BUNDESINSTITUT FÜR RISIKOBEWERTUNG

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Bundesinstitut für Risikobewertung

CLP Annex VIII - Workability Issues

Study on workability issues concerning the implementation of Annex VIII of Regulation (EC) No 1272/2008 on harmonised information relating to emergency health response and preventative measures

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BfR Unit Exposure Assessment of Mixtures

2018-11-19

Overview

1. Update on ‚Study on workability issues …‘
2. Description of problems identified so far by BfR

1 Update on ‚Study on workability issues …'

Main reference of this presentation:

Wood plc (Contractor):

Study on workability issues concerning the implementation of Annex VIII of Regulation (EC) No 1272/2008 on harmonised information relating to emergency health response and preventative measures

Project summary - 13 November 2018

(submitted to BfR on 2018-11-15)

- Study Contract in summer of 2018
- Contacting industry started in September 2018

About Contracting Company - Wood plc

- **Wood plc** previous names AMEC and Amec Foster Wheeler
- *"A global leader in technical, engineering and project services"*

en.wikipedia:

- public limited company
- founded 1982
- headquarter in Aberdeen, Scotland
- products: Oil and gas engineering, production support, gas turbine
- Website: www.woodplc.com

Study background

- During late discussions on legal proposal several sectors raised potential workability issues
- Some (paints, perfumes) were taken up in the proposal e.g. on generic product identifier (GPI)
- Very late concerns raised by petroleum, construction products and industrial gases sectors
- Agreed in REACH Committee to vote on the legal proposal provided that Commission studies the workability issues and Regulation is amended if necessary

Study Design

4 Tasks

Task 1: Workability issues of certain provisions of Annex VIII

Task 2: Mixtures in mixtures

(evaluate Safety Data Sheet (SDS) Information as part of submission)

Task 3: possibility of an EU toxicovigilance system (!)

Task 4: workshop

Task 1: Workability issues of certain provisions of Annex VIII

- Assess correctness of specific workability issues (petroleum products, industrial gases, construction products, commodity chemicals formulation, paints, perfumes)
- Estimate costs to businesses, benefits for emergency health response and case studies setting out challenges involved
- Identify options to address the workability issues and assess their costs and benefits

Task 2: mixtures in mixtures

- ‘Original mixtures’ … integrated by a downstream formulator into a mixture for consumer/professional use (‘final mixture’) considered as mixtures for consumer/professional use
- Information in Safety Data Sheet (SDS) may be sufficient in some such cases
- Describe main supply chains affected
- Analyse information on composition in SDS vs full MIM provisions in Annex VIII
- Overview of supply chains where information in SDS is and is not as detailed as under MIM provisions
- Analyse experiences from national notification schemes with detailed information requirements for such mixtures

Task 3: possibility of an EU toxicovigilance system

- Compare existing national systems (types of products, links with other systems, frequency of analysis, etc.)
- Identify specific actions taken at national level as a result and impact on incident numbers/severity
- Develop options for an EU-wide toxicovigilance system

Task 4: Workshop

- Half way through study (targeted for February 2019)
- Involving member state appointed bodies and interested stakeholders
- Validate draft conclusions and seek additional inputs

Current status

Focus so far has been on collating information from sectors affected by workability issues

Multiple discussions with sectors

Questionnaires to better understand the issues:

- Challenges posed
- Quantitative impacts of issues
- Potential options to address workability issues

Expect to collate information in interim report in December 2018

Inputs requested from Poison Centres

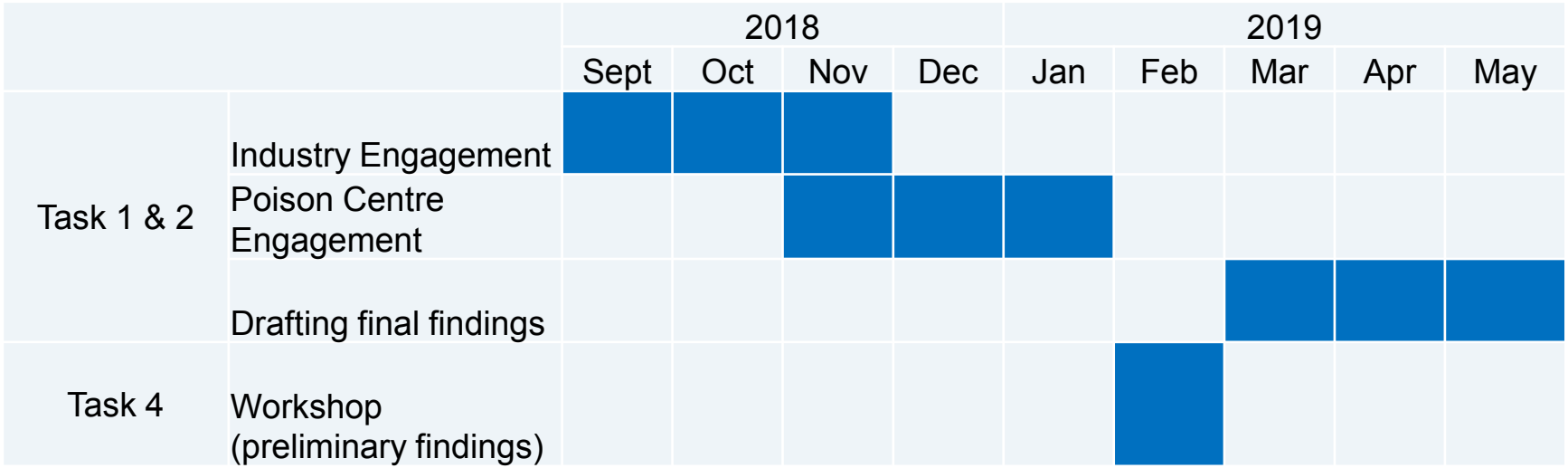
Poison centres in 28 member states contacted w/c 29 October

Planned telephone interviews throughout November and December 2018. Questions related to the identified workability issues will be provided in advance of the call.

In particular this will request inputs on:

- Poison centres' perspective on workability issues
- Cost implications of issues for PCs
- Views on possible solutions to the workability issues and implications for emergency health response

Timescales and planning



- The study began with industry engagement to fully understand the workability issues, which has included sector questionnaires running from Oct/Nov 18.

- The study will now move on engagement with poison centres the issues identified and how this may impact the function of poison centres, including solutions. This is targeted as interviews for Nov/Dec 2018

Wood project team

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2) Harmonised description of problems identified so far *by BfR*

Nomenclature

- If there is a change or a error in the submission dataset a **submission update** may be needed
  - UFI unchanged (in most cases)
- If there is a change in the formula technically a **new notification** may be needed
  - always new UFI
  - *also called ‚submission update‘*
    in Annex VIII B 4 – what hampers differentiation

Main problem(s) identified so far

- Downstream users (formulators) often use more than one supplier for a specific formula component of their mixtures
  - or even more suppliers for more than one component
- and, also often, components of natural origin differ in their physicochemical features, what triggers a need for change in the total composition

➢ Both changes may trigger a new submission containing a new UFI

Need for New Submission if Formula Has Changed

Case1: component that changes is a substance or a mixture of known composition (no MIM notification possible):

- a) if identity of substance(s) do not change and concentration(s) do only change within the allowed ranges according to Annex VIII:

➢ No new submission necessary

Need for New Submission if Formula Has Changed

Case 1: component that changes is a substance or a mixture of known composition (no MIM notification possible):

- b) at least one substance identity changes or at least one concentration changes beyond the allowed ranges according to Annex VIII:

➢ **new submission with new UFI necessary**

Need for New Submission if Formula Has Changed

Case 1: component that changes is a substance or a mixture of known composition (no MIM notification possible):

- c) a component added or a component deleted (occasionally) , e.g. stabilising agent

➢ **new submission with new UFI necessary**

Need for New Submission if Formula Has Changed

Case 2: component that changes is a mixture of unknown composition (MIM notification for component needed):

- at least one MIM changes (i.e. MIM comes with new UFI) (or at least one concentration changes beyond the allowed ranges according to Annex VIII):

➢ **new submission with new UFI necessary**

New Submission Needs if Formula Has Changed

- High workload according to rules in place
- many (new) submissions for mixtures with minor differences on substance level
  - As discussed with PC - in many cases without relevance for emergency health responses
- workability study will quantify this problem
  - to decide on need for update of regulation

Possible Solution(s) – For Discussion Only

- To allow more group notifications ...

Possible Solution(s) – For Discussion Only

- To allow notification of a component as group of similar substances or group of similar MIMs
  - e.g. concept of „*comparable MIMs*“ as proposal by construction industry associations
  - ‚Mortar X / assigned to UFI M‘ contains:
    - 20-22 % [‚Cement UFI1‘ or ‚Cement UFI2‘]
    - 78-80 % other fixed components

Possible Solution(s) – For Discussion Only

- To allow notification of a component as group of similar substances or group of similar MIMs
  - e.g. Cleaner XX (with UFI YY) containing
    - 88-90 % fixed components (to be notified in detail)
    - 10-12 % [‚surfactant 1‘ or ‚surfactant 2‘]
    - where ‚surfactant 1‘ and ‚surfactant 2‘ are chemically similar substances that differ in fatty acid chain length (distribution) only

Possible Solution(s) – For Discussion Only

One notification for a group of similar mixtures
(i.e. group submission extended to more components)

- technically realisation using more Generic Product Identifiers (GPI)
  - but: detailed list of all possible components needed in addition (as for perfums, Annex VIII, parts A 4.4, B 3.1)
- Challenge: how to decides on new GPIs and on the degree of sufficient similarity for such group notification?

Conclusion

- Workability study is in progress, preliminary result will be available soon
- All stakeholders will be involved soon
- No results predictable so far, but some proposals could be discussed

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Thank you for attention

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