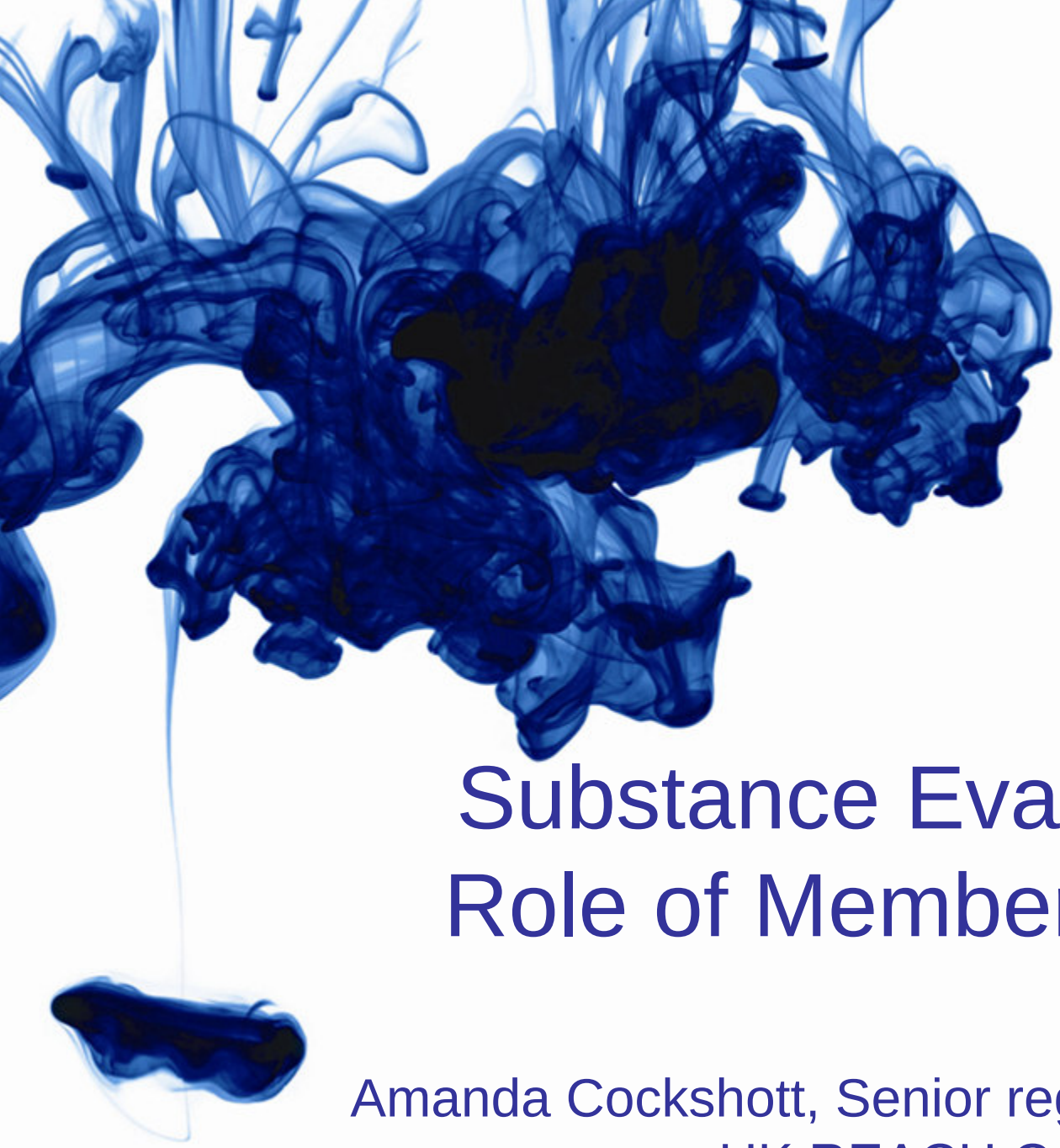

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Substance Evaluation: Role of Member States

Amanda Cockshott, Senior regulatory scientist
UK REACH CA

Overview

The Process – main steps to include

- **Scope**
- **Deadlines**
- **Deliverables**

Interactions between the evaluating Member State (MS) &;

- **Registrants**
- **Other MS**
- **ECHA**

UK experience to date

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The Process

Scope – Clarification of suspected risk

Evaluation - comprehensive vs targeted

Art. 47(1) – …..*In cases* ***where a decision on an evaluation has been previously taken in accordance with Article 51 or Article 52****, any draft decision requiring further information under Article 46 may be justified only by* ***a change of circumstances or acquired knowledge***

Focus on initial concern + screen other areas

Substance selection

- Proposed by the MS - work done previously
- Selection from the CoRAP candidate list

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Evaluation and outcomes (within 12 months)

MSCA evaluates information (registration dossiers & any other sources)

Concern(s)?

No → No further action needed

Yes → Action needed to reduce confirmed risk

STILL UNCERTAIN → Need further information to clarify concern(s)

MSCA produces evaluation report

Additionally;

MSCA produces draft decision

Deadline exceeded – evaluation deemed to be finished (Art. 46 (4))

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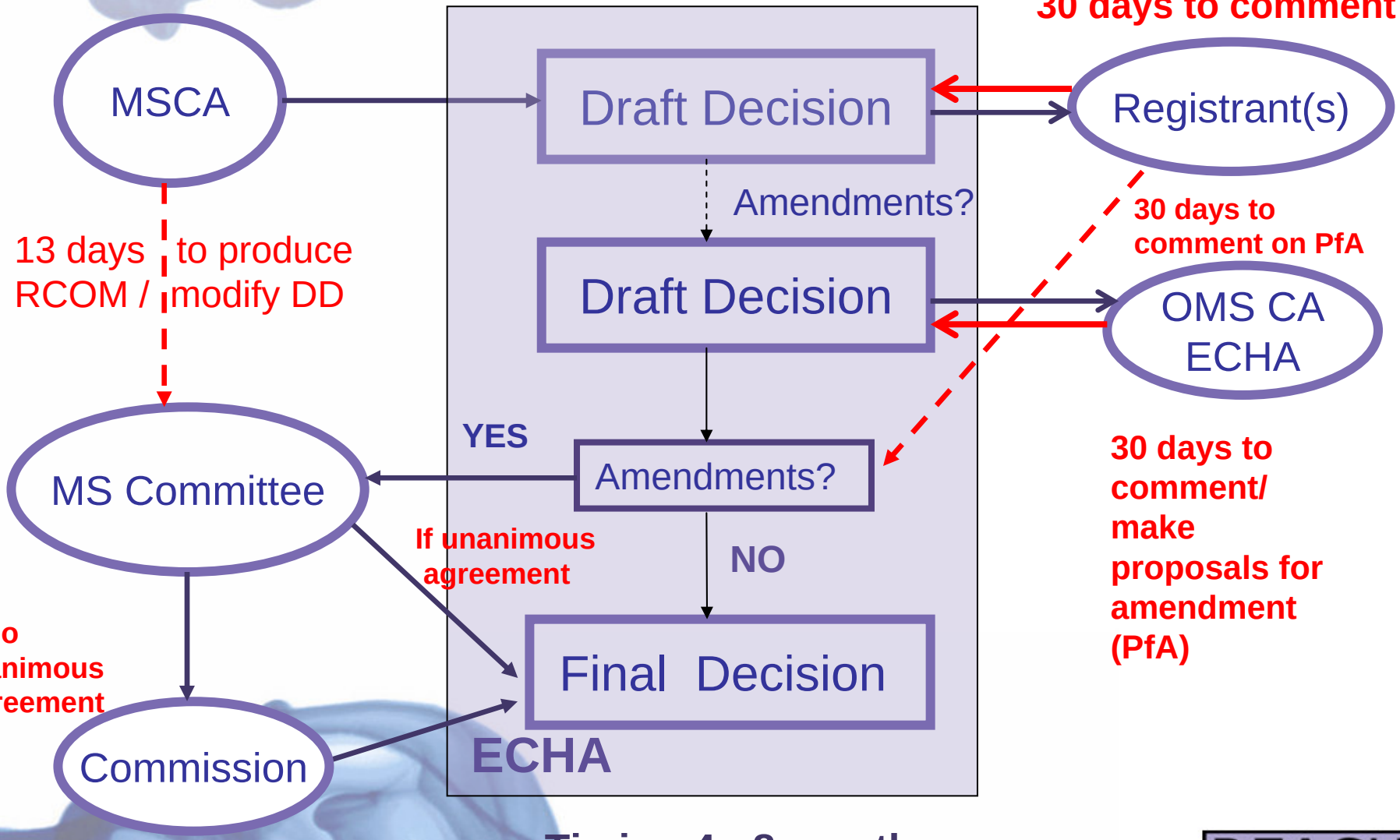
Decision procedure under Substance Evaluation



Timing 4 - 8 months

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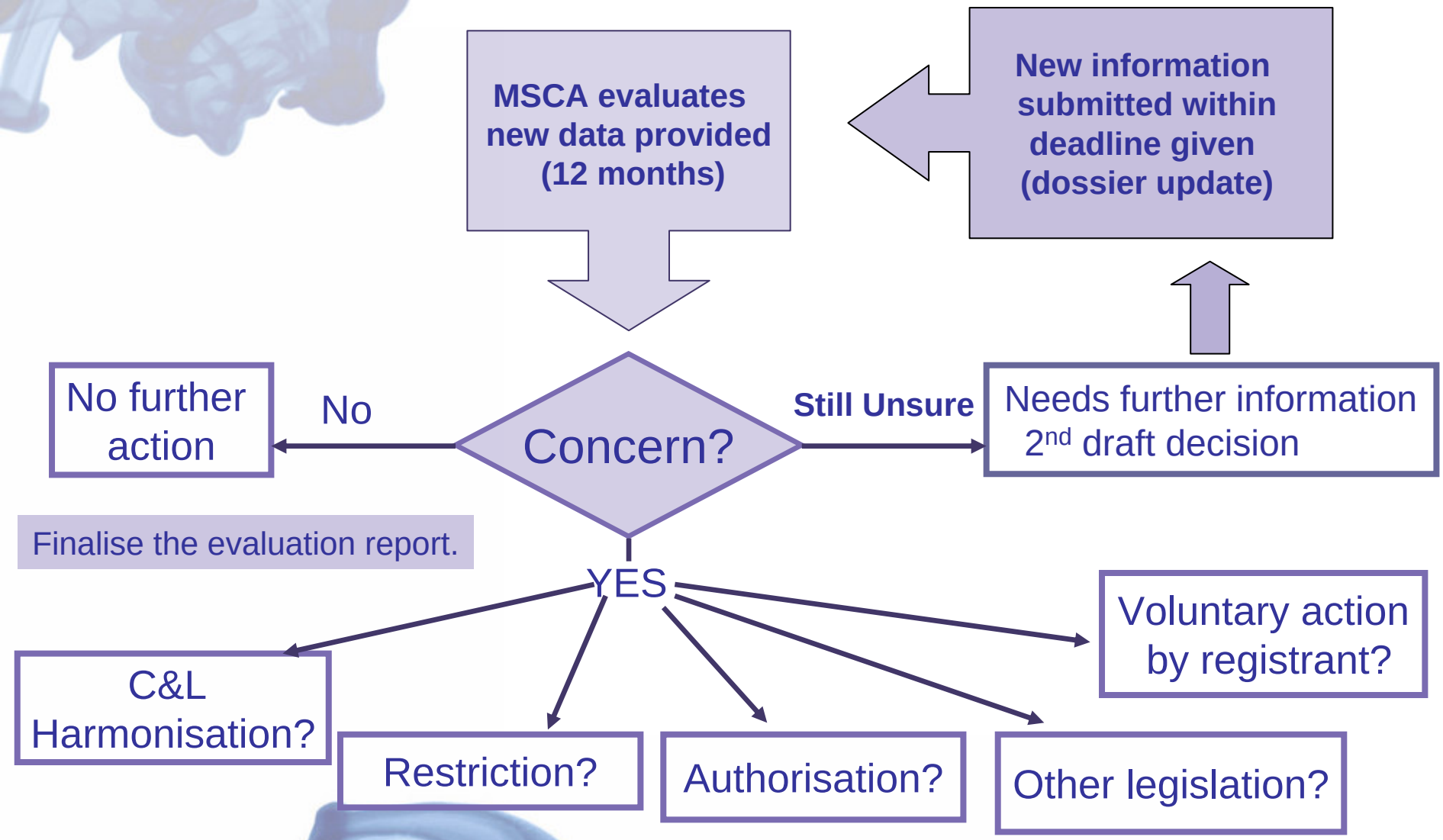
Follow up to Substance evaluation



The MSCA informs ECHA of its conclusions as to whether or how to use the information obtained **(Art. 48 – Follow-up)**
ECHA informs the Commission, the registrant and the OMS CAs.

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Interaction with Registrant(s)

Formally – opportunity to comment on a draft decision

Value of a co-ordinated response from registrants

Informally – Registrant(s) can contact the MS

(details on the CoRAP)

– MS can contact registrant(s)

Issues with submission of updates/pending studies

Work on-going on a harmonised policy across MS

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Interaction between MS

Joint evaluations – collaboration between MS

Commenting – formally only on a draft decision
- No peer review of documents

Information sharing – particularly where registrants are in another MS

Harmonised approach – workshops, commenting on documents

Informal discussion groups?

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Interaction with ECHA

ECHA have a co-ordination role
- Ensuring a harmonised approach
- organising guidance, workshops etc

Specific contact person in ECHA allocated for each substance

Preparation of the CoRAP
– screening activities

Updating prioritisation criteria

Preliminary experiences to date

UK substances for 2012

UK	206-019-2	288-32-4	Imidazole	Human health/CMR; Exposure/Wide dispersive use, high tonnage
UK	284-366-9	84852-53-9	1,1'-(ethane-1,2-diyl) bis[pentabromobenzene] (EBP)	Environment/Suspected PBT; Exposure/Wide dispersive use, high aggregated tonnage
UK	287-477-0	85535-85-9	Alkanes, C14-17, chloro (MCCPs)	Environment/Suspected PBT; Exposure/Wide dispersive use, high aggregated tonnage

2012/13 – UK Proposed timeline

12 months evaluation period – 1st March 2012 to 28th Feb 2013

Evaluation of information by UK REACH CA team

- Registration dossiers and any other information

(Informal correspondence where appropriate)

Finalising the Report & draft decision

Submission of report to ECHA

***Set date after which no further information can be taken into account**

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Summary

New process – limited experience

Tight deadlines – limited flexibility

Opportunities to communicate/ collaborate – ensuring a harmonised approach.

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Thank you

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