CALL TO ACTION

12 new SVHCs added to the Authorisation list

Some Notes

- *It is assumed that attendees have basic knowledge about REACH.*
- *Based on the answers to the questionnaire during registration, the webinar will focus on basic information on authorisation.*
- *Let us make this webinar interactive, please send questions*
  - *We try to answer during the webinar, if not possible, we will use email*

REACHLaw in a nutshell

What we do? We provide global regulatory compliance and environmental sustainability services to ensure market access and operational sustainability for global businesses

KEY FACTS ABOUT US

- ✓ Established in Helsinki
- ✓ Offices in Brussels, New Delhi and Istanbul
- ✓ 30+ toxicologists, chemists, lawyers, socio-econ. analysts, business and environmental specialists
- ✓20+ local partners in Europe, Asia, Latin-America and the USA
- ✓ 500+ REACH registrations
- ✓ Language support in 10+ different languages
- ✓ more info about Us: www.reachlaw.fi

SERVICE AREAS

✓ Global chemicals regulatory compliance, e.g.

REACH	CLP
Biocides	China REACH
TCCA-Korea	Turkey

✓ We prepare the required dossiers to authorities, SDSs, labels and provide related business strategy, legal and monitoring support.

✓ www.compliantsuppliers.com

OUR CLIENTS

✓ More than 350 customers from 40+ countries, from Fortune 100 companies to SMEs.

✓Major industries served: Oil, chemicals, specialty chemicals, metals, space sector and other downstream users (DU) industries

✓ Our customers are manufacturers, importers, traders, DU´s, industry associations and governmental organizations.

REACHLaw's Authorisation Experiences

Substance(s)	Activity	Status
As_2O_3	DU authorisation application	Authorisation granted
As_2O_3	DU authorisation application	Authorisation granted
MOCA	Supplier authorisation application	On-going
$Na_2Cr_2O_7$	DU authorisation application	Final opinion
CrO_3 + other chromates	Space task force use survey, scoping study and application preparation	One application Final opinion
CrO_3	Joint DU authorisation application (CRAN)	Final opinion
CrO_3	DU authorisation application	Final opinion
Na_2CrO_4	DU authorisation application	Final opinion
CrO_3	DU authorisation application/CSR (APEAL)	On-going
$Na_2Cr_2O_7$	Supplier authorisation application	Final opinion

REACHLaw's Advocacy Support Experience

Substance(s)	Activity	Status
PFOA	Prepared public consultation input for the restriction proposal for two industry sectors	Two derogations/ exemptions were granted.
DOTE	Strategic planning and public consultation input	Re-classification on-going
DMTE	Strategic planning for RMOA input	SVHC process halted
Other organotins	Strategic planning for RMOA input	No regulatory actions needed
N_2H_4	Exemption study & position paper & SEA analysis	EC feedback pending

Content

12 SVHC substances added to the authorisation list

Are you affected?

Develop an application strategy

Prepare the dossier

Interactions with the authorities and the decision making process

Review period

Next Steps After EC Decision

Entry Nr	Substance	Intrinsic property(ies) referred to in Article 57	Latest application date	Sunset date	Exempted (categories of) uses	Review period
32	1-Bromopropane (n-propyl bromide) EC No: 203-445-0 CAS No: 106-94-5	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	-	-
33	Diisopentylphthalate EC No: 210-088-4 CAS No: 605-50-5	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	-	-
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7 rich EC No: 276-158-1 CAS No: 71888-89-6	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	-	-
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters EC No: 271-084-6 CAS No: 68515-42-4	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	-	-
36	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear EC No: 284-032-2 CAS No: 84777-06-0	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	-	-
37	Bis(2-methoxyethyl) phthalate EC No: 204-212-6 CAS No: 117-82-8	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	-	-

Entry Nr	Substance	Intrinsic property(ies) referred to in Article 57	Latest application date	Sunset date	Exempted (categories of) uses	Review period
38	Dipentylphthalate EC No: 205-017-9 CAS No: 131-18-0	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	-	-
39	N-pentyl-isopentylphthalate EC No: — CAS No: 776297-69-9	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	-	-
40	Anthracene oil EC No: 292-602-7 CAS No: 90640-80-5	Carcinogenic (category 1B, PBT, vPvB	4 April 2019	4 October 2020	-	-
41	Pitch, coal tar, high temp. EC No: 266-028-2 CAS No: 65996-93-2	Carcinogenic (category 1B, PBT, vPvB	4 April 2019	4 October 2020	-	-
42	4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (covering well-defined substances and UVCB substances, polymers and homologues) EC No: — CAS No: —	Endocrine disrupting properties (Article 57(f) — environment)	4 July 2019	4 January 2021	-	-
43	4-Nonylphenol, branched and linear, ethoxylated (substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof) EC No: — CAS No: —	Endocrine disrupting properties (Article 57(f) — environment)	4 July 2019	4 January 2021	-	-

Content

12 SVHC substances added to the authorisation list

Are you affected?

Develop an application strategy

Prepare the dossier

Interactions with the authorities and the decision making process

Review period

Next Steps After EC Decision

Are you affecte?

- Are you using the substance?
- Can the uses be exempted?

Exemptions from authorisation

- Existing exemptions in REACH Regulation
  - Use as intermediate
  - In medicinal products for human or vetenary use
  - Used in food or feedingstuffs
  - SR&D
  - (a) uses in plant protection products; (b) uses in biocidal products; (c) use as motor fuels; (d) uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.
  - Use of CMR substances or substances identified only because of hazards to human health in cosmetic products or food contact materials
  - Use of CMR substance in preparation below the lowest of the concentration limits according to CLP
  - Use of non-CMR substances in preparation below a concentration limit of 0.1% (w/w)
  - To be established by industry (+ clarified with authorities / discussed during public consultation on Annex XIV)

Exemptions from authorisation

- Exemptions which may be included in Annex XIV
  - PPORD,
  - the risk is properly controlled on the basis of existing specific Community legislation imposing minimum requirements relating to health and environment (Art. 58(2))
  - To be claimed by industry before/during priority setting
- Special case: Defence exemption (REACH Article 2 (3)):
  - To be granted by the Member State where the substance is manufactured, placed on the market or used – limited to the territory of the Member State in question
- *Future exemptions based on political pressure*

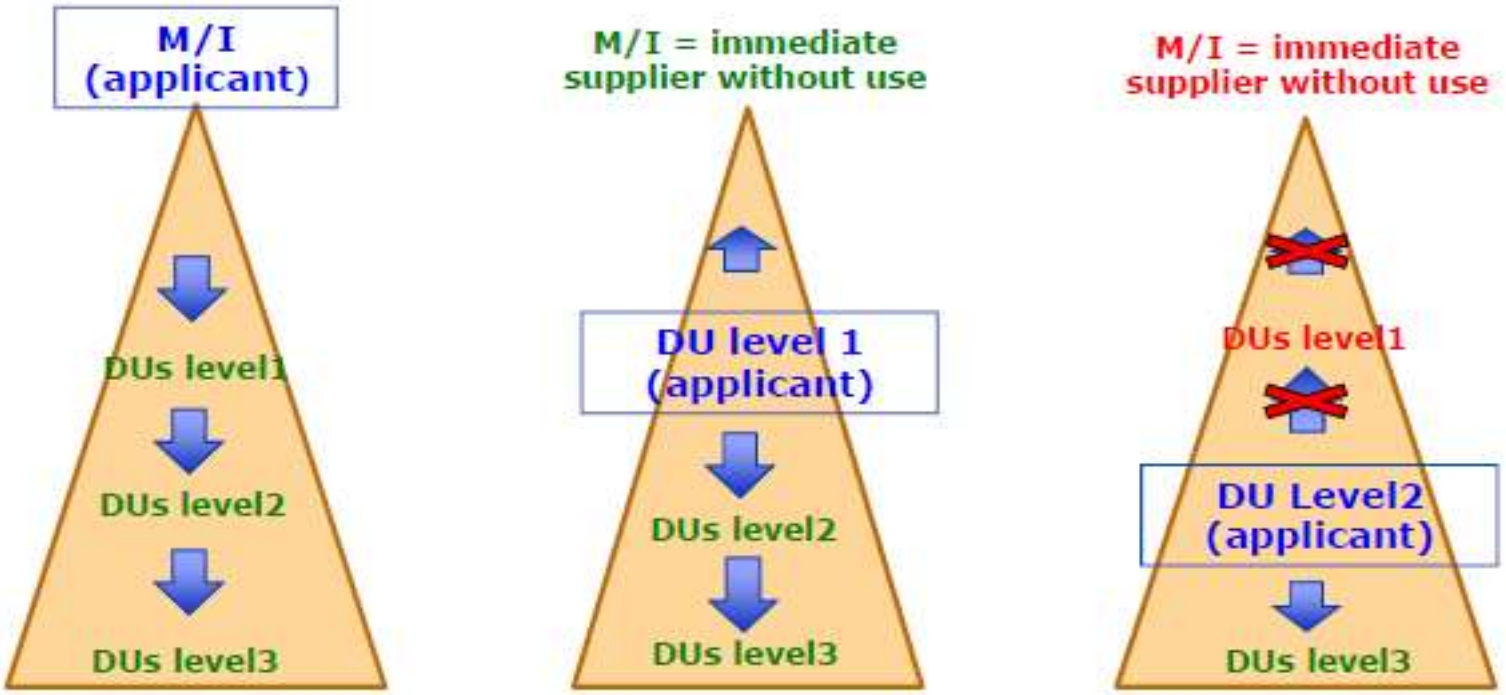
List of Exemptions from REACH Authorisation

Substance used	Legal basis	Reason for exemption
is **outside the scope of REACH**	Article 2 (1) – (3)	Several, mainly existing Community legislation
in **medicinal products for human or veterinary use**	Article 2 (5) (a)	Existing Community legislation covers risk management
in **food or feedingstuffs**	Article 2 (5) (b)	Existing Community legislation covers risk management
As on-site isolated and transported isolated **intermediates** (Article 3 (15))	Article 2 (8) (b)	Transformation into another substance
in **scientific research and development** (Article 3 (23))	Article 56 (3) 1	Carried out under controlled conditions in volumes < 1 t/y; encourage innovation
in **plant protection products ("pesticides")**	Article 56 (4) (a)	Existing Community legislation covers risk management
in **biocidal products**	Article 56 (4) (b)	Existing Community legislation covers risk management
as **motor fuels**	Article 56 (4) (c)	Existing Community legislation covers risk management
as **fuel in mobile or fixed combustion plants of mineral oil products** and use as **fuels in closed systems**	Article 56 (4) (d)	
in **cosmetic products**	Article 56 (5) (a)	Existing Community legislation covers risk management Exemption only applies if SVHC status is based on CMR properties or "equivalent level of concern " for human health
In **food contact materials**	Article 56 (5) (b)	
in **mixtures below certain concentration limits**	Article 56 (6)	considered as not giving rise to concern
in **medical devices**	Article 60 (2)	Existing Community legislation covers risk management Exemption limited to risks for human health
for **product and process orientated research and development - PPORD** (Article 3 (22))	Article 56 (3) 2, IF specified in Annex XIV with maximum quantity exempted	Encourage innovation
Risk from (categories of) use(s) is properly controlled	Article 58 (2), IF specified in Annex XIV , intitially or later (on a case and substance basis)	Existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance

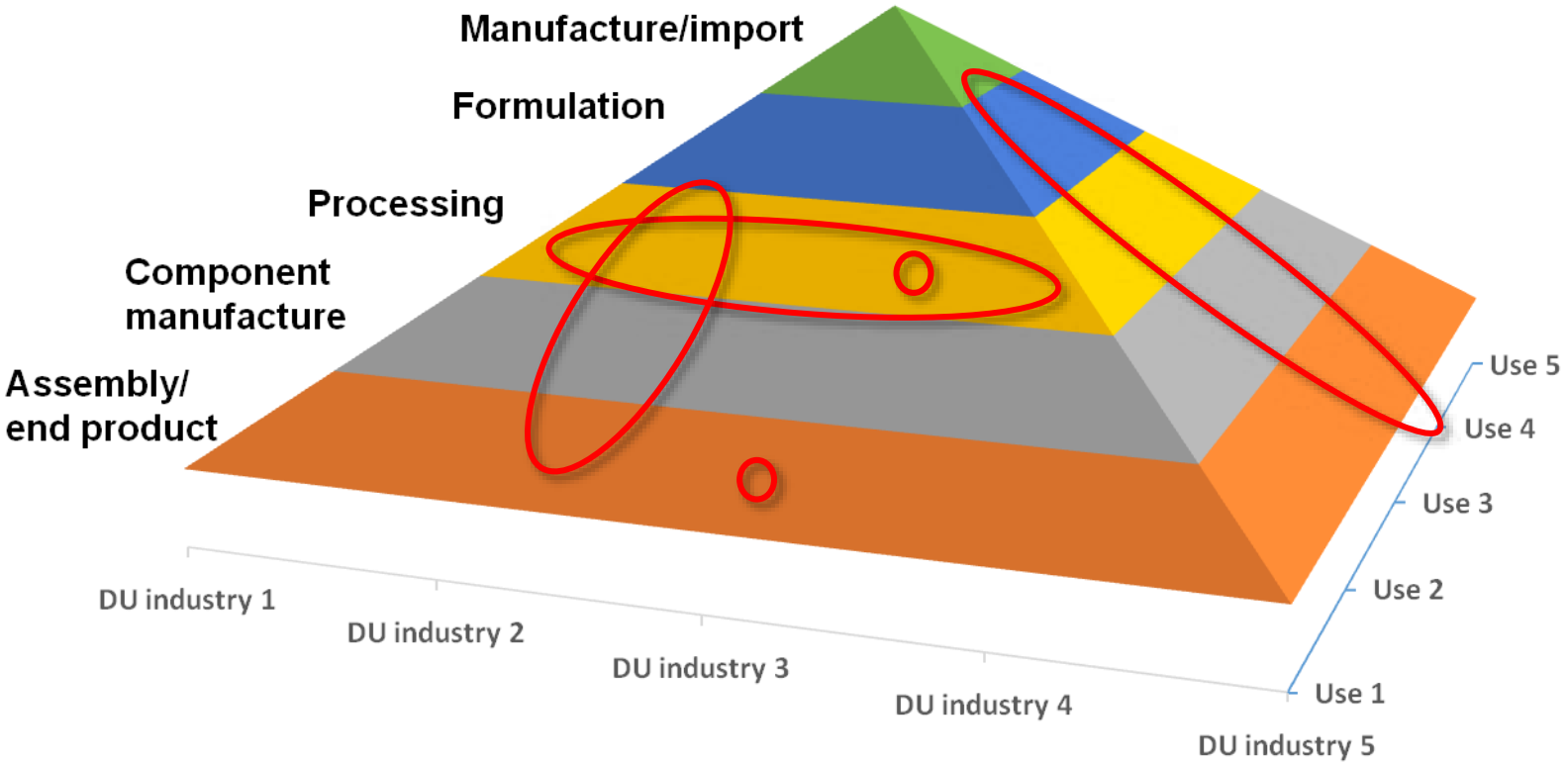
Content

Supply chain consideration per legal text

- Use coverage: top-down but NOT bottom-up
  (Source: ECHA)

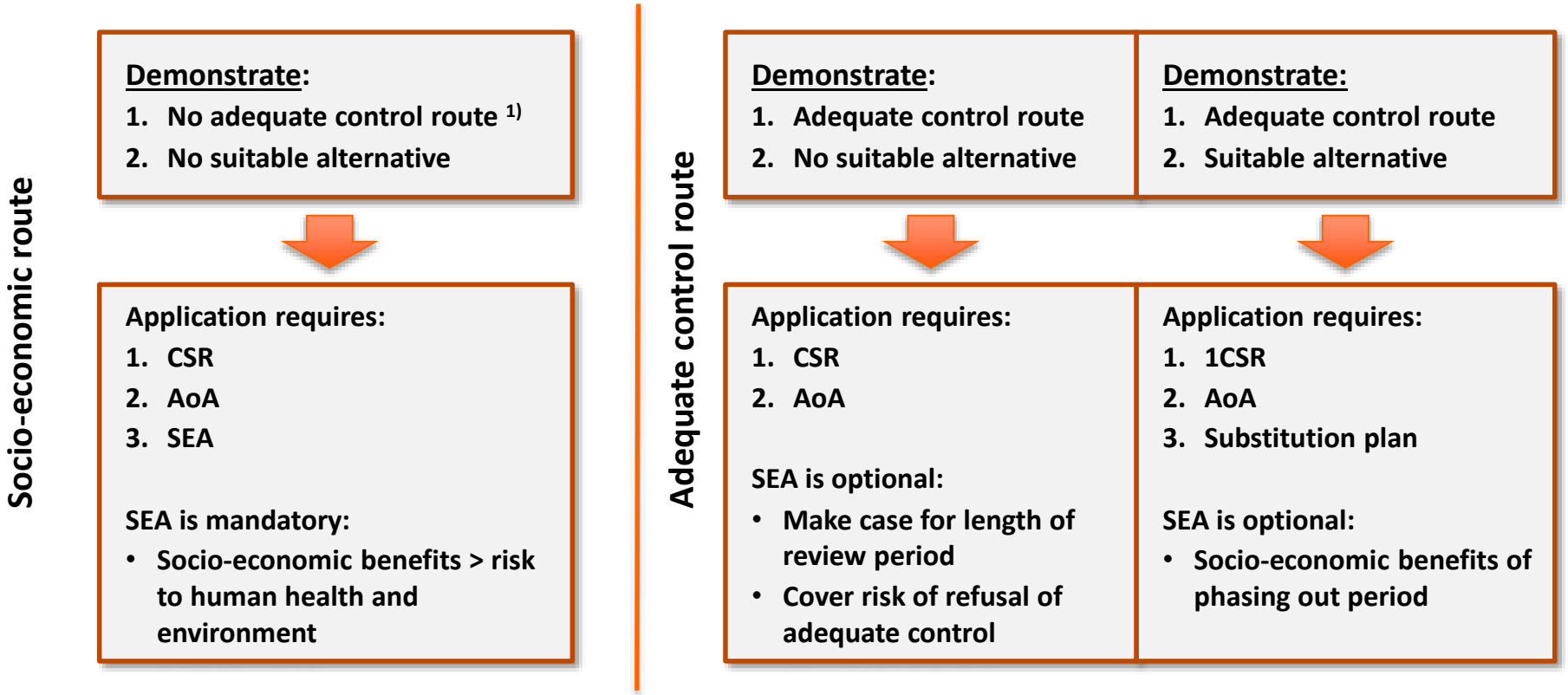


Different ways to get organized



Content

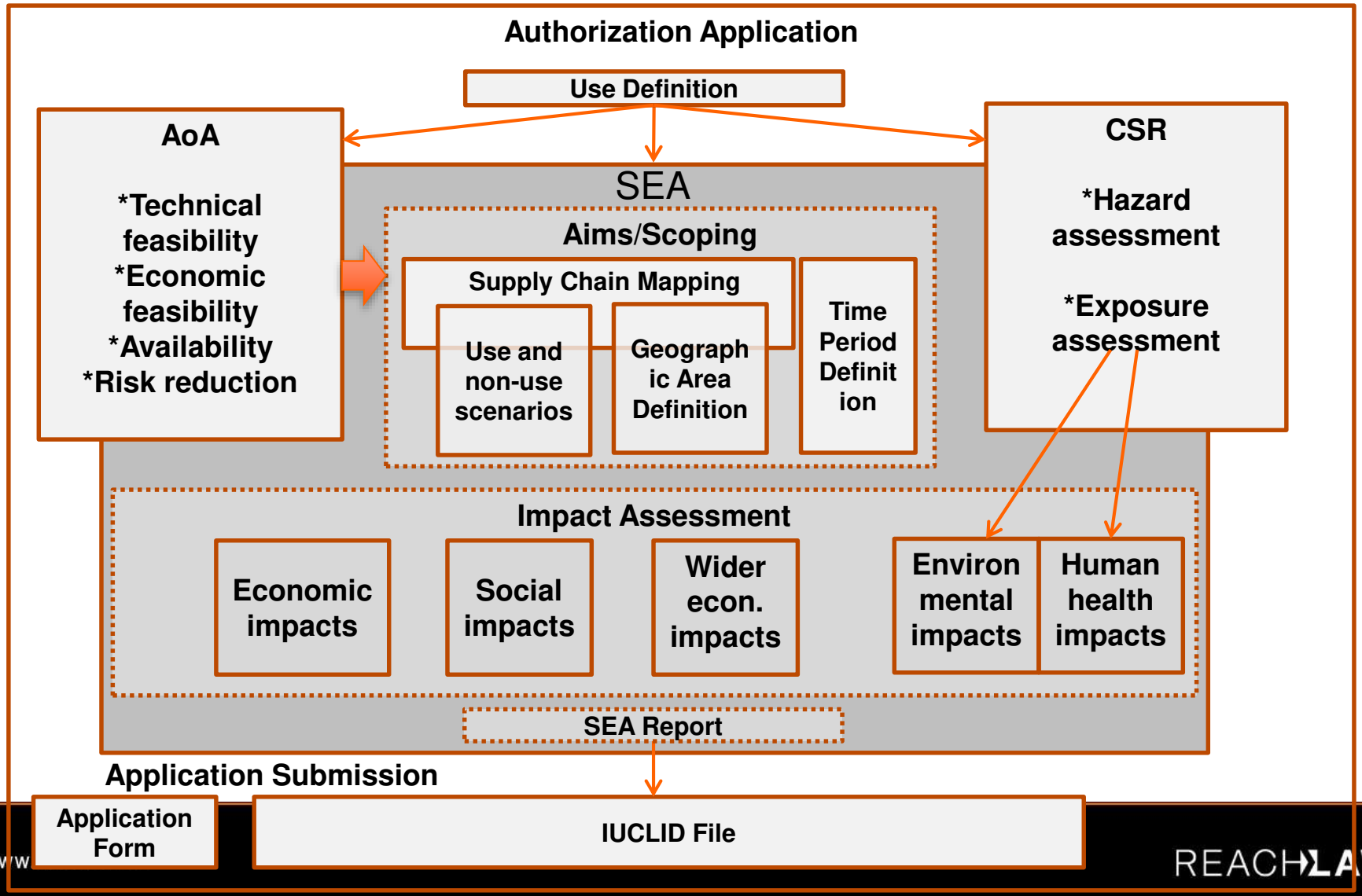
Authorization Workflow & Overview
Socio-economic Route



Analysis of Alternatives (AoA) provides financial information and the Chemical Safety Report (CSR) provides environmental and human health related information for the SEA

Authorization Scope, Workflow & Overview

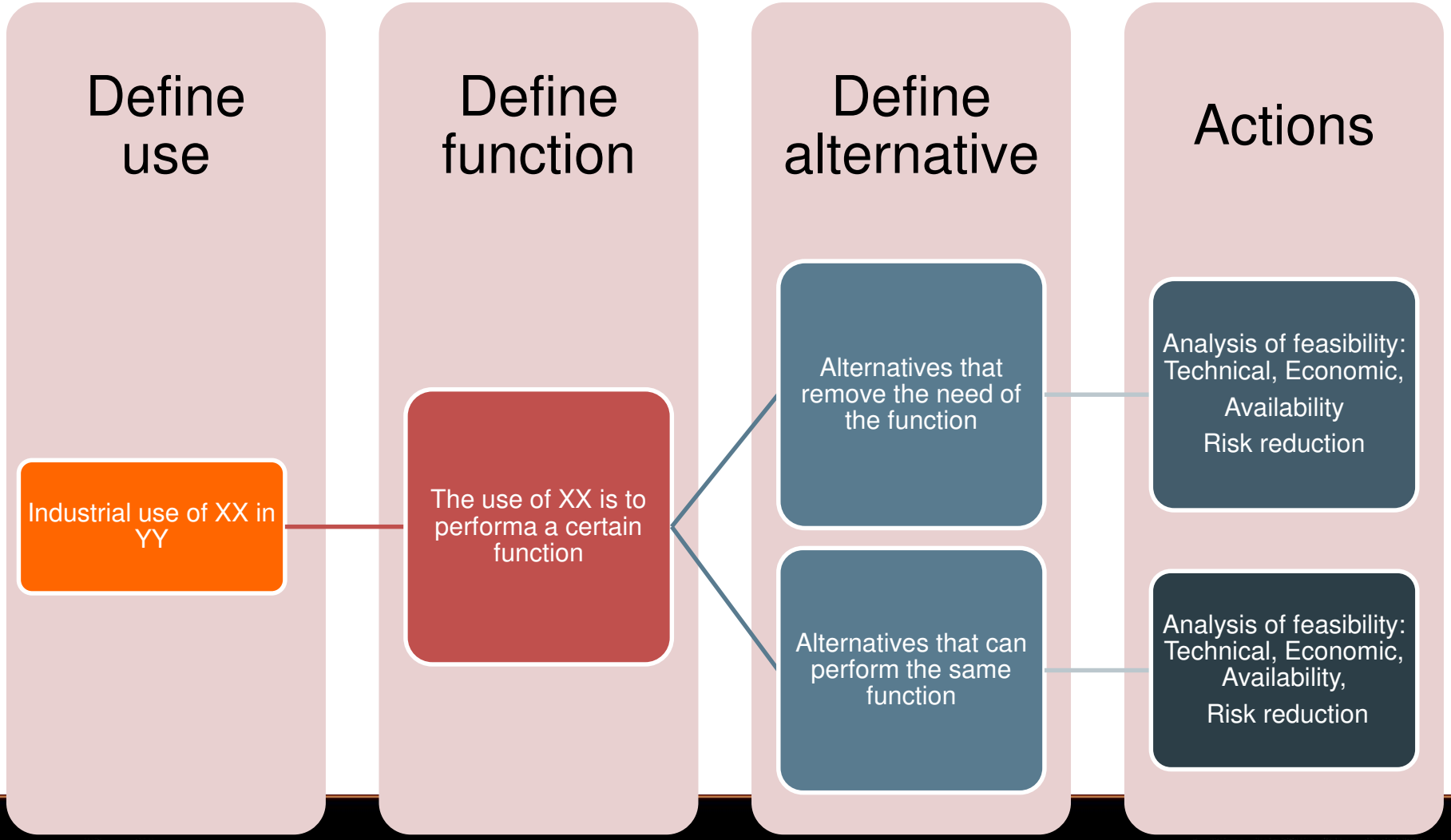
Authorisation Flow Chart with Components



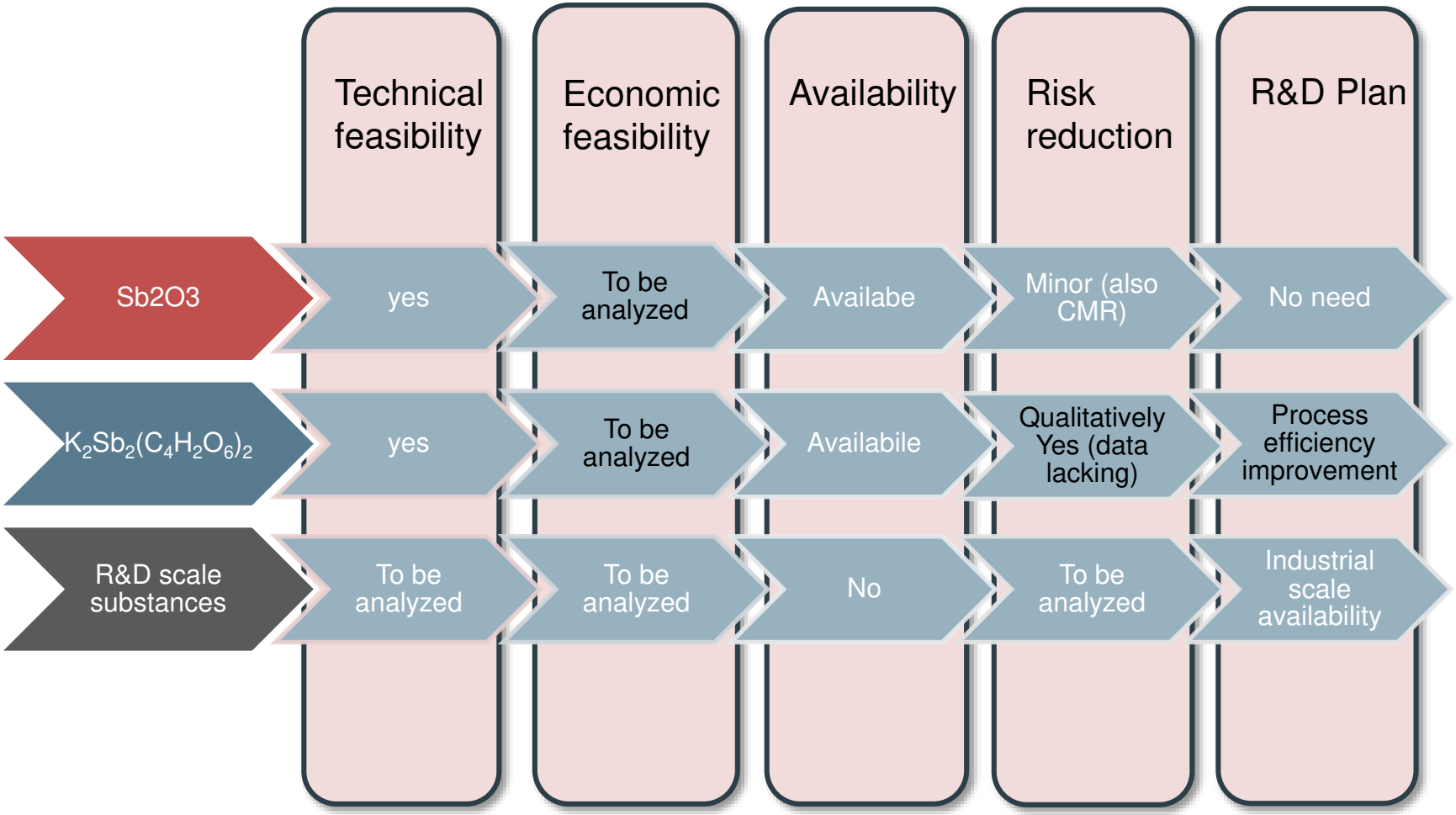
CSR – site specific exposure assessment

Task number	*Proposed process activity/task* (PROC) Description of the task carried out	1: No. of w orkers/ task, 2: Frequency of the task, d/year, 3: Duration of task/exposure, hours/shift	User's description of Operational conditions, procedures and methods used	Risk management measures	Personal protective equipments (PPEs) used	Other task related information
1	*Transport of substance*					
2	*Storage of substance*					
3	*Unloading/Mixing of substance with other materials*					
4	*Main process*					
5.	*Cleaning the site and handling of chemical waste*					
6 7. 8.	*Maintenance of euipment*					

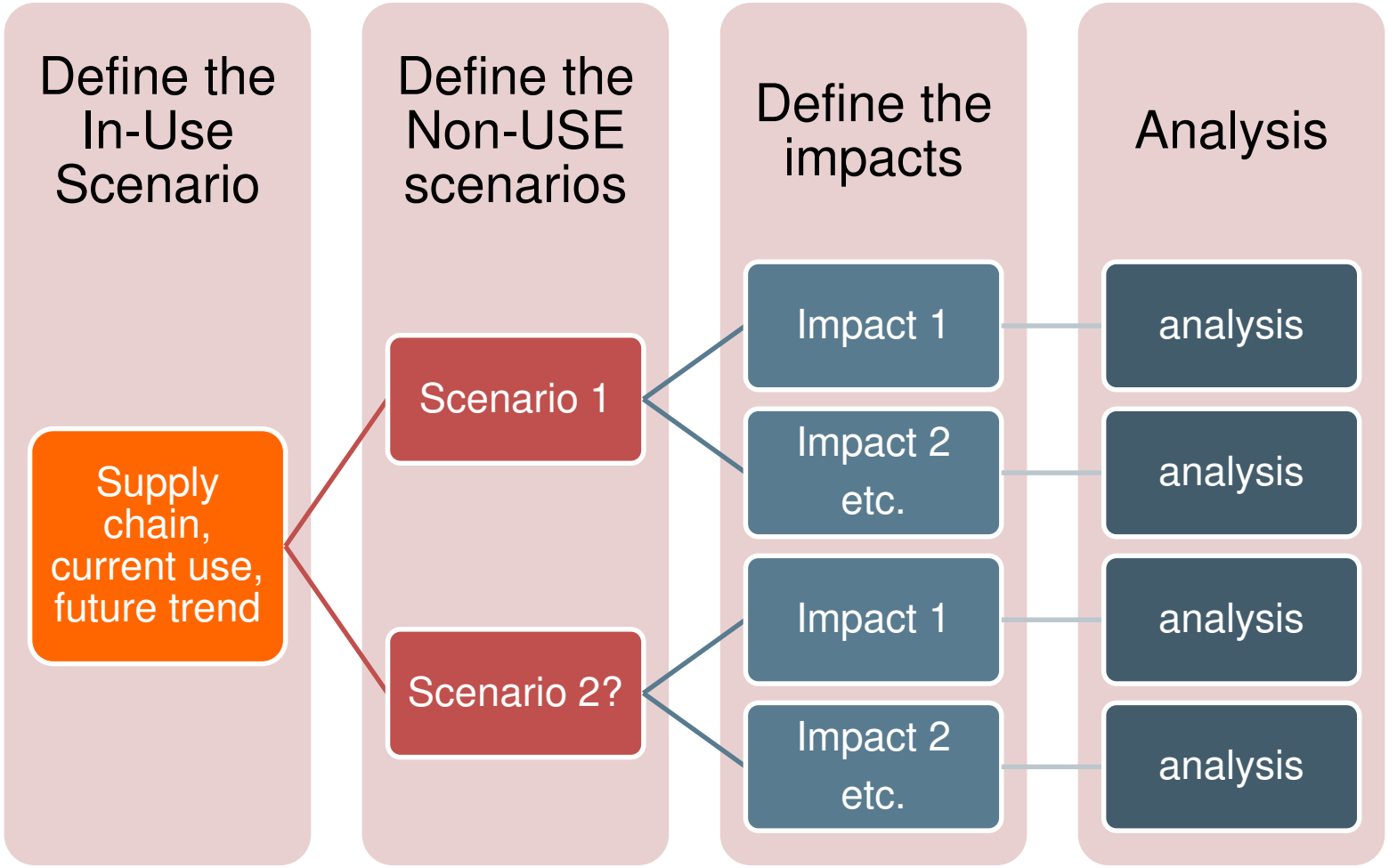
Analysis of Alternatives



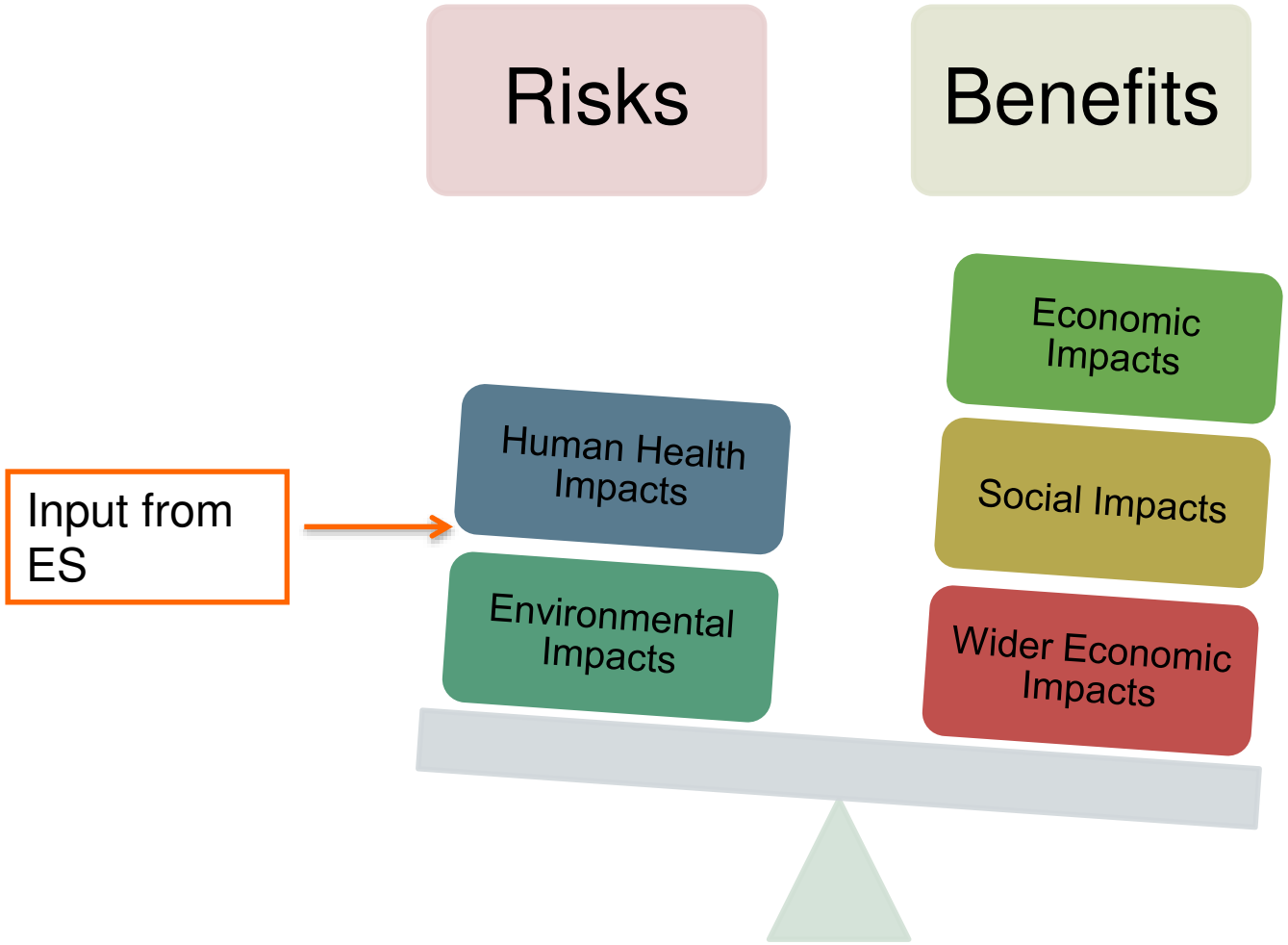
Analysis of Alternatives - 2



SEA process

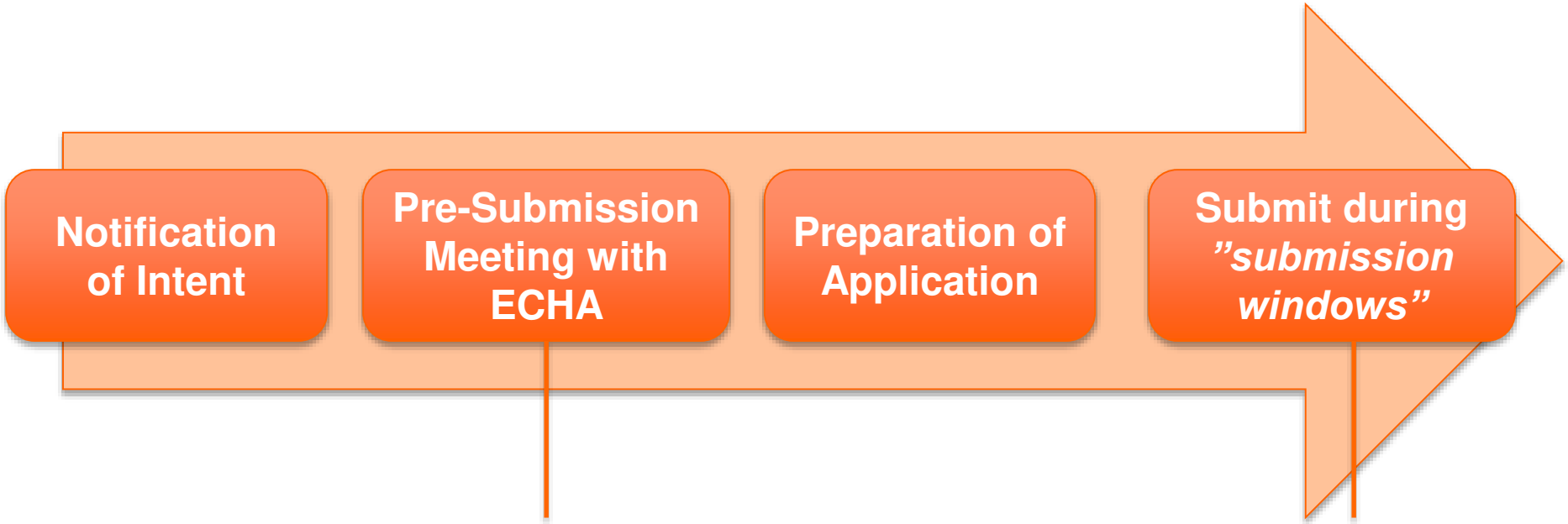

Define the In-Use Scenario
Define the Non-USE scenarios
Define the impacts
Analysis
Supply chain, current use, future trend
Scenario 1
Scenario 2?
Impact 1
Impact 2 etc.
Impact 1
Impact 2 etc.
analysis
analysis
analysis
analysis

Socio-economic analysis (SEA) process



Content

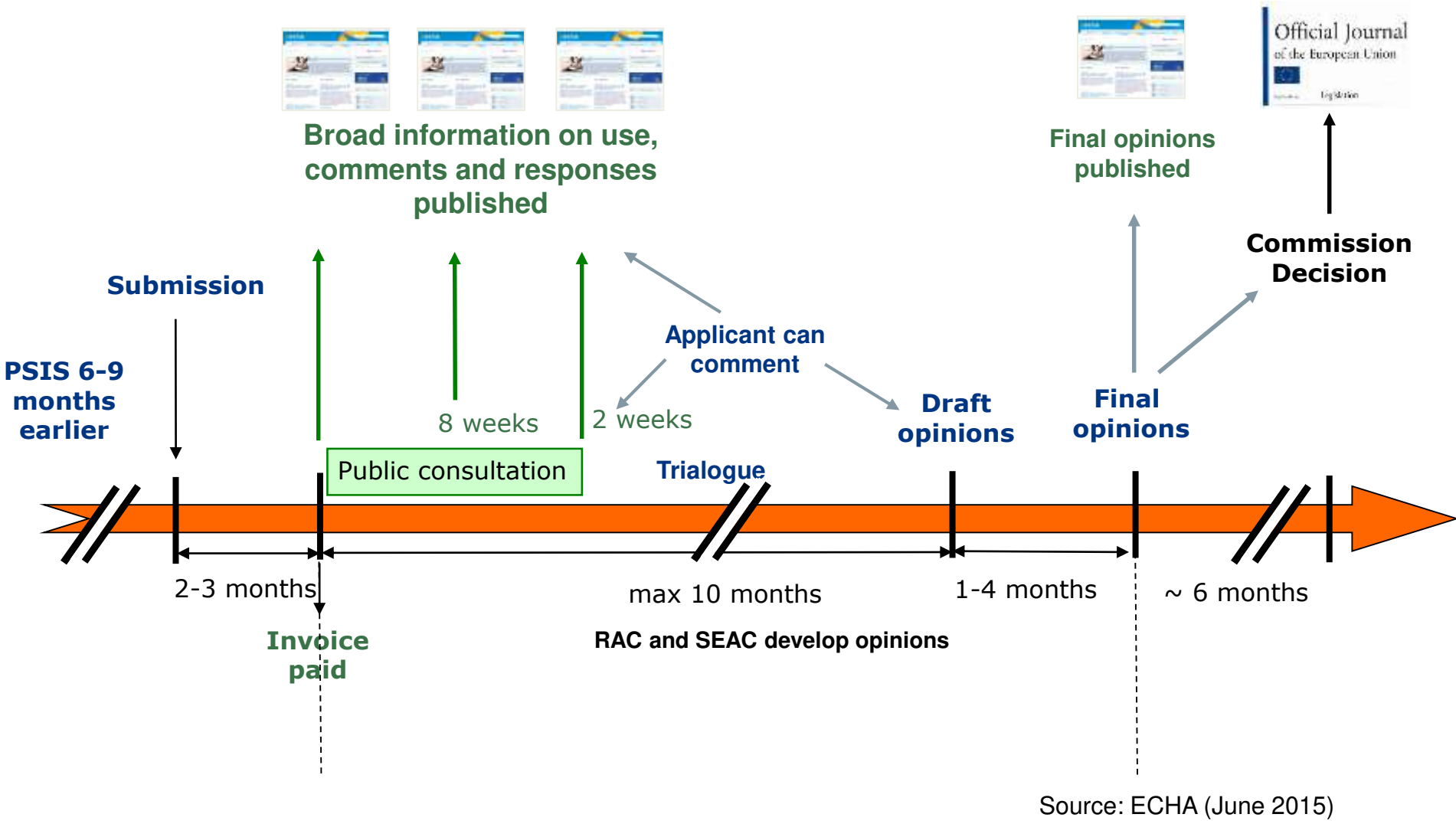
Interaction with ECHA till submission



- Offered by ECHA to allow better planning on both sides
- Clarify how to technically prepare and submit an application
- Have a preliminary discussion on "broad description of uses"
- Not: discussion of application content, including the assessment and conclusions drawn by the applicant
- In principle, one session per application.

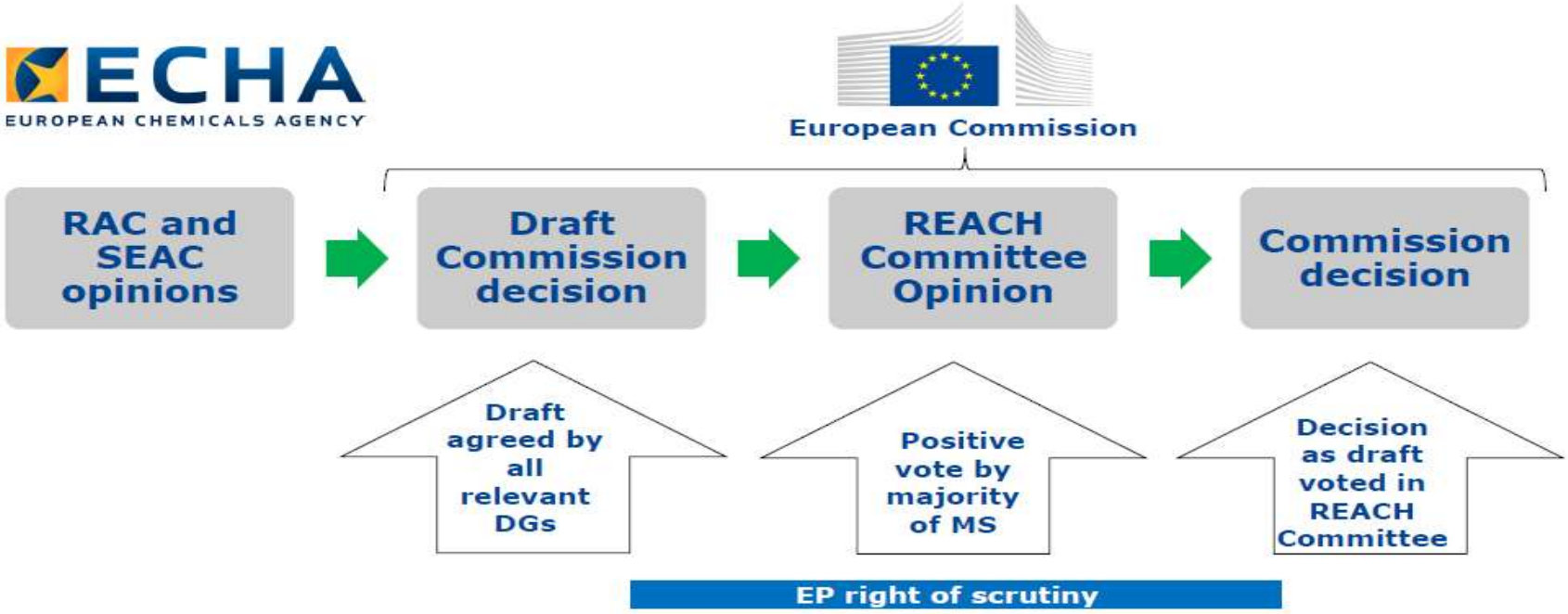
Facilitate ECHA Committee work, see ECHA website

Decision making: ECHA process



Source: ECHA (June 2015)

Decision making: post ECHA process
"Weak" right of scrutiny for AfA decisions



Right of scrutiny for the European Parliament and the Council (Art. 11 of Regulation (EU) No 182/2011):

Either the European Parliament or the Council may at any time indicate to the Commission that, in its view, a draft implementing act (here: draft AfA decision) *exceeds the implementing powers provided for in the basic act* (here: REACH Regulation). *In such a case, the Commission shall review the draft implementing act, taking account of the positions expressed, and shall inform the European Parliament and the Council whether it intends to maintain, amend or withdraw the implementing act* → **No blocking right under the Examination Procedure**

Diagram source: EC (November 2015)

Application for authorisation process
List of authorisation decisions

- Latest update available at: http://ec.europa.eu/growth/sectors/chemicals/reach/about/index_en.htm

Last update: 15/01/2016

EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SME's

Consumer, Environmental and Health Technologies
REACH

REACH Authorisation Decisions

List of authorisation decisions adopted on the basis of Article 64(8) of Regulation (EC) No 1907/2006 (REACH). The list also includes reference to related documentation concerning all applications for authorisation on which an opinion has been adopted by the Committee for Risk Assessment and the Committee for Socio-economic Analysis of ECHA on the basis of Article 64(5) REACH.

Substance name	Authorisation decision	Summary in OJ	Applicant(s)	Exposure scenario(s) from application (CSR)	Further details[1]
Bis(2-ethylhexyl) phthalate (DEHP)	C(2014) 5551 final	OJ C 260, 9.8.2014, p. 10	Rolls-Royce plc	DEHP 1-CSR-ES	ECHA documentation – DEHP1
	PENDING ADOPTION Submission planned to REACH Committee in February 2016	PENDING ADOPTION OF DECISION	Vinyloop Ferrara S.p.A. Stena Recycling AB Plastic Planet srl	DEHP 4-use-1-CSR-ES DEHP 4-use-2-CSR-ES	ECHA documentation - DEHP4 use 1 ECHA documentation - DEHP4 use 2

Content

Review period

Review period: Runs from the sunset date. The applicant needs to re-apply 18 months prior to the end of this period if they wish to continue to use/place on the market for a use

- SEAC's criteria during opinion-making:
  - RAC's recommendation regarding magnitude and uncertainty in remaining risks and the risks of alternatives
  - Time to transition to an alternative or to find a suitable alternative, including certification and other regulatory requirements
  - Other socio-economic factors and relevant considerations, such as investment cycles, bridging applications, spare parts, uncertainties etc.
- Length of the review period: standard (7 years), short (e.g. 4 years) or long (12 years)

Content

Next Steps After EC Decision

Authorisation Granted	Authorisation number on label	DU notification (3 months)	Minimise exposure and emissions	Review report (18 months before review period ends)
Authorisation Refused	Do not supply / use			
In both cases	SDS update	Registration update	*Challenge adverse EC decision before General Court*	

Enforcement of authorisation provisions
First pilot project: Three non-compliance cases

- Co-ordinated by the ECHA Forum, 18 Member States participating
  - Conducted during 2015
- Substances checked: **MDA** and **Musk xylene**
  - **sunset date: 21.8.2014**
  - no authorisations granted for these substances
- 421 inspections (235 on-site, 186 desktop)
- **3 non-compliances** (case of Musk xylene)
  - Self import of a small quantity of third country products by an etno shop (shop with folk culture articles)
  - Raw material mix containing Musk xylene in stock at a formulators premises, which was not used and finally was disposed of.
  - Sell off after the deadline of business stock by a formulator.
- Measures taken: written advice, an administrative order and a fine
- Enforcement report: http://echa.europa.eu/documents/10162/13577/first_forum_pilot_project_authorisation_en.pdf

Exemptions used:
- Intermediate
- R&D
- in mixtures below 0.1%
- in biocidal products

Contact details

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Thank You
köszönöm
Kiitos
Vinaka
Maake
Asante
Shukria
Dhanyavadagalu
감사합니다
спасибо
Dankscheen
Kam Sah Hammida
Manana
Dankon
Matondo
Terima Kasih
Dank Je
Mauruuru
Biyan
Diolch i Chi
Taiku
Blagodaram
Dziekuje
Chokrane
Tack
Grazie
Juspaxar
Arigato
Mochchakkeram
Gracias
Khap
Tingki
நன்றி
धन्यवाद
cảm ơn bạn
Paldies
Gratias Tibi
Ua Tsaug Rau Koj
Bedankt
Dakujem
Grazas
Mèsi
Obrigado
Děkuji
Nuwun
Nirringrazzjak
Kia Ora
Kop Khun
ありがとう
Suksama
Rahmat
Matur Nuwun
謝謝
хвала
Welalin
Di Ou Mèsi
Djiere Dieuf
Misaotra
Danke
Merci
Go Raibh Maith Agat
Eskerrik Asko
Salamat
ขอบคุณ
Najis Tuke