UPSTREAM APPLICATIONS FROM A RISK PERSPECTIVE

Experience from Trichloroethylene and other upstream AfA covering multiple uses

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Introduction

Upstream AfA – new to Industry and Authorities

Aim of Process: to assure that the risks from SVHC are properly controlled and that these substances are progressively replaced by suitable alternatives

Advantages of upstream applications:

- **One application – multiple DU covered**
- **Less of a burden for SME's AND ECHA**
- **Coverage of all users further down the supply chain**
- **Prevention of supply interruption, due to lack of awareness**

Content:

learnings/experiences from submitting supplier authorisations for trichloroethylene

comments from other parties involved in preparing or having submitted supplier applications (Bipro as consultant, an Importer and an OEM).

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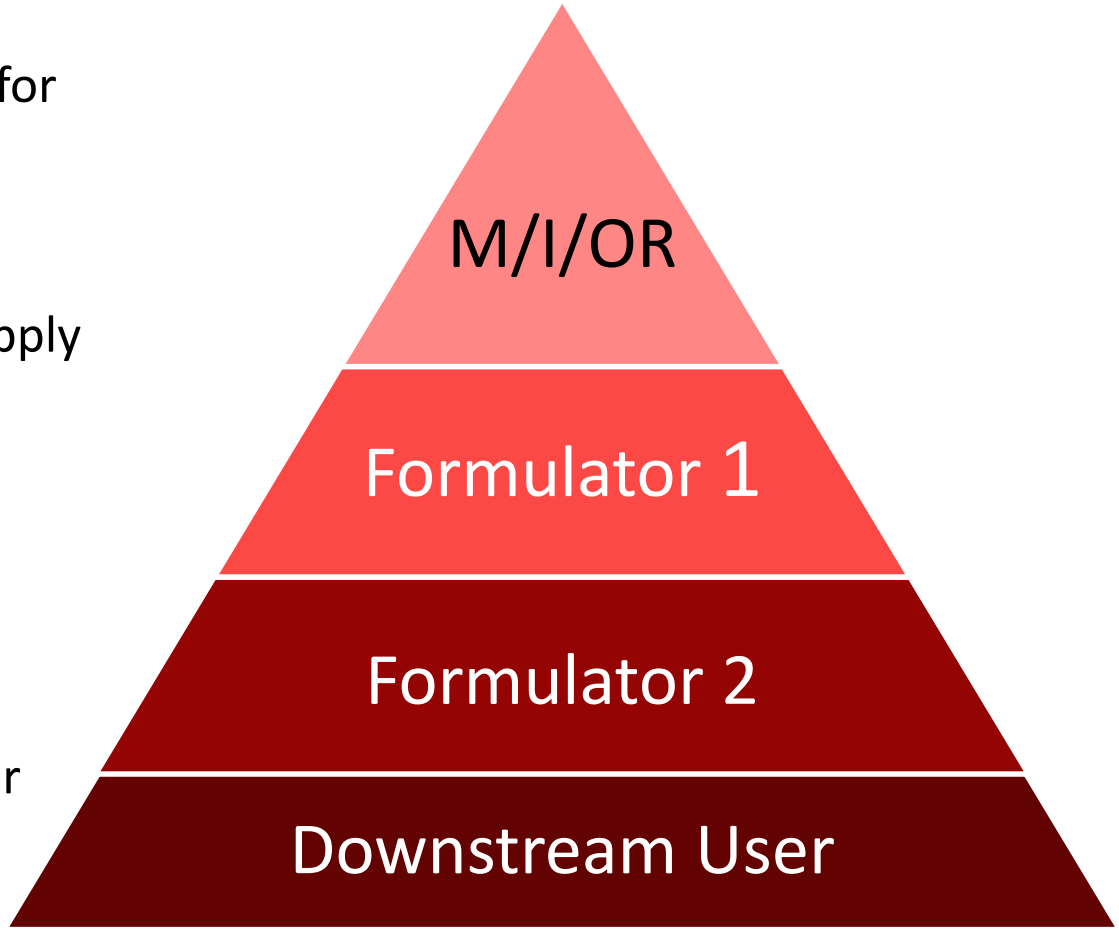
Who are upstream applicants ?

- M/I/OR can apply for formulation and downstream uses
- Formulators can apply for own and downstream uses
- Formulators authorisation only covers supply by immediate supplier



M/I/OR = Manufacturer/Importer /Only Representative

Authorisation – a complex process: Why apply as upstream?

Bottom – up:

Push by Downstream users

- **Direct supplier – DU relationship**
- **Service expectations**
- Limited regulatory (REACH) knowledge of SME's, process seen as complex
- Time constraints (process understanding, decision making, Latest Appl. Date)
- Small quantities do not support high consultancy costs

Top – Down:

Parties further up in the supply chain want to assure, that substance will be available for use

- **Insurance that all users down the supply chain are covered**
- **Complex supply chain**
- **not all sub-suppliers known**
- Limited regulatory (REACH) knowledge of SME's, process seen as complex
- Time constraints
- Small quantities do not support high consultancy costs

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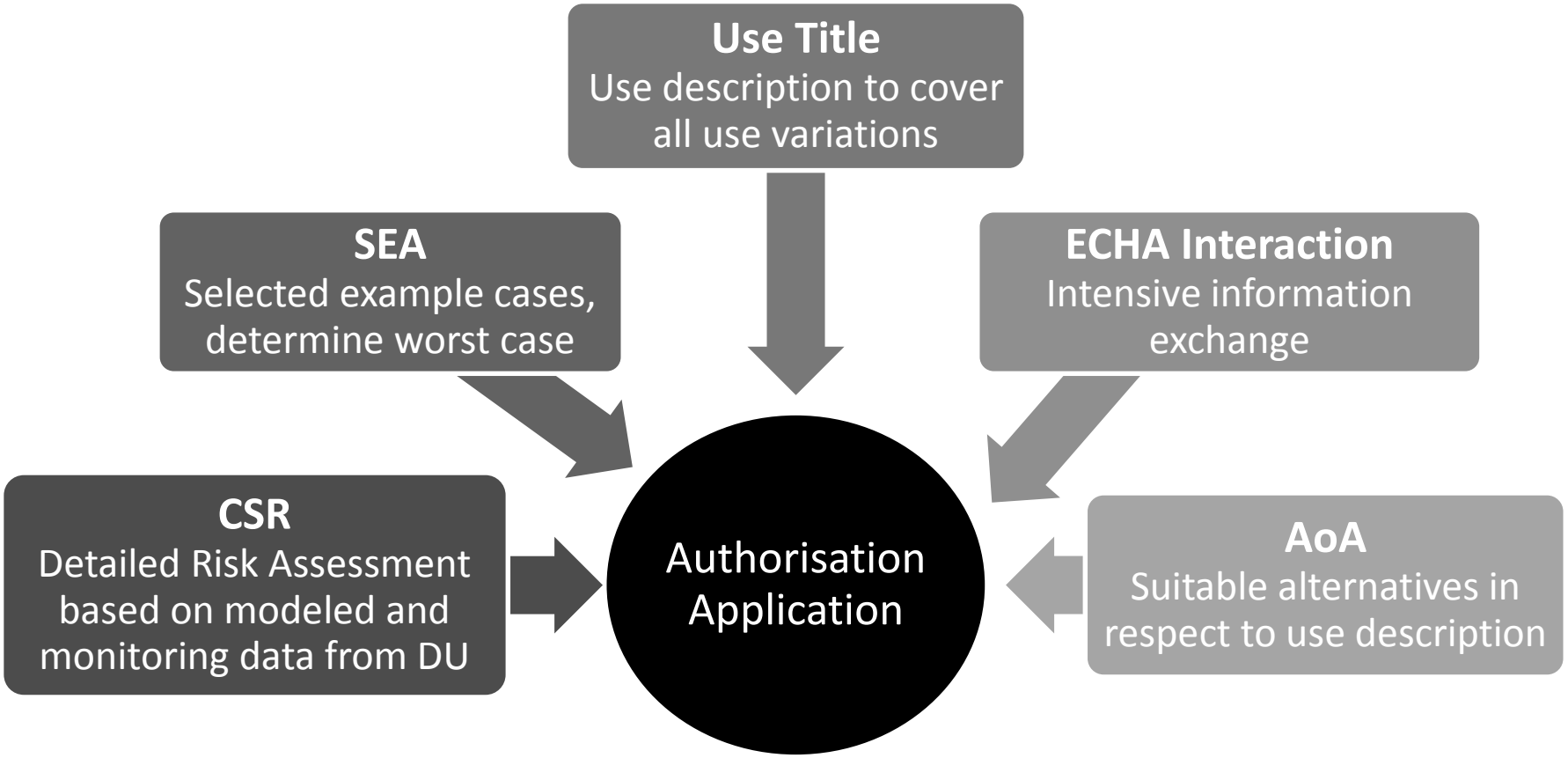
AfA Dossier
What's Specific for an Upstream Application



Interaction with DU –
Provide and get Information – start early

For upstream applicants: **early and continued downstream user communication**:

- to raise awareness
- to identify each affected actor in a complex supply chain
- to make process and impacts understood
- to receive sufficient information to define scope under which no suitable alternative exist
- to maintain trust that authorisation has a chance to be granted

Interaction with DU:

directly (supplier – DU) ***or*** via DU consortium as platform to exchange information

Exchange of confidential information :

confidentiality/competition law concerns limit information exchange with applicant - trustee function required

DU "expects" **early clarification of conditions** under which he can continue to use the substance (used to comply to OSH)

➡ early clarification on authorisation route (adequate control/SE-route)
early publication of Reference DNEL!

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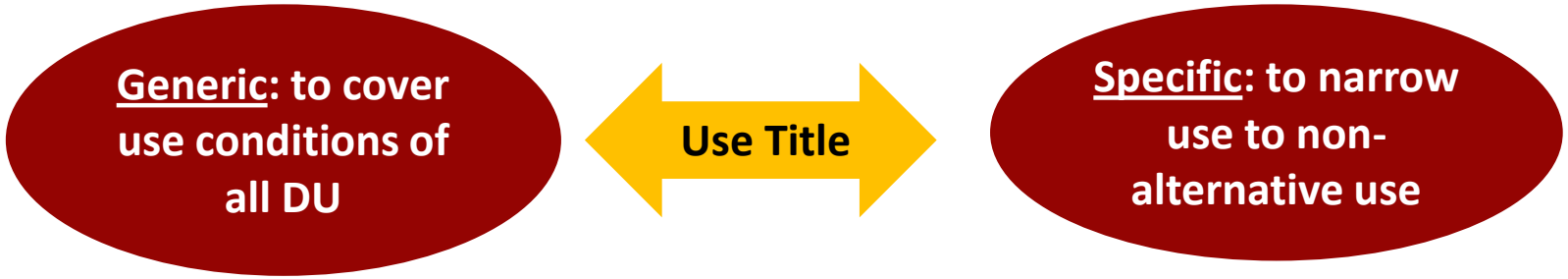
Use title – use description

Challenge: alternatives exist for a generic use ….BUT under certain use conditions , no alternative is available and substance is essential



Example Trichloroethylene Authorisation:

"Use Of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters)* exist"

CSR – Exposure Assessment

Historical Data:

Mostly incomplete due to lack of information of conditions (machine type, working conditions etc.)

or not applicable as not reflecting technical progress

Monitoring Data:

Preferred data

How many data points to be representative?

Use of modeled data

High quality modelling data complementary to monitoring data

Limitations to determine combined exposure

…and for subsequent (trichlorethylene) applications:

Monitoring Arrangements: Collection of annual monitoring data from all DU required as part of a subsequent application

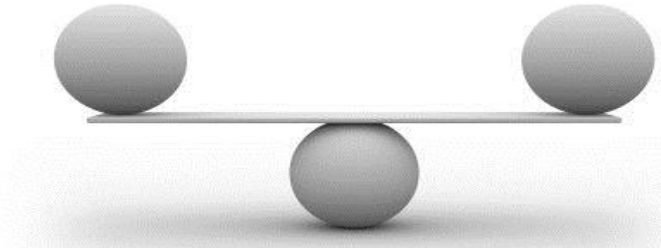
Data collection

RAC prefers:
Data from all variations:

- all **different activities**
- **different operation sizes**
- **all countries where use exist**
- **Different industry sectors**

Applicants constrainst:

- **Short time to organize monitoring campaigns**
- **Or no access to DU**
- **Limited Co-operation or no access to DU**
- **Costs**



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CSR – Definition of Risk Management Measures

Upstream authorisation applications by definition **cover a variety of use scenarios/use conditions:**

Operations of different sizes | **Different end requirements** | **Different industry sectors**

Overall use/substance function is the same

Committees appreciate:

Detailed process description using pictures, process schemes, case descriptions

Define RMM's – Process Variations in:

size of operation, frequency

country variations, national implementation of OSH/OEL

Aim: to set one most appropriate set of RMM's to sufficiently limit the risk and cover all variations

One possibility: Catalogue of RMM's acceptable (to select acc. to operation size and conditions)?

What is by RAC considered to "sufficiently limit the risk" for a non-threshold substance ?

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CSR – Definition of Risk Management Measures

The Downstream user is responsible to implement RMM's!

To support implementation and analysis of alternative by DU…

RMM **may go beyond process measures** and could include:

- ❑ Frequent training on safe use and available alternatives
- ❑ DU Declarations prior to use
- ❑ Reference to state of the art Safe-Handling procedures as described in national guidance (acceptable?)

Different supply models such as chemical leasing can increase confidence in implementation of RMM's

(To what extend is the applicant expected to support control of RMM implementation?)

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Interaction with ECHA

- **P**re **S**ubmission **I**nformation **S**ession – very useful, early clarification of concept

- RAC/SEAC written information exchange: several rounds of questions

  (might be streamlined, when further guidance on amount/representativeness and relevance of data and information available)

  (More convenient windows for information provision appreciated)

- **Trialogue** Meeting – useful to clarify parts of the application with RAC/SEAC members present

Conclusions

- Upstream authorisations cover several DU at once and reduce workload for single DU and for ECHA
- Upstream authorisations are complex and resource/labor intensive for upstream applicants
- Necessitates reasonably long review periods to accommodate efforts and costs and provide market security
- Close cooperation of all parties is key to provide a most complete application
- Early clarification of basis for risk assessment needed
- Clarification on what is considered representative data
- Clarification on expectation to applicants to encourage/ control implementation of RMM's
- Further guidance specific to upstream applications appreciated (use definition, "sufficient limitation of risk", risk assessment, SEA) - Examples appreciated

"The only source of Knowledge is experience"
(Albert Einstein)

THANK YOU FOR YOUR ATTENTION