



Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

# **Pilot Project on Intermediates**

## **State of Play**

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# Outline

- **ECHA's Article 36 letters**
- **Pilot Project – background information**
  - Objectives and participants
  - Scope of the project
- **Pilot Project – state of play**
  - Progress report
  - Planned activities

# ECHA's Article 36 letters (I)

## Legal background: Article 36 (1) REACH

### Obligation to keep information

1. Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation [...].

That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request to any competent authority of the Member State in which he is established or to the **Agency** [...].

## ECHA's Article 36 letters (II)

### September 2011

- ECHA's Evaluation Unit sends out 37 „decisions according to Article 36 (1) of REACH“
- including requests for information on SCC & RMM
- to registrants in 14 countries\*

\* AT, BE, CY, CZ, DE, ES, FR, IR, IT, NL, PL, RO, SE and UK.

### November 2011

- 35 responses received by ECHA, currently revised by ECHA's Dossier Evaluation Group

 **Follow-up ?**

# Pilot Project – Objectives and participants

**Forum-10 (10/2011) → Decision to start Pilot Project**

## **Objectives:**

1. Define the status quo of intermediates with regard to the pending Article 36 (1) decisions of ECHA through coordinated enforcement actions.
2. Collect information on the outcome of the enforcement actions and prepare a document identifying best practice.

## **Participants:**

AT, BE, DE, FR, IT, NL, NO, SE and UK

# Pilot Project – Scope

## „Small-scale project“

= project is limited to follow-up actions on Art. 36 letters

## Extension of scope?

- i.e. checking registrants' compliance with Art. 18 (4)
- discussed at Forum-11: Forum members agreed to keep limited scope of the project for the time being
- extended project remains possible after completion of the pilot

# Pilot Project – Progress so far

## Tasks completed:

- 1) Compile Forum Members' comments on MS experiences and future plans regarding the enforcement of intermediates

Output: Compilation table containing responses from 16 MS

- 2) Collect and compile comments from participants of the pilot project on ECHA's evaluation templates

Output: Compilation of comments forwarded to DEG

# Evaluation template - example

## Decision Support Document for the Follow-up of Verification of Intermediate Status

<p><b>Substance</b>  <b>Reference Substance name:</b>  <b>EC number:</b>  <b>CAS number:</b>  <b>Registration number:</b></p>
<p><b>Dossier profile</b>  <b>Dossier UUID (latest):</b>  <b>Latest submission number:</b>  <b>Tonnage band: &gt;1000 t TII</b>  <b>Registrant:</b>  <b>Country of the MSCA:</b>  <b>[Lead/joint]:</b>  <b>Date of the decision on the Follow-up outcome:</b></p>
<p><b>Requested information</b>  <b>Legal basis:</b> Art. 36  <b>Request:</b> Basic Art. 36 letter</p>

Information requested	1. Information requested addressed?	2. Clear evidence that the requirements are not met?	3. Need for clarification on site?
1. Information on the status of the intermediate			
a. Information on the status at the registrant's site			



# Pilot Project – Planned activities (I)

## 1) Operational phase

### Inspections

- Operational phase will start after evaluation of the registrants' responses is completed
- Evaluation – preliminary findings:
  - half of the cases can be terminated without further action
  - in about 1/3 of the cases ECHA might invite follow-up actions by NEAs

### Reporting

- Could include: measures taken by NEAs, results of inspections, further comments on templates, ...

# Pilot Project – Planned activities (II)

## 2) Reporting phase

### Report to Forum

- Could include both ECHA's findings and results from NEAs' inspections
- Will contain a recommendation to the Forum regarding the necessity of future enforcement activities in this field

### Document describing best practice

- Could include recommendations for the enforcement of intermediates, including best practice

# Thanks for your attention

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