europa.eu**

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FCM links with REACH Regulation 1907/2006

Recital 12 of FCM Regulation 1935/2004

When specific measures include a list of substances authorised within the Community for use in the manufacture of materials and articles intended to come into contact with food, those substances should undergo a safety assessment prior to their authorisation. **The safety assessment and authorisation of those substances should be without prejudice to the relevant requirements of the Community legislation concerning the registration, evaluation, authorisation and restriction of chemicals.**

FCM links with REACH Regulation 1907/2006

Substances used in FCMs are generally in the scope of REACH. However, some exemptions apply:

Registration and notification of substances: REACH chemical safety report does not need to include considerations of the risk to human health from the use in FCM.

FCM and REACH Data requirements

REACH

- **1 t < Production < 10 t**

Ames (+ follow-up if positive), acute toxicity (oral), skin and eye irritation, skin sensitisation

- **10 t < Production < 100 t**

in vitro gene mutation, chromosome aberration, 28 day study (rat), (existing) toxicokinetic data, acute toxicity (2nd route), reprotox screening study

100 t < Production < 1000 t

reprotox, development tox, in vivo genotoxicity (if in vitro positive), 90 day study

- **Production > 1000 t**

carcinogenicity + chronic toxicity (concern-based), developmental tox (2nd species)

FCM

- **Migration < 50 ppb**

Ames, gene mutation, chromosome aberration

- **50 ppb < Migration < 5 ppm**
  - 90 day study (rat)
  - bioaccumulation
  - (toxicokinetic)
- **5 ppm < Migration < 60 ppm**

chronic toxicity, carcinogenicity, reprotox, developmental tox, 2 year study (rat)

FCM links with REACH Regulation 1907/2006

Authorisation of substances (Annex XIV): Those classified for CMR properties or posing human health hazards of equivalent concern are exempt – however they are subject to authorization for environmental concern e.g. persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) or fulfilling the criteria under Article 57 (f) such as EDC for the environment

There are currently no authorised substances in plastic FCM that are listed in Annex XIV of REACH for environment or PBT/ vPvB reasons

However additional classification e.g. EDC for environmental concerns means that this may change

FCM links with REACH Regulation 1907/2006

***Restrictions (Annex XVII)**:* No general exemption for FCMs from REACH restrictions concerning the manufacturing and use of substances or placing on the market of articles, unless a specific exemption is stated in Annex XVII or the restriction is not relevant

Examples of restrictions applicable to FCM:

- Phthalates (DBP, BBP and DEHP): childcare feeding articles
- Cadmium: plastic articles, metallic equipment for food
- PAHs: plastic drinking utensils and domestic appliances
- PFOA: in all articles

Examples of specific <u>exemptions</u> applicable to FCM:

- Lead
- Organostannic compounds
- Phthalates in other plastic FCMs besides childcare feeding articles

Use of information under REACH

Recent examples of examination of new REACH information

- Commission mandate concerning phthalates (DBP, BBP and DEHP +DINP and DIDP) – new reprotox data
- Commission mandate concerning BPS - EFSA to work on new tox data with ECHA and rapporteur Member State

Legal requirement for business operators:

- Article 11 (5) states "The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance shall immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, the Authority shall then review the assessment.

Use of information under REACH

Examination of relevant information under REACH

- Substances subject to
  - Authorisations
  - Restrictions
  - Candidate list of SVHC or equivalent
  - Evaluation under CoRAP
- What information is new or subsequent to the scientific assessment on which the FCM authorization is based and is it relevant for this FCM authorization?
- Possible use to prioritise substances currently without SML

Non-REACH chemicals legislation relevant to FCM

Regulation of same substances

- *Biocides – direct links to FCM*
- *Toys*
- *Cosmetics*
- *Drinking water*
- *Medical Devices*