Authorisation:

There is more to it than (just) making the dossier

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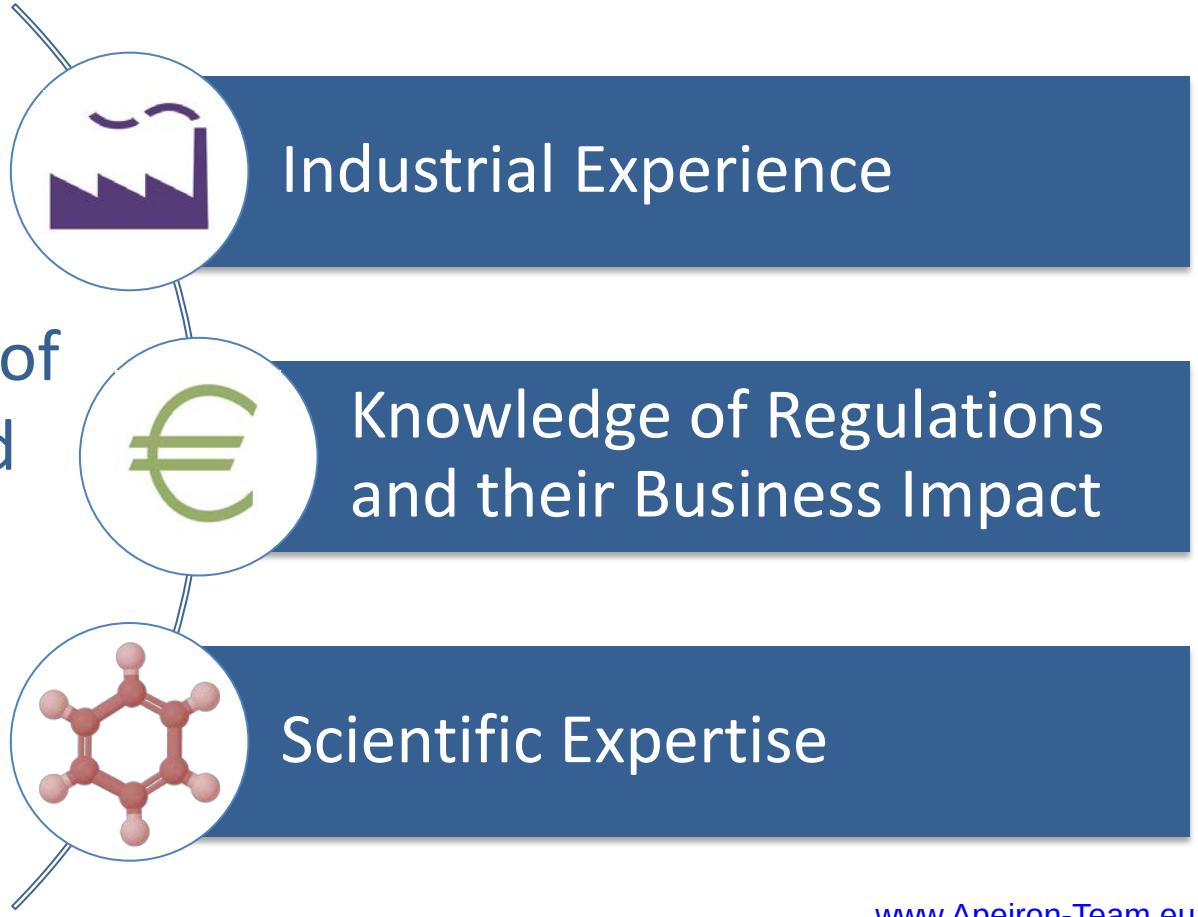
29/04/2014

Apeiron-Team

where Strategy, Science and Efficiency meet

Cost Efficient Implementation of Chemical Related Regulations and Policies



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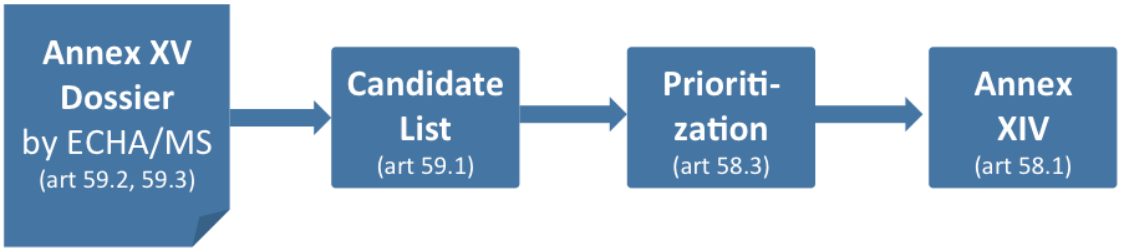
Expertise of Apeiron in Authorisation

Scientific Advocacy

- Public consultations
- Meetings with authorities
- Positive result for several substances



Authorisation Dossiers for DU, SEA-route (non-threshold)

- Strategy deployment
- Negotiation with registrants on access to hazard info
- Generation of dossier (CSR, AoA, SEA)
- Negotiations in the upstream supply chain (ensure future supply)
- Project management, incl. team at client
- Report on status & risks in management committee

Authorisation Dossier for a DU consortium

Complexity!
Synergy

- Chairman of technical committee in the consortium
- Several applicants, several supply chains, several uses
- Strategy deployment
- Alignment btw members, finding common denominator
- Deliver input for dossier, critical review & improvements

Authorisation:

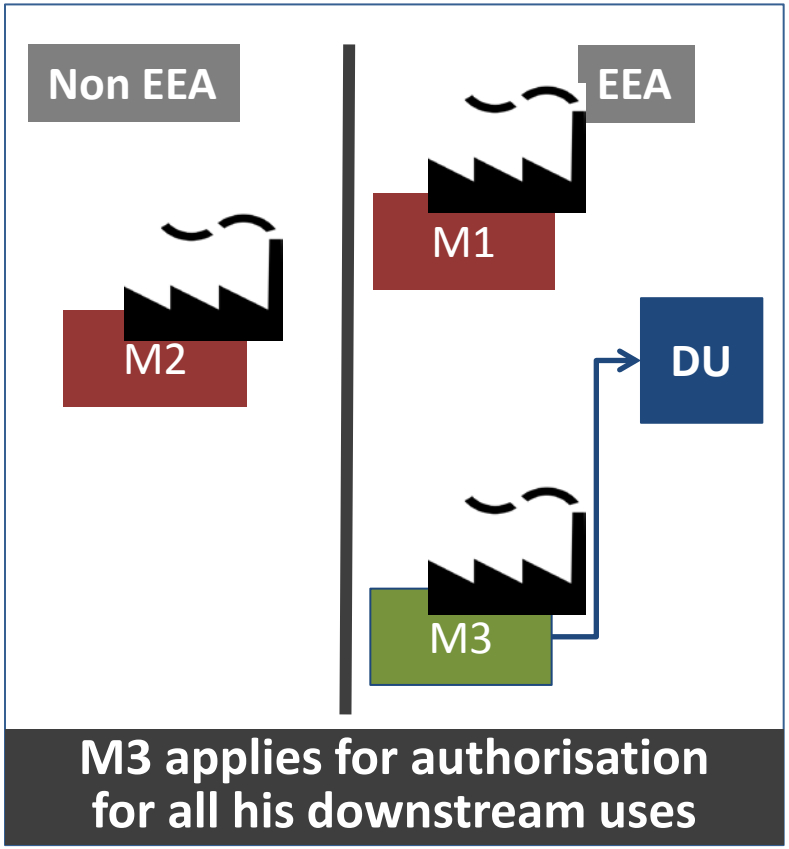
There is more to it than (just) making the dossier

- Mitigating the risk of supply chain disruption — For today
- CSR
  - ✓ HAZARD: Legitimate access to the CSR
  - ✓ EXPOSURE: Fine-tuning the exposure scenario; EA for authorisation is significantly more detailed than for registration
- The challenge to define a credible non-use scenario
- What makes your case strong? How to document?
- Advantages of making own dossier — For today

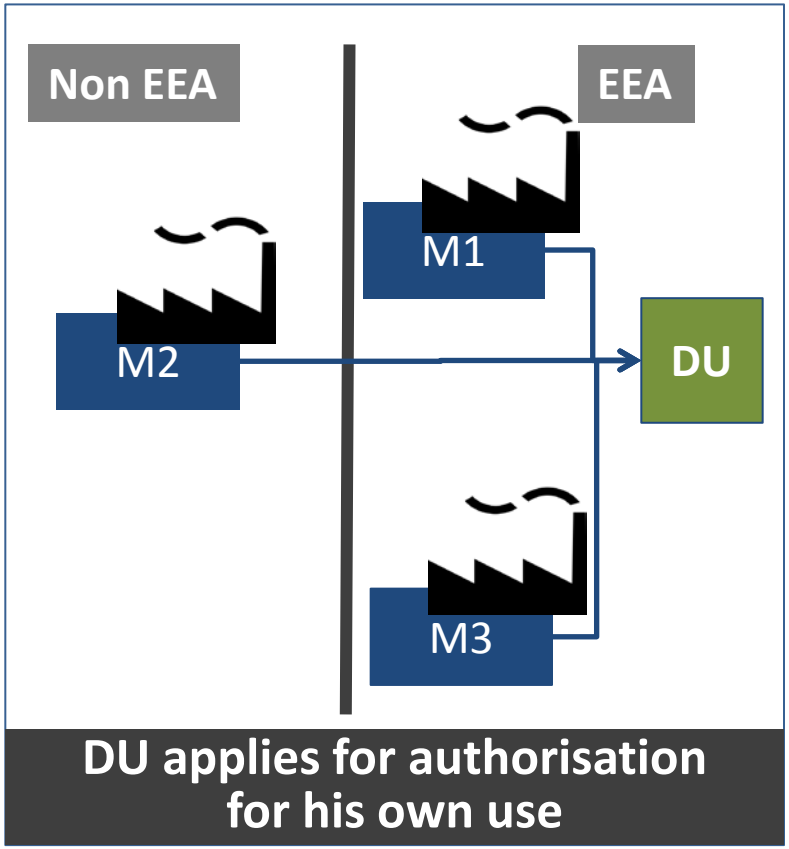
Agenda

- **Mitigating the risk of supply chain disruption**
- CSR
  - ✓ HAZARD: Legitimate access to the CSR
  - ✓ EXPOSURE:
    - Fine-tuning the exposure scenario;
    - EA for authorisation is significantly more detailed than for registration
- Advantages of making own dossier
- Key Messages

Choice to make:
Rely on supplier or make own dossier?



M3 applies for authorisation for all his downstream uses

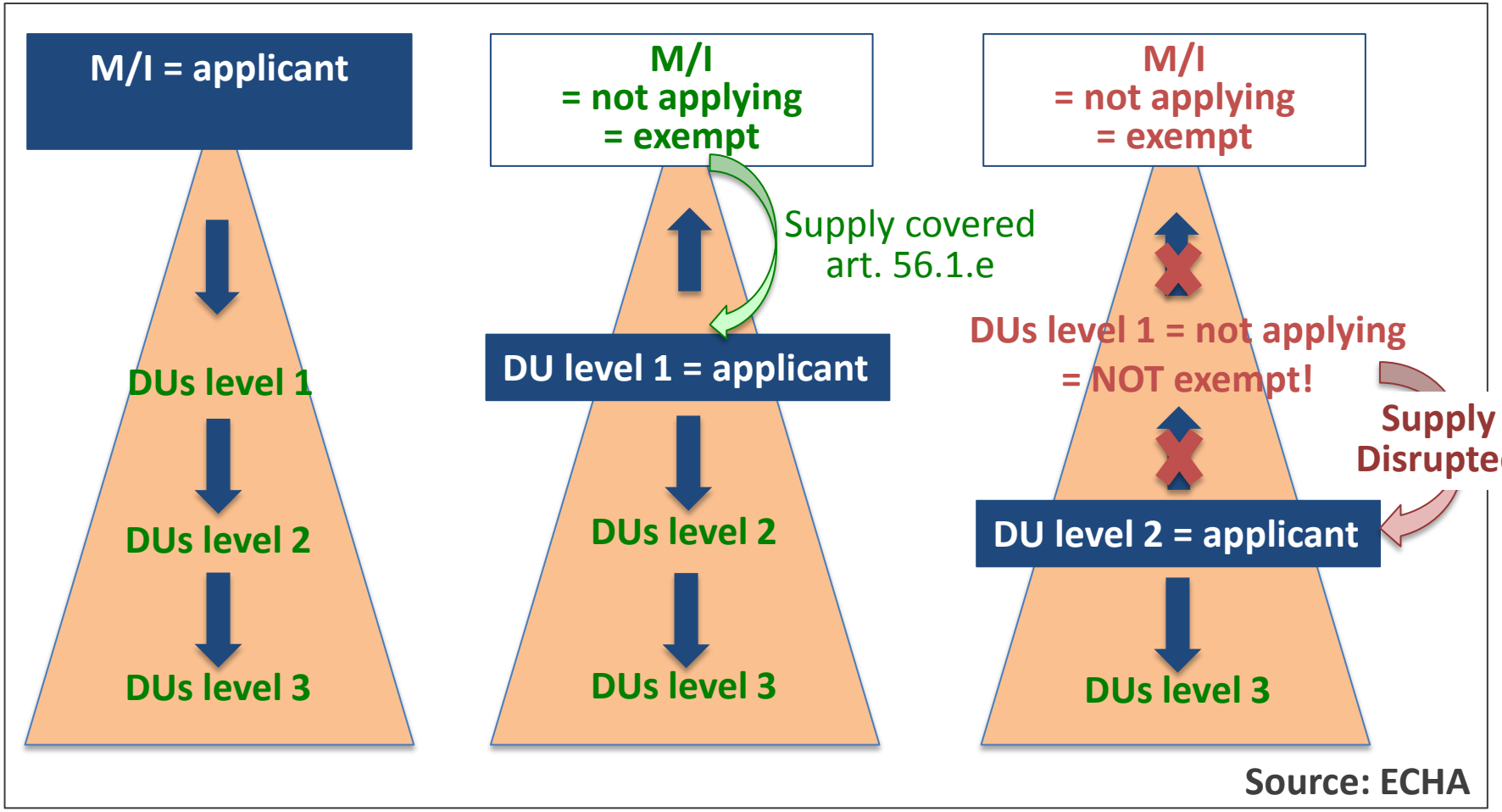


DU applies for authorisation for his own use

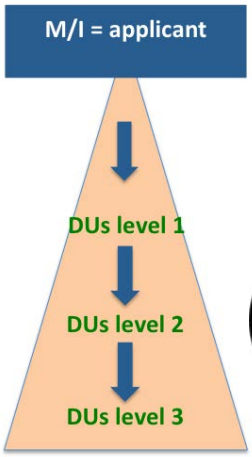
FLEXIBILITY ↑, remark: LoA for CSR

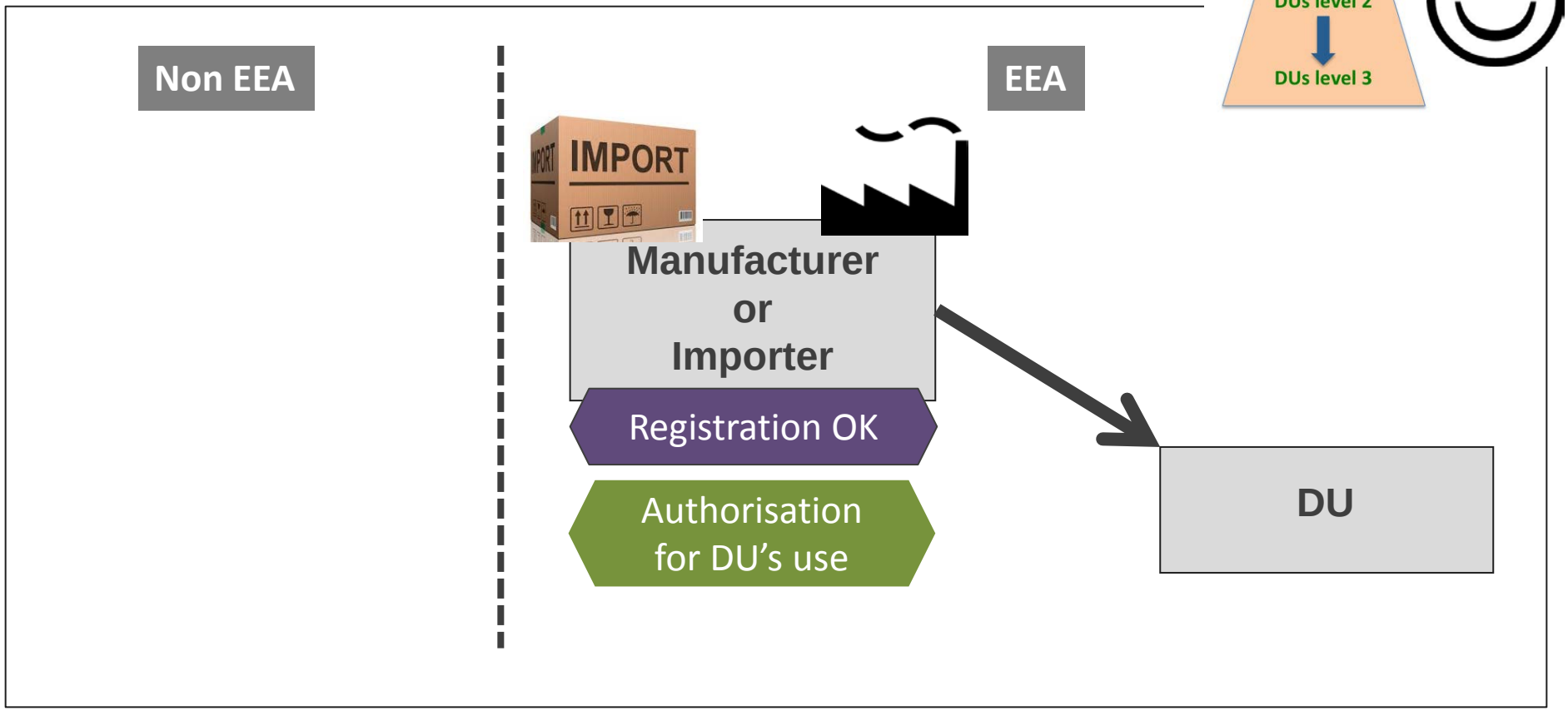
Who applies and who is covered?

Top-down , **but not bottom-up** → watch-out for supply chain disruptions !

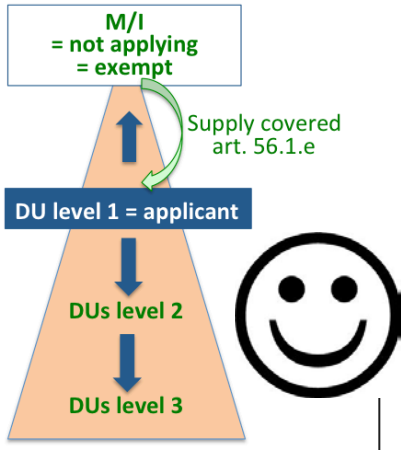


Scenario 1:
DU – directly supplied by M / I, and M / I applies for authorisation





Scenario 2:
DU – directly supplied by M / I, and M / I does NOT apply for authorisation



Non EEA

EEA

Manufacturer or Importer

Registration OK

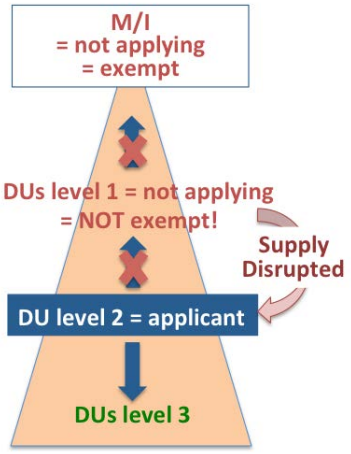
Authorisation for DU's use

Supply covered art. 56.1.e

DU

Authorisation

Scenario 3:
DU – indirect supply, and
M / I does NOT apply for authorisation



Non EEA

Manufacturer
or
Importer

Registration OK

Authorisation
for DUs

Who???
DU? Distributor?

???

Who???
DU? Distributor?

DU

Authorisation

Distributor & Authorisation obligation?

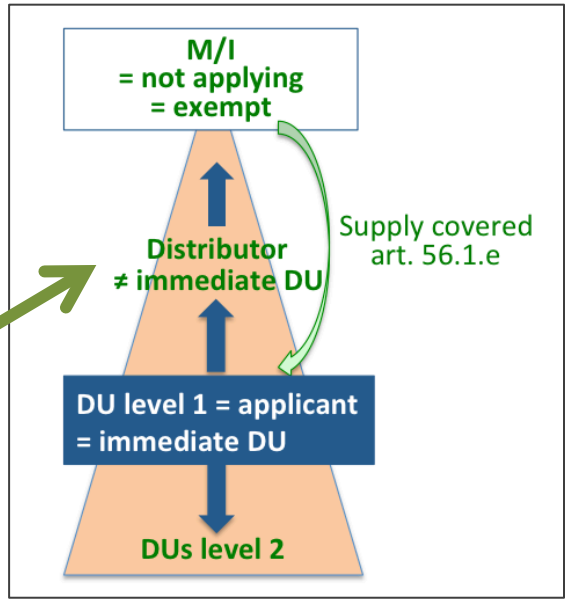
DISTRIBUTOR as understood in industry

Retailer	Storage provider	Trader	Re-filler

DISTRIBUTOR under REACH Does not use and/or only stores substance	DU under REACH uses the substance

No authorisation ← → Authorisation

Q&A 577

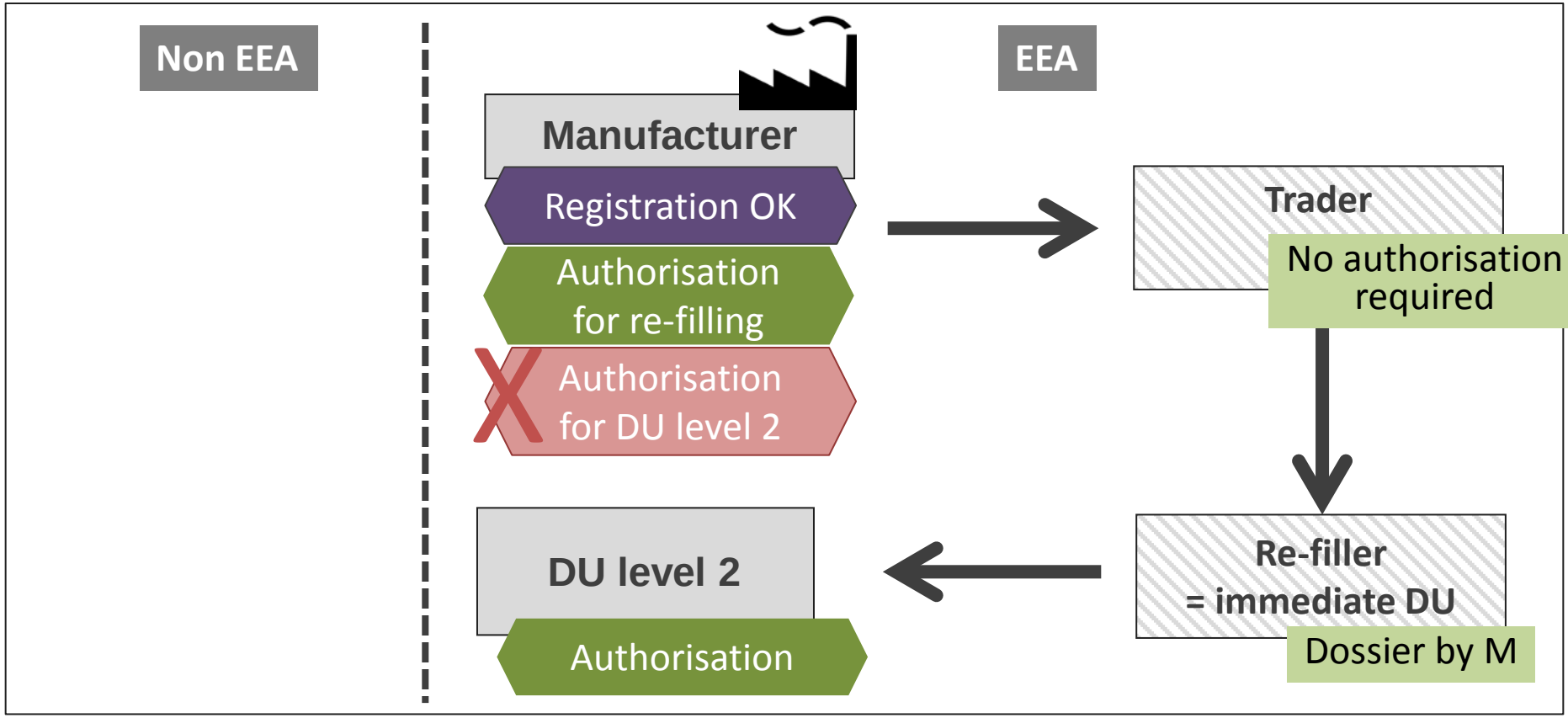


Thus:

(1) If supplier is re-filling, then not distributor, he is DU and therefore subject to authorisation

(2) If there is a distributor in the supply chain, he is not "an immediate DU" as meant in art 56.1.e The first next DU = immediate DU, supply covered

Clarification of our case (after several months discussing)



- Request written confirmation of intention to apply for the specific use (not generic!)
- Check dossier once published, follow-up on draft opinion
- Check timely for alternative options (other supplier?, time for trials?)

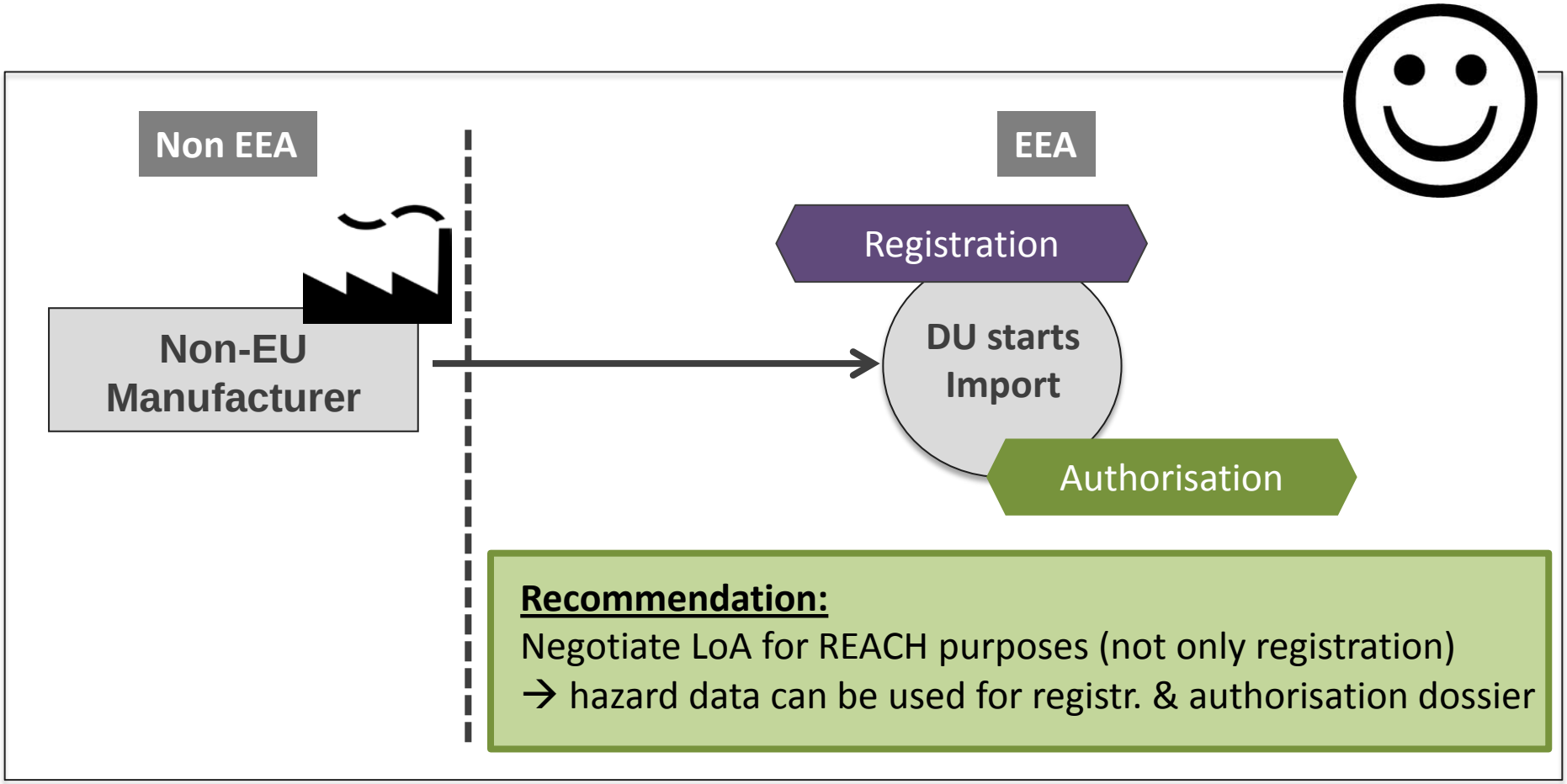
Risk

- DU spends time / effort / COST to apply for authorisation
- If dossier OK, authorisation is granted
- BUT…no supply if upstream NOK → **Business continuity risk!**

Solution

- Find "the top" = Contact registrant(s) [easy to find via disseminated dossier, ECHA site]
- Get the right people around the table → knowledge of REACH & supply
- Map supply chain, define roles [DU (re-filler, formulator,…) or distributor?]
- Understand the interests → indication of likelihood of application upstream
- Contact the parties involved and request written confirmations
- **Check draft opinions RAC/SEAC → if NOK, alternative supplier or import**

Scenario 4: DU imports



Agenda

- Mitigating the risk of supply chain disruption
- **CSR**
  - ✓ **HAZARD: Legitimate access to the CSR**
  - ✓ **EXPOSURE:**
    - **Fine-tuning the exposure scenario;**
    - **EA for authorisation is significantly more detailed than for registration**
- Advantages of making own dossier
- Key Messages

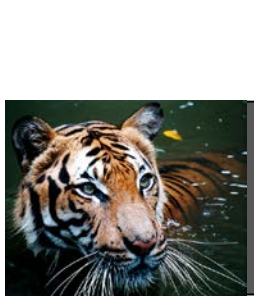
Chemical Safety Report = part of authorisation dossier

Article 62.4:
An application for authorisation shall include the following information:
(a) … ; (b)… ; (c) … ;
(d) Unless already submitted as part of the registration, a **chemical safety report** in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV

THUS:

- **M / I** applying for authorisation can **refer to his registration** dossier for the CSR
- **DU** is not a registrant, therefore he has no registration dossier of his own to which he can refer. So, what can he do?
  - ✓ He pays for legitimate access to the CSR and **submits CSR as part of** his own authorisation dossier (= typical situation).
  - ✓ He pays for legitimate access to the CSR and **refers to** the registration dossier.

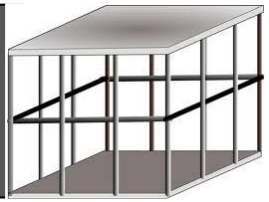
Elements of the CSR



Hazard

Risk???

Exposure



HAZARD DATA

Acute Oral Toxicity GLP

QSAR

OCs
RMMs
Monitoring

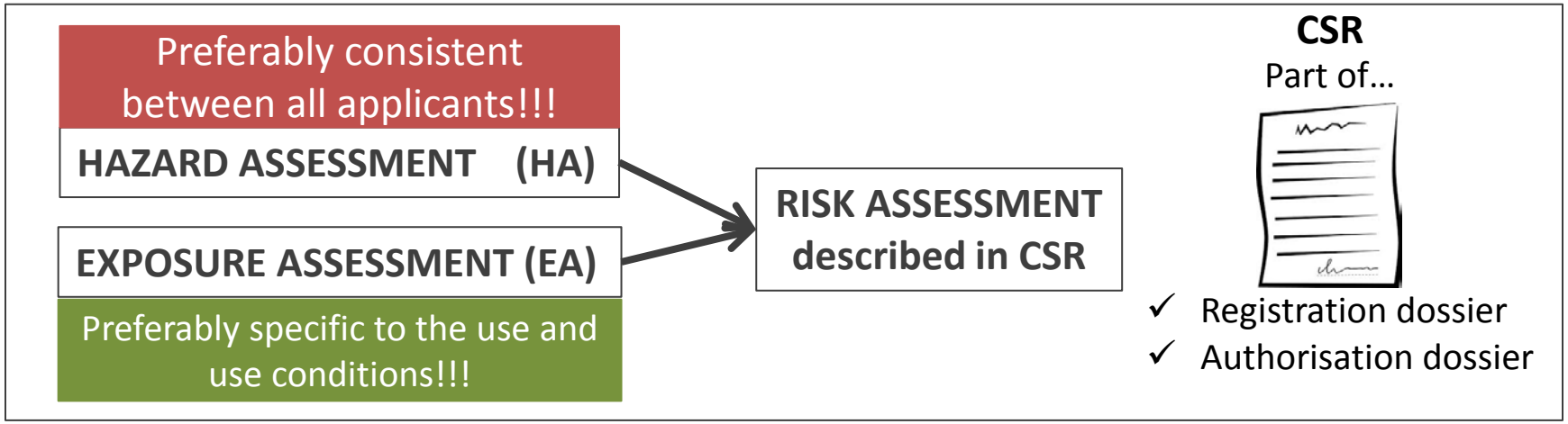
USE SPECIFIC INFO

HAZARD ASSESSMENT

EXPOSURE ASSESSMENT

RISK ASSESSMENT → Safe Use

Which data does DU need from M/I ?



- **HAZARD:**
  - ✓ DU typically does not have as much information/knowledge as the registrant
  - ✓ Importance of consistency between applicants
  - ✓ ***Recommendation*: purchase legitimate access to the hazard assessment**
- **EXPOSURE:**
  - ✓ The application for authorisation is **for your specific use**
  - ✓ Use description in registration dossier is typically generic, not specific.
  - ✓ You know the details of your use conditions best, describe them well
  - ✓ ***Recommendation*: make your own use specific exposure assessment**

What part of the hazard info does the DU need?

Article 62.4:
"*An application for authorisation shall include the following information:*
(a) … ; (b)… ; (c) … ;
(d) Unless already submitted as part of the registration, a ***chemical safety report*** *… ."*

HAZARD

✓ Art. 62.4.d says the applicant needs CSR (= HA + EA)
✓ Art. 62.4.d does NOT say you need the underlying hazard data (the studies)!

✓ **Thus: DU needs access to the hazard assessment, not to the study reports!**
✓ ***Recommendation*: Buy legitimate access to the hazard assessment (the document)**

➔ Problem solved for registrant → cannot give access persé if he does not own the study
➔ Problem solved for DU → he has legitimate access to the info he needs
➔ Hazard assessment is based on a complete data-set, i.e. from the registrants
➔ Hazard assessment of different applicants is the same ☺ = mutual interest

➔ Side remark: It can happen that M/I has no interest in providing access to the info needed by the DU.
Important to understand the situation early in the negotiations.

How to “buy” legitimate access?
Letter of Access (LoA)

LoA = contract that stipulates access to data
It gives “the right to refer to” data, e.g.

To 1 or more study report(s) → robust study summaries
To RSS + CSR (HA+EA) = entire registration dossier
To RSS + HA= part of registration dossier
To HA alone → choice we made

- **Win-win!**: Collaboration between the LR (on behalf of registrants = owners of HA) and Apeiron on behalf of 2 DUs and legal advisor to draft a LoA-agreement reflecting the needs of all
- 2 specific provision for the DU:
  - ✓ *When the registrants update their REACH registration dossier, more specifically the hazard section, then they shall provide a copy thereof to the DU.*
  - ✓ *In case of inquiries from authorities to the DU regarding the hazard assessment, the registrants shall provide the authorities direct insight in the study reports*
- In our case, registrants provided the HA for a (very) fair price
- Discussions on LoA resulted in further collaboration on alignment of dossier approach, i.e. overall positive experience.

Hazard Information from ECHA
DNELs, Dose-Response Curves

- RAC intends to provide threshold values/Dose-Response for Annex XIV endpoint

- **Result:**
  - ✓ Applicant knows RAC opinion on threshold/non-threshold prior to submission.
  - ✓ Applicant can refer to this information in the hazard section of CSR
  - ✓ Applicant no longer needs legitimate access to the hazard assessment

- **However:**
  - ✓ Not possible for PBT, vPvB (will RAC provide rate of degradation in env.?)
  - ✓ Gives information only on Annex XIV endpoint
  - ✓ For comparison of alternatives (in AoA), other hazard info also needed
  - ✓ Also in CSR, other hazard info is useful (e.g. phys-chem)

- **Thus:**
  - ✓ Still useful to purchase LoA to HA (if data owner wants to sell; if price = fair)
  - ✓ **Information from ECHA goes hand-in-hand with approach to purchase LoA to HA**

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Advantages of making own dossier

(1) No official collaboration = …
…No negotiation on consortium agreement,
…No political discussions due to different interests
…No CBI risk, No Competition law risk

(2) IP Protection

(3) It is our dossier = …
…all information is close at hand
…our use and not a common denominator: our OCs, our RMMs, our strengths
…our timing

(4) Collaboration still possible, but without the hassle
- With other applicants that are not competitors
- With M applying for authorisation
- Synergies, alignment possible, without all the difficulties of consortium

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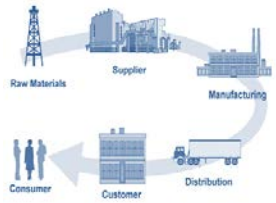
Key Messages



Avoid supply chain disruption

- ✓ Contact the "top" of the supply chain → registrant(s)
- ✓ Map supply chain and define roles & responsibilities
- ✓ Communicate/Negotiate (start early) & understand the interests
- ✓ Have a Plan B ready (altern. supplier/import)
- ✓ Check draft opinion → if not OK = activate Plan B

Legitimate access to the CSR

- ✓ Communicate with registrants asap, emphasize mutual interests
- ✓ Understand reasons of M/I when he does not give access to the data
- ✓ *Hazard*: LoA to HA (not study reports);
- ✓ *Exposure*: make your own specific assessment
- ✓ Approach goes hand-in-hand with hazard info from RAC

Apart from the challenges, there are interesting advantages to own dossier

Not rocket science, but a lot to consider → multidisciplinary team with passion