WORKSHOP

Gestión global de la seguridad de productos químicos. ¿Se aplica REACH globalmente?

Benchmarking of Chemical Safety Systems – EU in comparison to APAC and the USA

Dr. Michael Cleuvers
Managing Director
Industrial Chemicals & Biocides
Dr. Knoell Consult GmbH

knoell worldwide registration

- Intro
- Comparison (EU, USA, APAC) regarding
  - Coverage of regulations
  - Registration schemes
  - Data requirements
  - Dossier evaluation
  - Risk assessment and procedures for Substances of Very High Concern
- Summary

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A look back:
World Summit on Sustainable Development (WSSD), Johannesburg 2002

Political commitment on the goal to achieve:

*«By 2020, chemicals are used and produced in ways that lead to the **minimization of significant adverse effects on human health and the environment**»*

What do we need to get there?

Summary of recommendations (OECD)

- Increase cooperation and mutual acceptance of data
- Improve understanding of adverse effects of chemicals on individuals and populations and better quantify sources of exposure
- More preventative action to avoid harm from chemicals
- Promote sustainable use of chemicals
- Improve the public's right to know
- Improve enforcement of regulations

Aim of chemical regulations

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REACH:

The purpose of this Regulation is to ensure a ***high level of protection of human health and the environment****,……..as well as the free circulation of substances on the internal market while* ***enhancing competitiveness and innovation****.*

This Regulation is based on the principle ***that it is for manufacturers, importers and downstream users to ensure*** *that they manufacture, place on the market or use such substances* ***that do not adversely affect human health or the environment****.* ***Its provisions are underpinned by the precautionary principle****.*

TSCA:

Adequate information should be developed with respect to the effect of chemical substances…..on ***health and the environment*** *and that the* ***development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures****;*

(2) adequate authority should exist to ***regulate chemical substances…..which present an unreasonable risk of injury to health or the environment****, and to take action with respect to chemical substances and mixtures which are imminent hazards; and*

(3) authority over chemical substances and mixtures should be exercised in such a manner as ***not to impede unduly or create unnecessary economic barriers*** *to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures* ***do not present an unreasonable risk of injury to health or the environment.***

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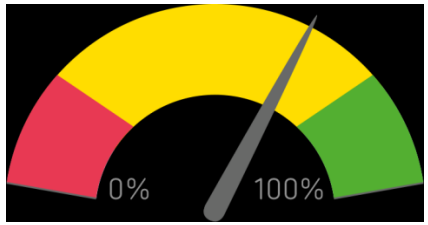
Coverage of regulations (substances subject to full registration)

- EU REACH:
  All substances > 1t/a (existing and new ones)
- US-TSCA:
  Only new substances > 10 t/a (< 10 t/a subject to a Low Volume Exemption, LVE)
- Japan CSCL:
  Only new substances > 10 t/a (< 10 t/a subject to LVE or Small Quantity Permit, SQP)
- Korean REACH (AREC):

  Only new substances > 1 t/a (< 1t/a simplified registration), only designated existing substances (*will be amended January 1st, 2019 to all existing chemicals > 1 t/a*)
- China REACH (MEP Order No.7)

  Only new substances > 1 t/a (< 1 t/a simplified registration),
- Taiwan TCSCA:
  Only new substances > 1 t/a (< 1 t/a simplified registration) and prioritized existing chemicals

Benchmark „coverage“



While all mentioned regulations cover new substances,

- Currently only EU REACH covers also all existing substances (> 1t/a)
- K-REACH and Taiwanese TCSCA cover only selected existing substances
- US TSCA, Japanese CSCL and Chinese MEP Order No 7 currently don´t have general registration obligations for existing substances

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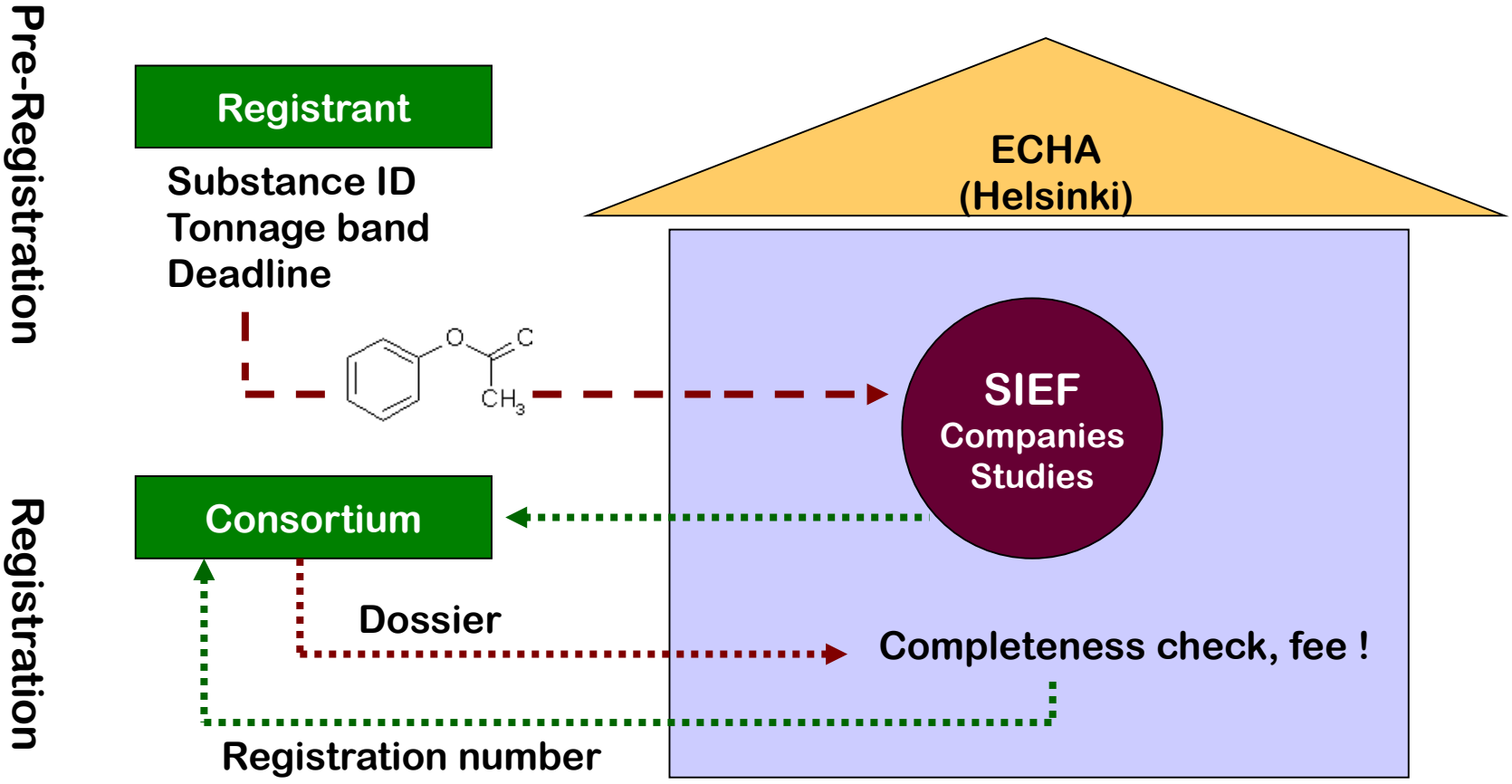
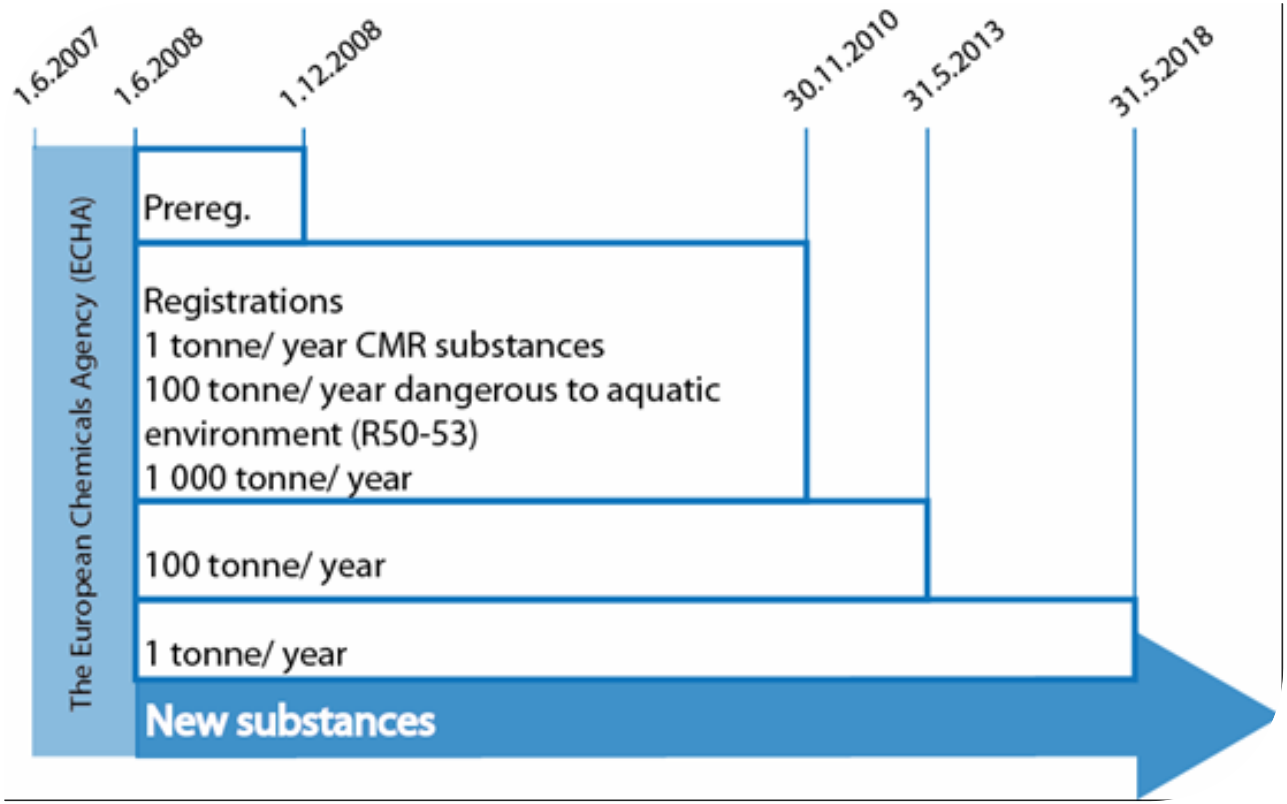
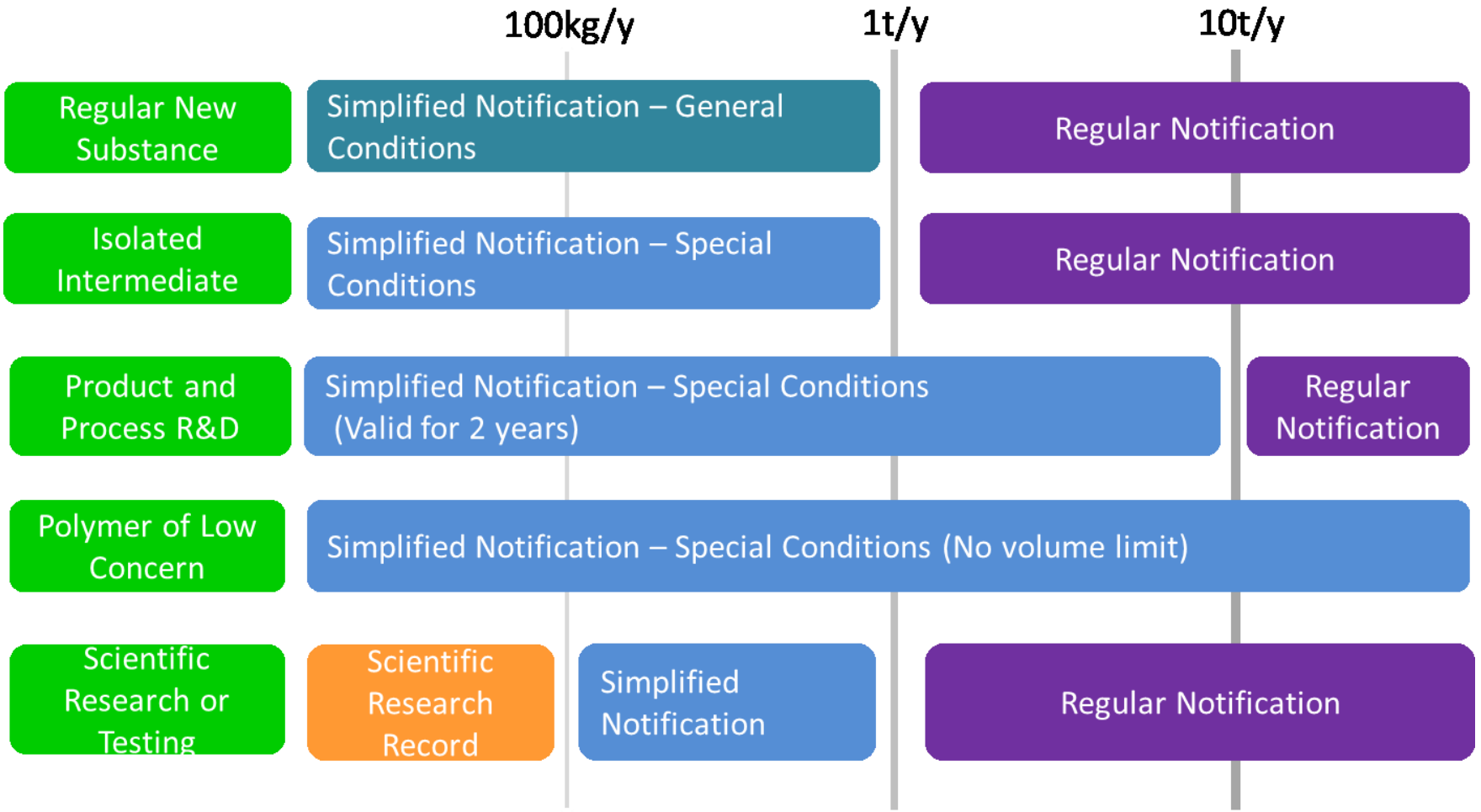
EU REACH


Pre-Registration
Registrant
Substance ID
Tonnage band
Deadline
ECHA
(Helsinki)
SIEF
Companies
Studies
Registration
Consortium
Dossier
Completeness check, fee !
Registration number

EU REACH registration scheme / timeline



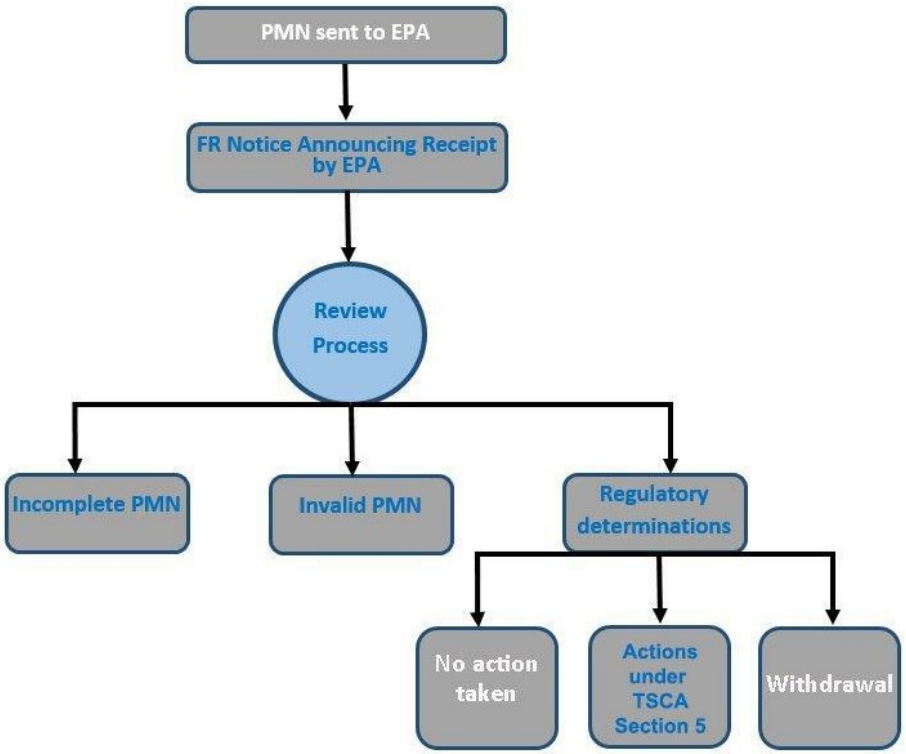
China: MEP Order No. 7



TSCA: PMN procedure for new chemicals

What is a "new chemical"?

For purposes of regulation under TSCA, if a chemical is on the TSCA Inventory, the substance is considered an "existing" chemical substance in U.S. commerce. Any chemical that is not on the Inventory is considered a “new chemical substance. The original Inventory was compiled in 1978-79 with very limited data and no risk assessment by the Agency.

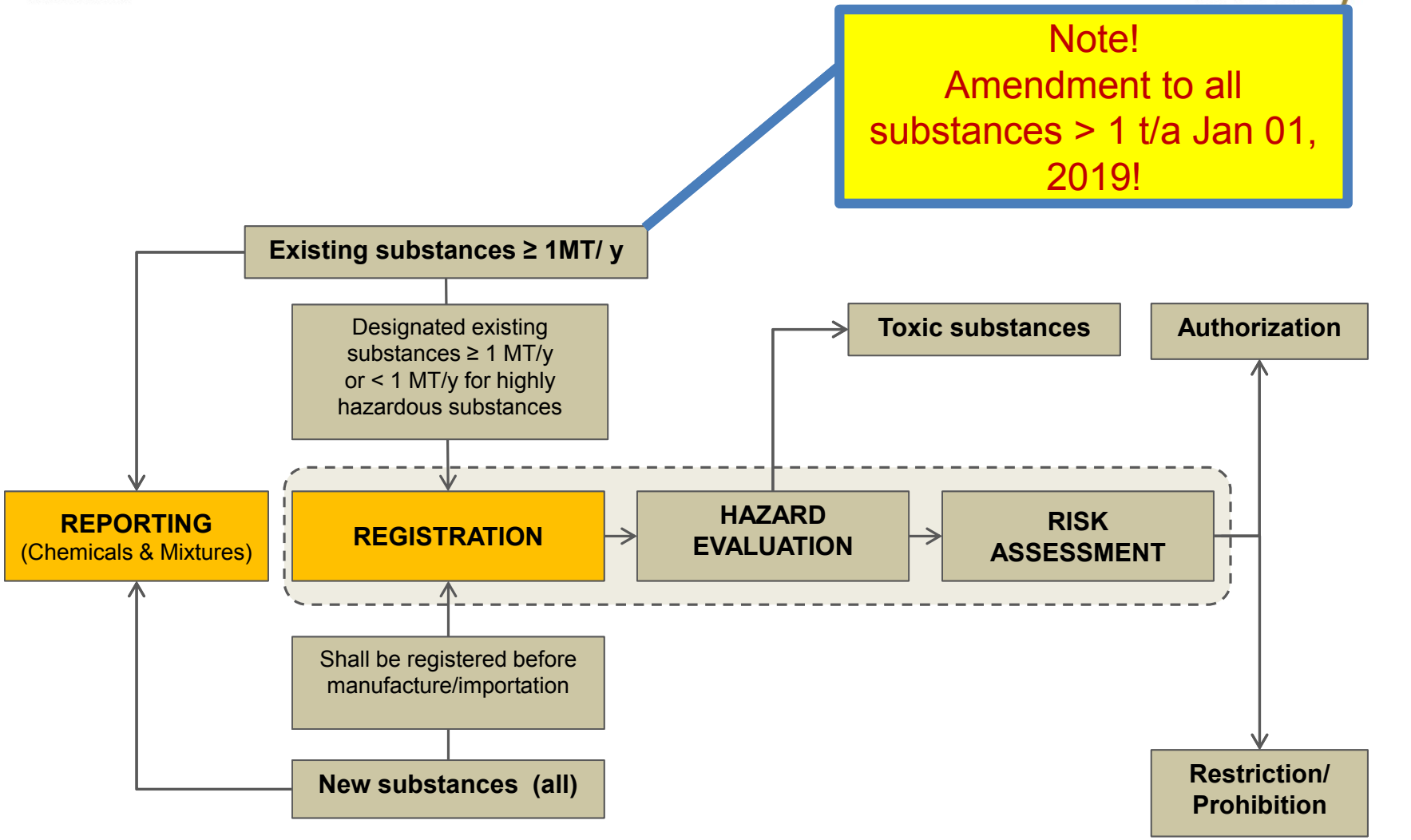


PMN Outcomes

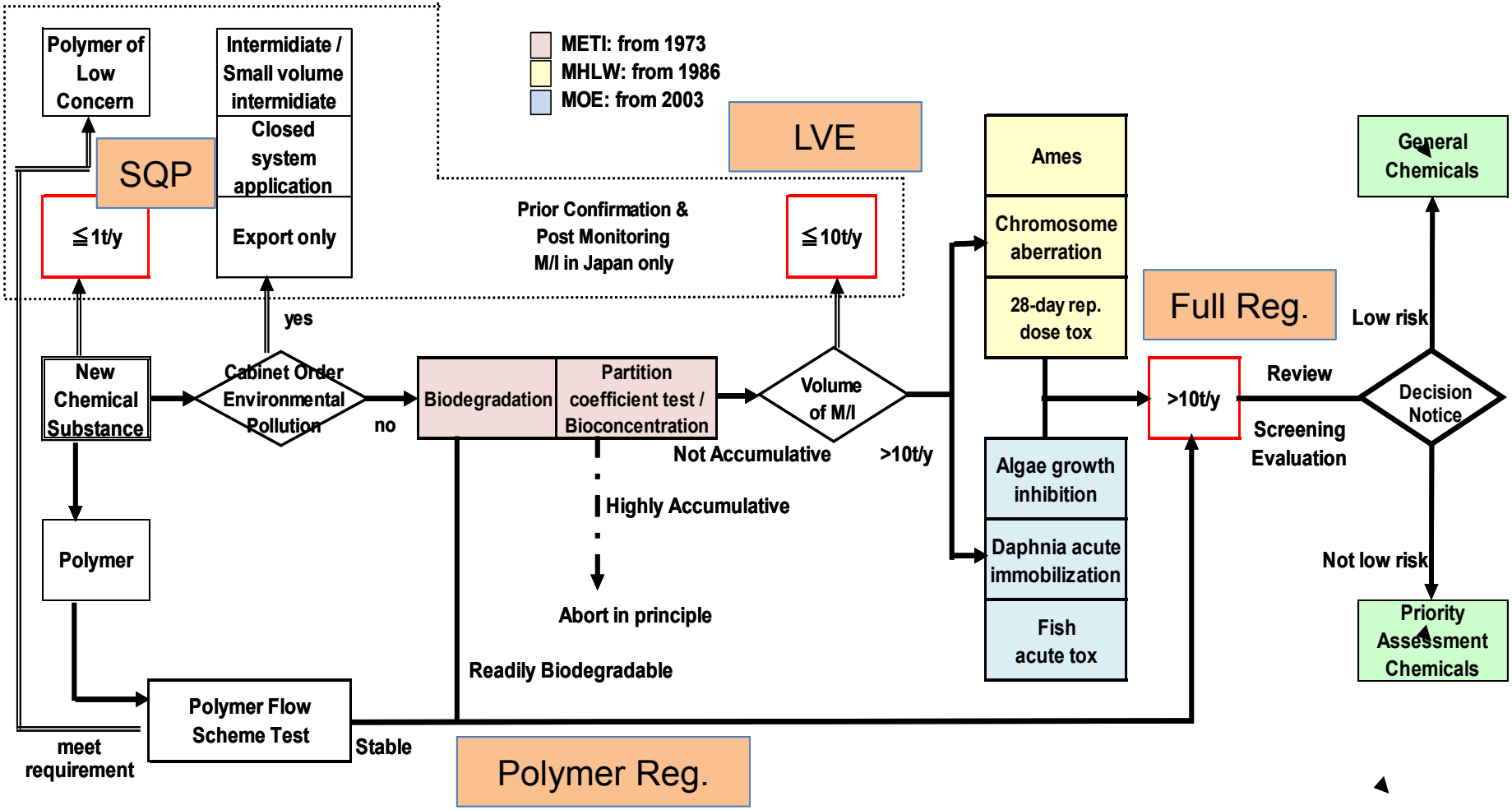
A	Presents an unreasonable risk
B	Information is insufficient or May present unreasonable risk or Has substantial production and exposure
C	Not likely to present unreasonable risk

- If A must regulate or ban
- If B
  - must issue a Consent Order with controls sufficient to mitigate risk **and**
  - must promulgate a Significant New Use Rule (SNUR) or explain why it is not necessary **or**
  - stop the review and require additional data be submitted
- If C must publish the basis for the decision
  - If "C" decision is published before the 90 day review expires the submitter is free to begin commercialization
  - A Notice of Commencement (NOC) must be submitted within 30 days of the first commercial manufacture/import

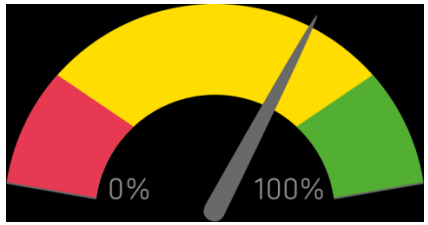
Korean AREC


Note!
Amendment to all substances > 1 t/a Jan 01, 2019!
Existing substances ≥ 1MT/ y
Designated existing substances ≥ 1 MT/y or < 1 MT/y for highly hazardous substances
Toxic substances
Authorization
REPORTING
(Chemicals & Mixtures)
REGISTRATION
HAZARD EVALUATION
RISK ASSESSMENT
Shall be registered before manufacture/importation
New substances (all)
Restriction/ Prohibition

Japan CSCL: Registration Scheme



Benchmark „registration schemes“



While all registration schemes are well explained,

- There are differing levels of complexity
- Japan CSCL is complex and „special“ compared to other, more REACH-like regulations
- The amount of available guidance for EU REACH is overwhelming and unique
- Besides the written „guidance“, there are some „unwritten“ rules in China
- No practical experience with new TSCA

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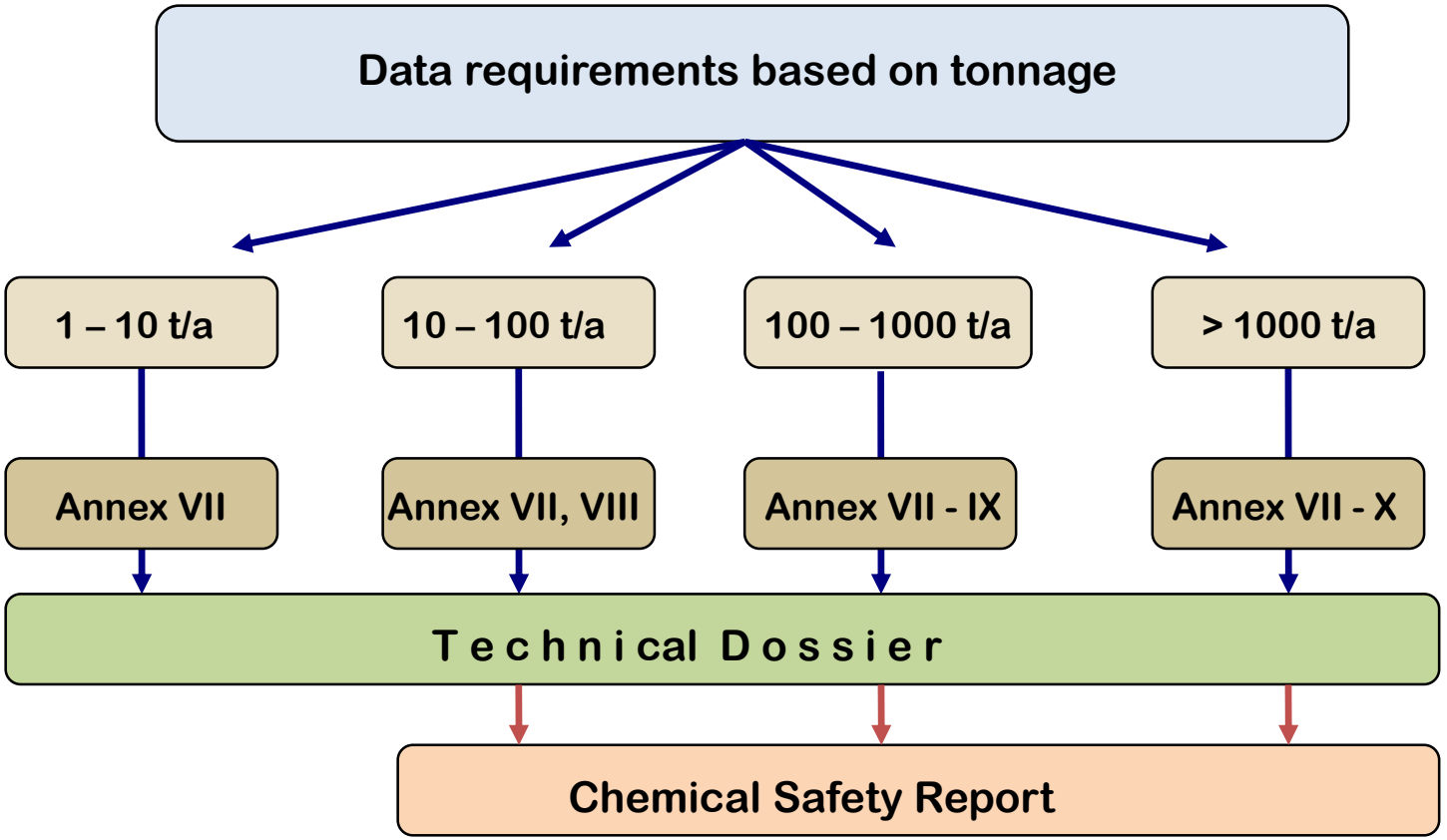
EU REACH: Data requirements



Data requirements APAC and USA

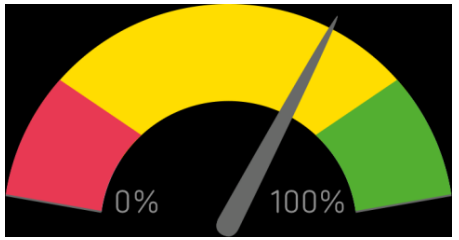
- The data requirements in Korea, Taiwan and also China (after the announced amendment of MEP Order No. 7) are pretty much aligned with EU REACH.
- Some ecotox studies (incl. biodegradation) for China has to be performed in China !
- Major difference in „waiving“ options (read-across, QSARs etc.)
- For a PMN under TSCA, there is no minimum data set but:
  - If the substance falls in a “Category of Concern”, or
  - Potential exposure causes a concern, or
  - The EPA has insufficient information to make a determination

  Data will likely be required. To fill data gaps EPA uses models to estimate exposures and releases and QSAR data to fill gaps in physical property and hazard information
- Japan again is “special”. If the substance is < 10 t/a, you need only a biodegradation study and the log Kow (to indicate the potential for bioaccumulation). Also for higher tonnages the standard data set is limited.

Japan study requirements

Type	No polymer (Low molecular weight chemicals)	Polymer
SQP (≦1t/y)	No study	No study
LVE (≦10 t/y)	- Biodegradation (to be done in Japan!) - Partition coefficient, logPow ≧3.5 → bioconcentration study	Polymer Flow Scheme (PFS) Test
Full (＞10 t/y)	(in addition to the above) - Ames test - Chromosome aberration study - 28-day repeated dose toxicity study - Acute fish toxicity study - Acute daphnia immobilization study - Algae growth inhibition study	

Benchmark „data requirements“



- US approach is considered to be very pragmatic. You have to deliver only the data in your possession and additional data only on request (if there is a concern)
- REACH is „data hungry“ (also for „harmless“ substances), but there are accepted options for alternatives to testing
- These alternative options are not or only partially accepted in APAC!
- China is problematic because ecotox studies (incl. biodegradation) has to be performed in China !
- Japan again is very “special”. Biodegradation testing has to be done in Japan. You may have to do testing even for metabolites (if they are new substances)

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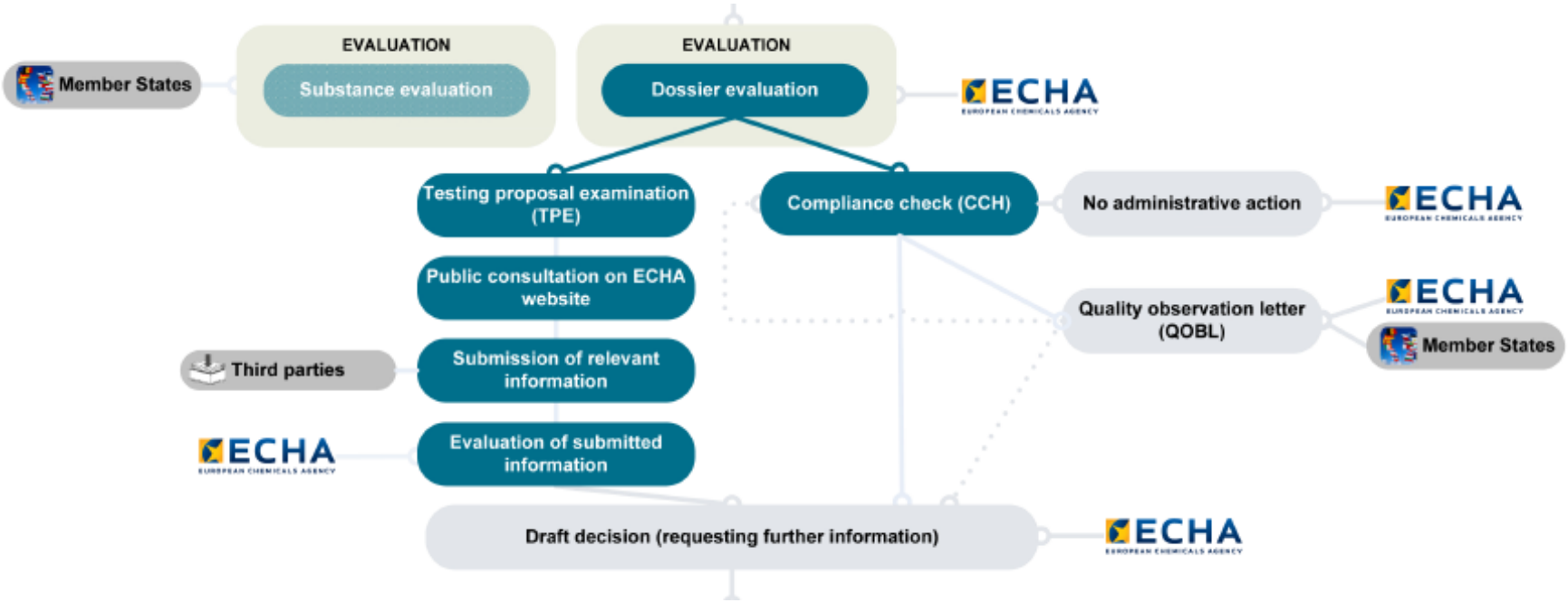
Evaluation under EU REACH



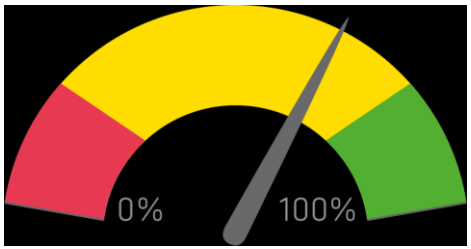
- Not all dossiers will be evaluated (5% target….)
- Dossiers are not selected randomly, but due to prioritizations (targeted compliance checks)
- Some dossiers will be evaluated more than once for different sections !

Evaluations in APAC and the USA

- Due to a different setup (number of dossiers is much lower, often only new chemicals) in APAC and the USA, in general all dossiers will be evaluated before acceptance of the authority

- The evaluation process is less standardized and less transparent compared to EU REACH, particularly in China

Benchmark „evaluation“



It is not easy to compare the dossier / substance evaluation, as the procedures are completely different and not always transparent.

It is assumed that the evaluation under EU REACH is the most sophisticated one involving different authorities.

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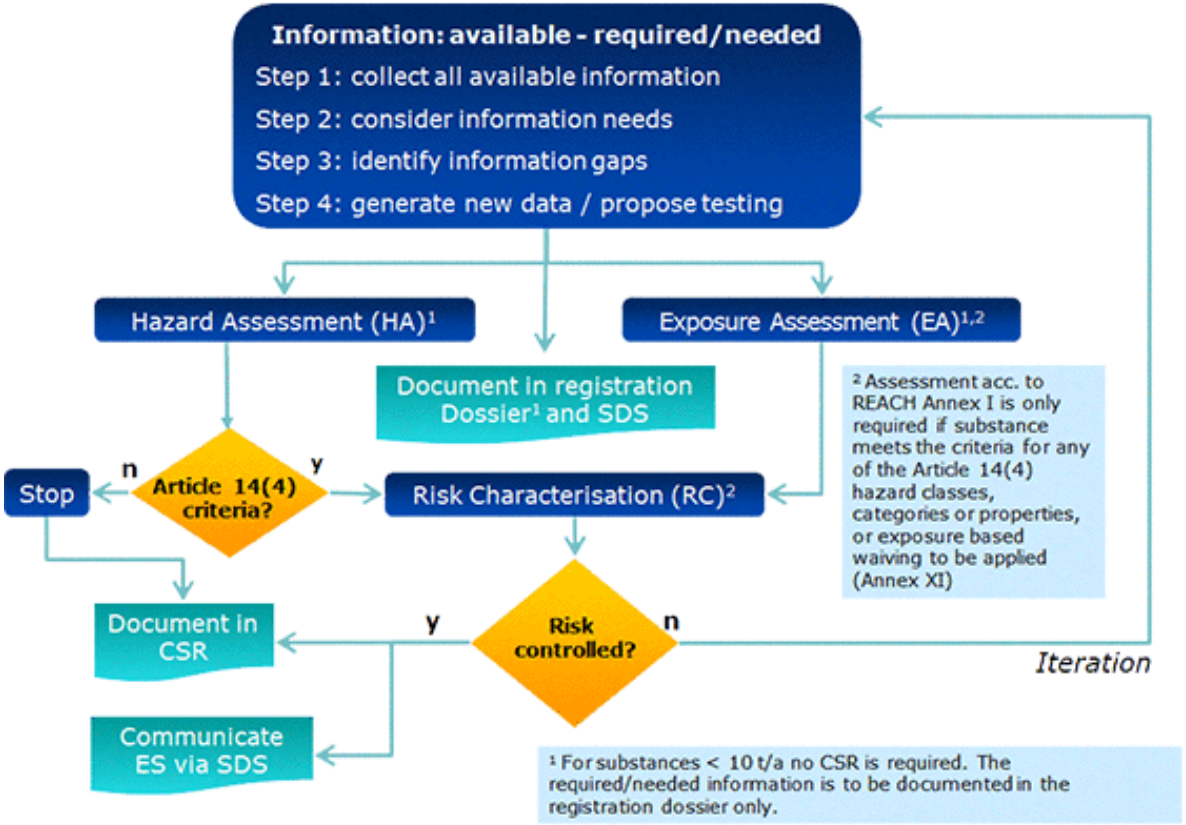
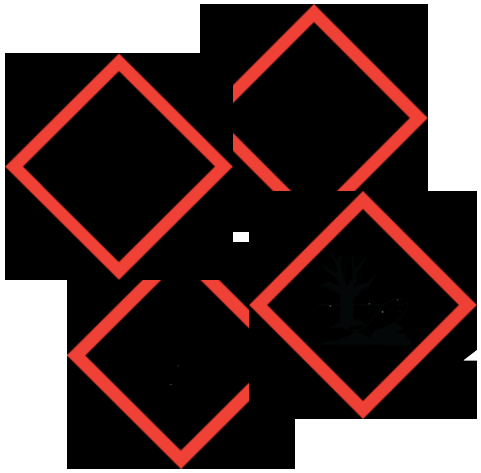
EU REACH: Risk Assessment



Risk assessment procedure



Exposure

Hazard

Environment

PEC

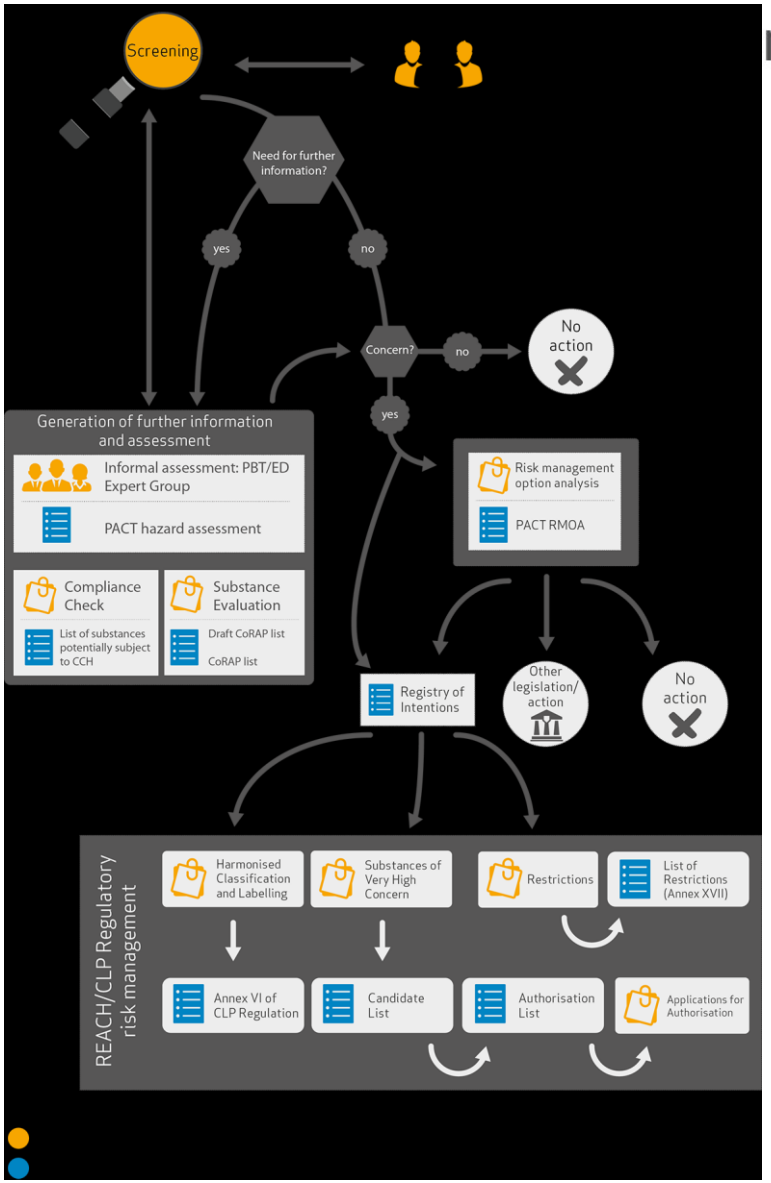
PNEC

Worker

OE/dose

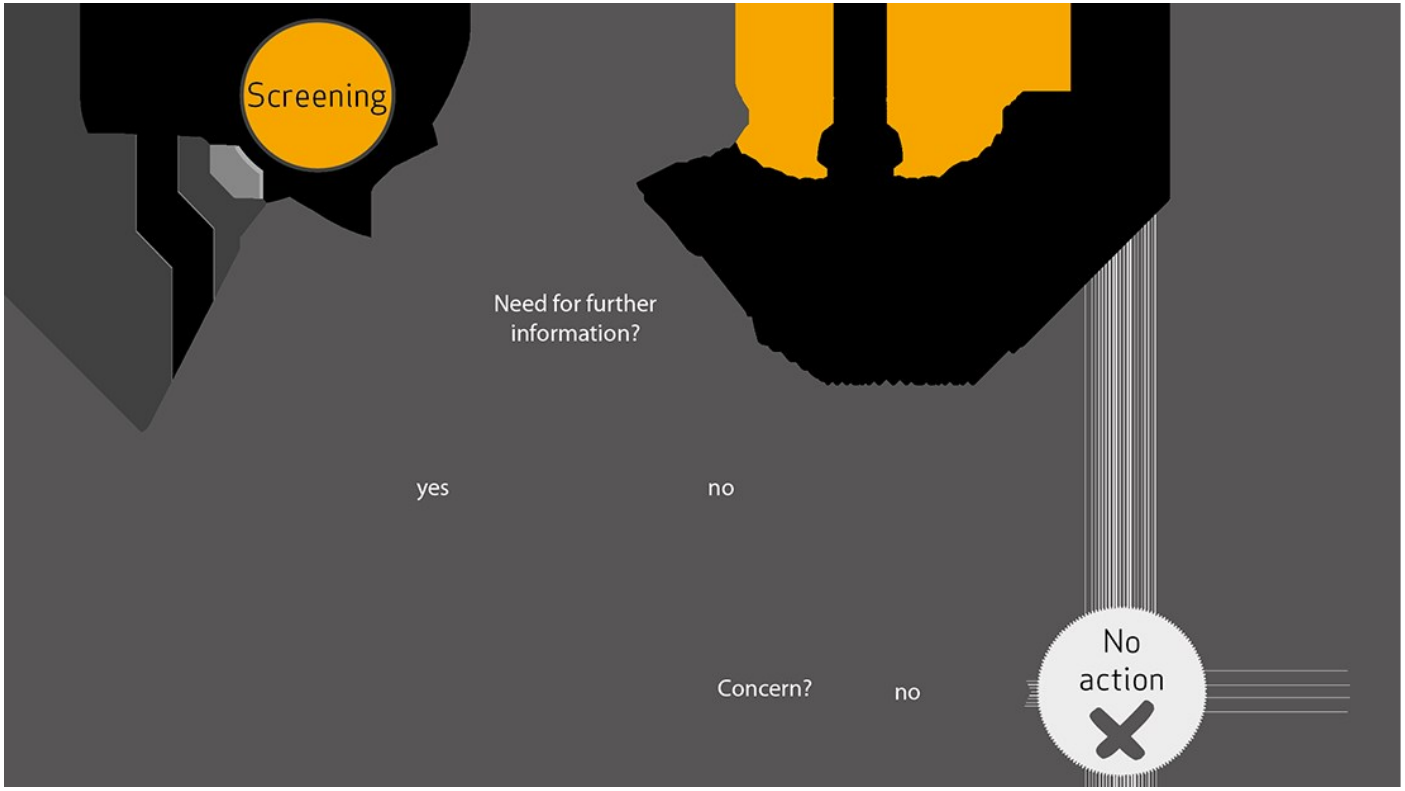
DNEL

Substances of potential concern



http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

Substances of potential concern

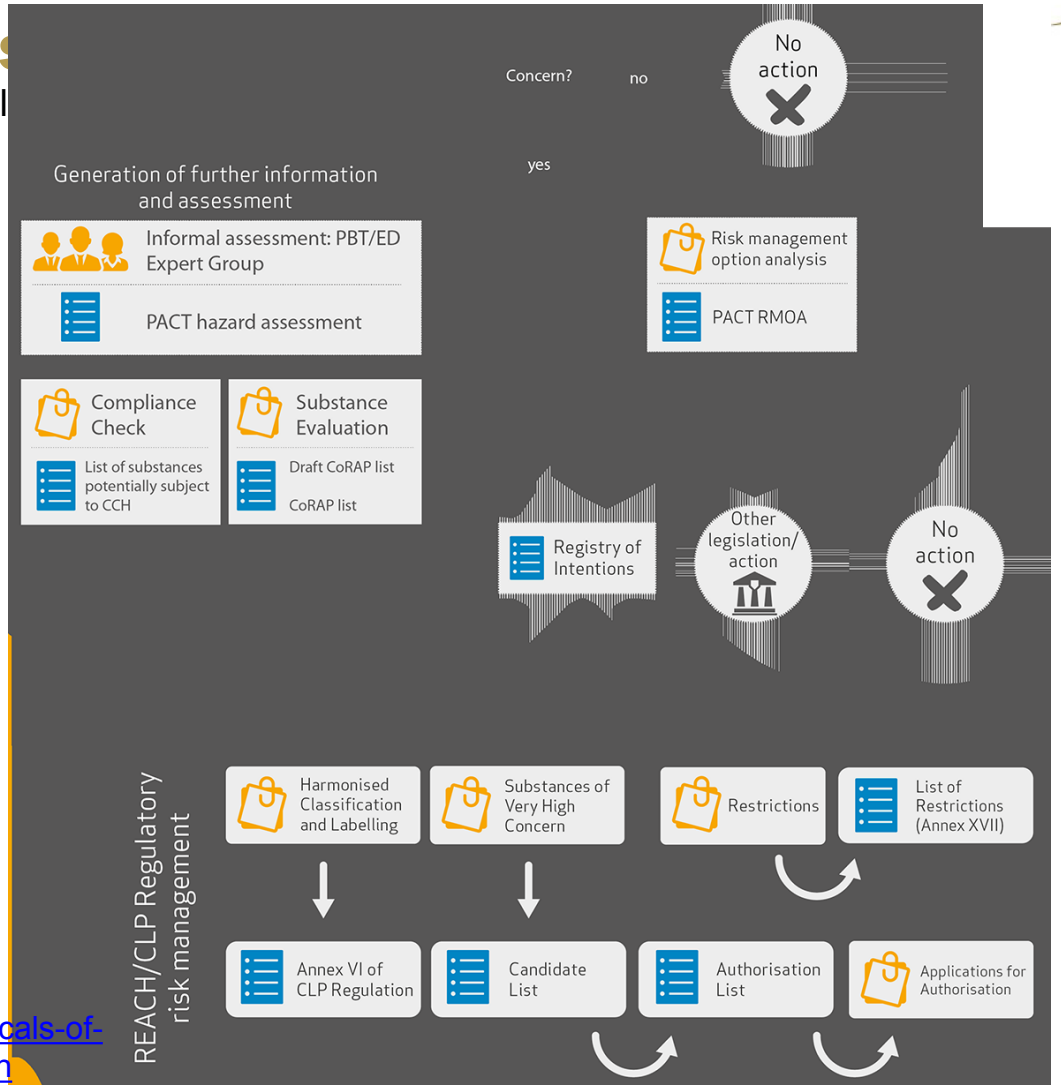


http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

PACT – central pos

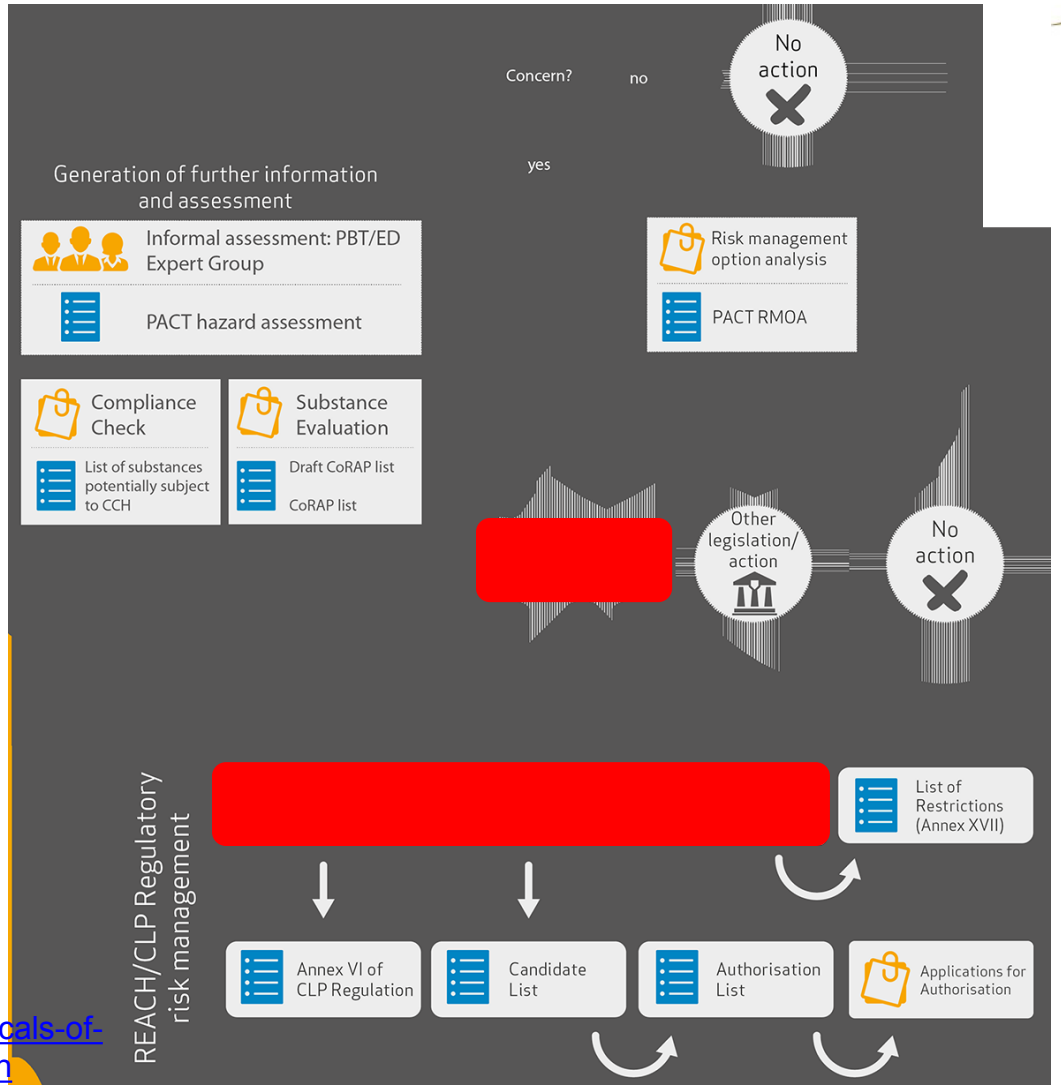
Public Activities Coordination Tool

PACT lists the substances for which a risk management option analysis (RMOA) or an informal hazard assessment for PBT/vPvB (persistent, bioaccumulative and toxic / very persistent and very bioaccumulative) properties or endocrine disruptor properties is either under development or has been completed



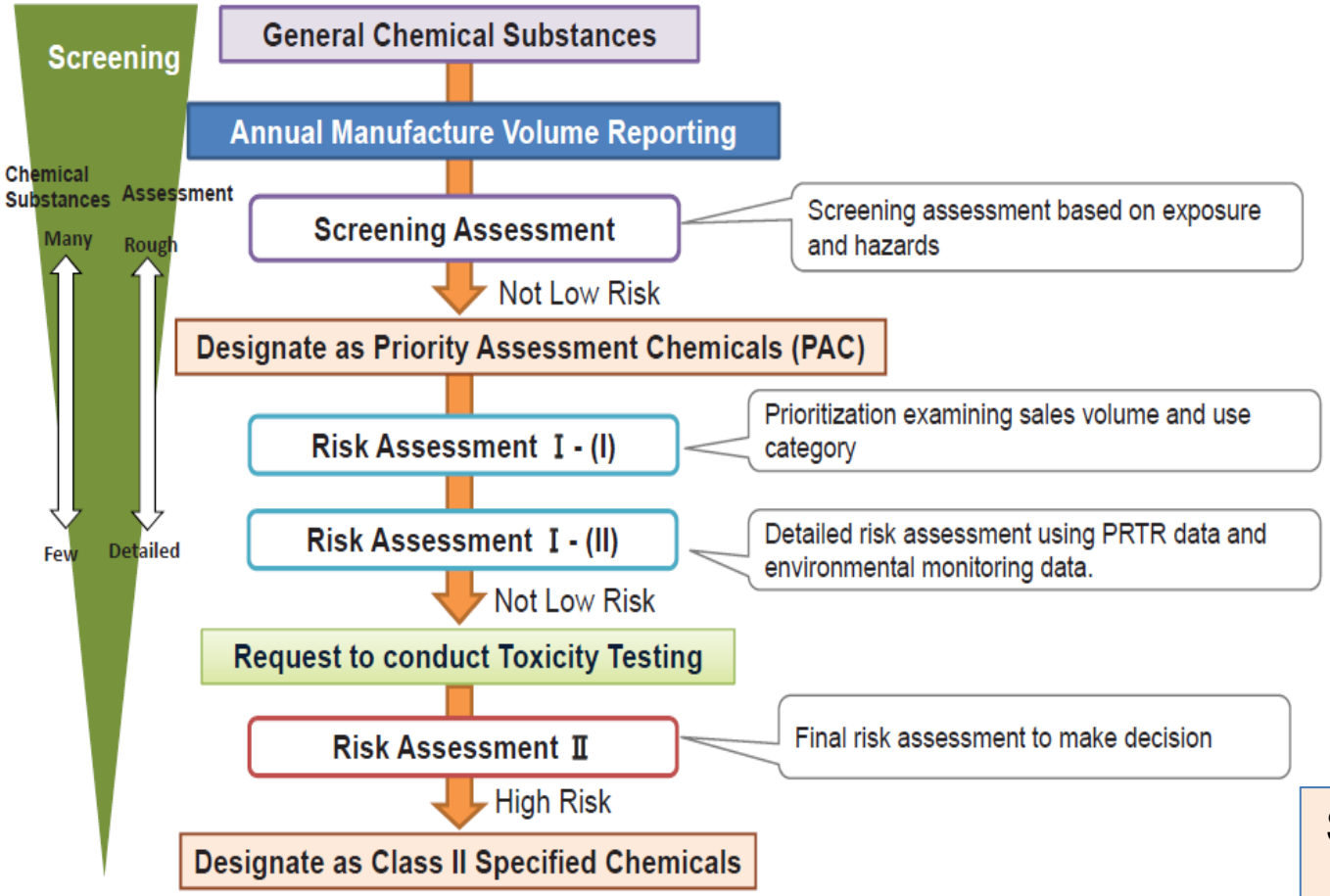
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

Further actions



http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

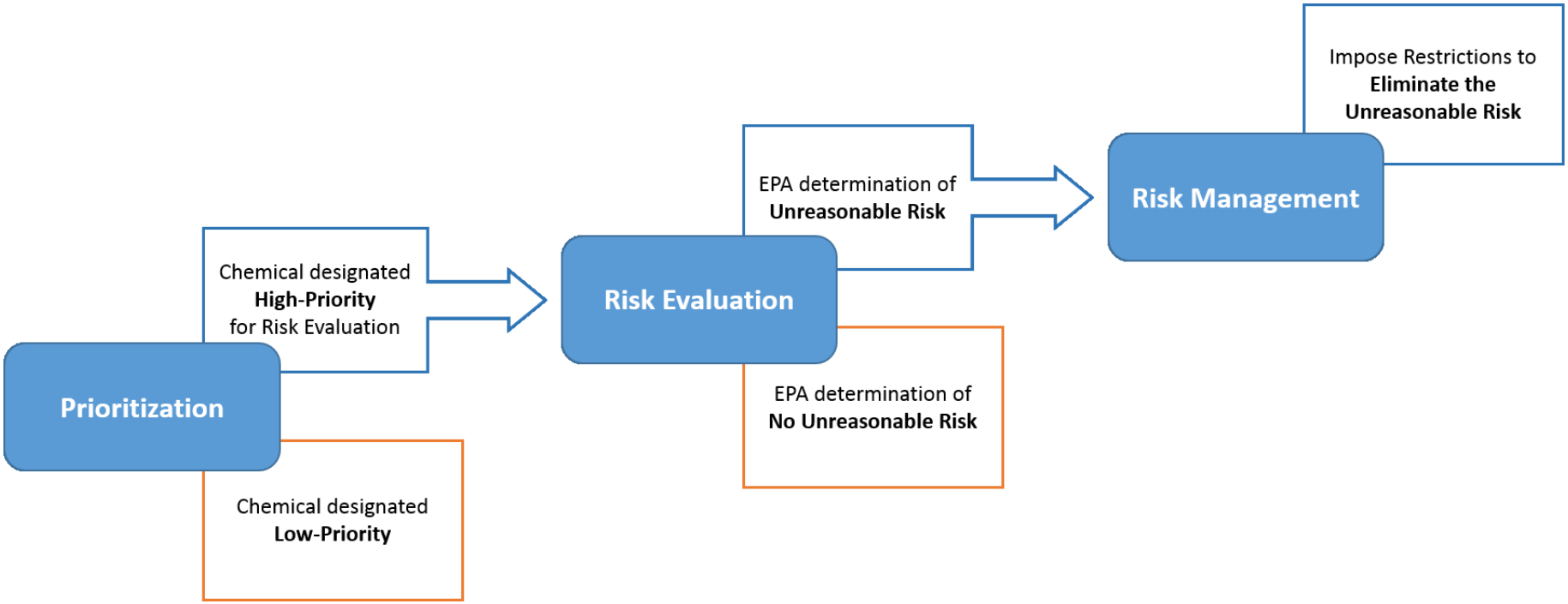
Japan: Risk Assessment by Authority



Substances or uses might be restricted or banned!

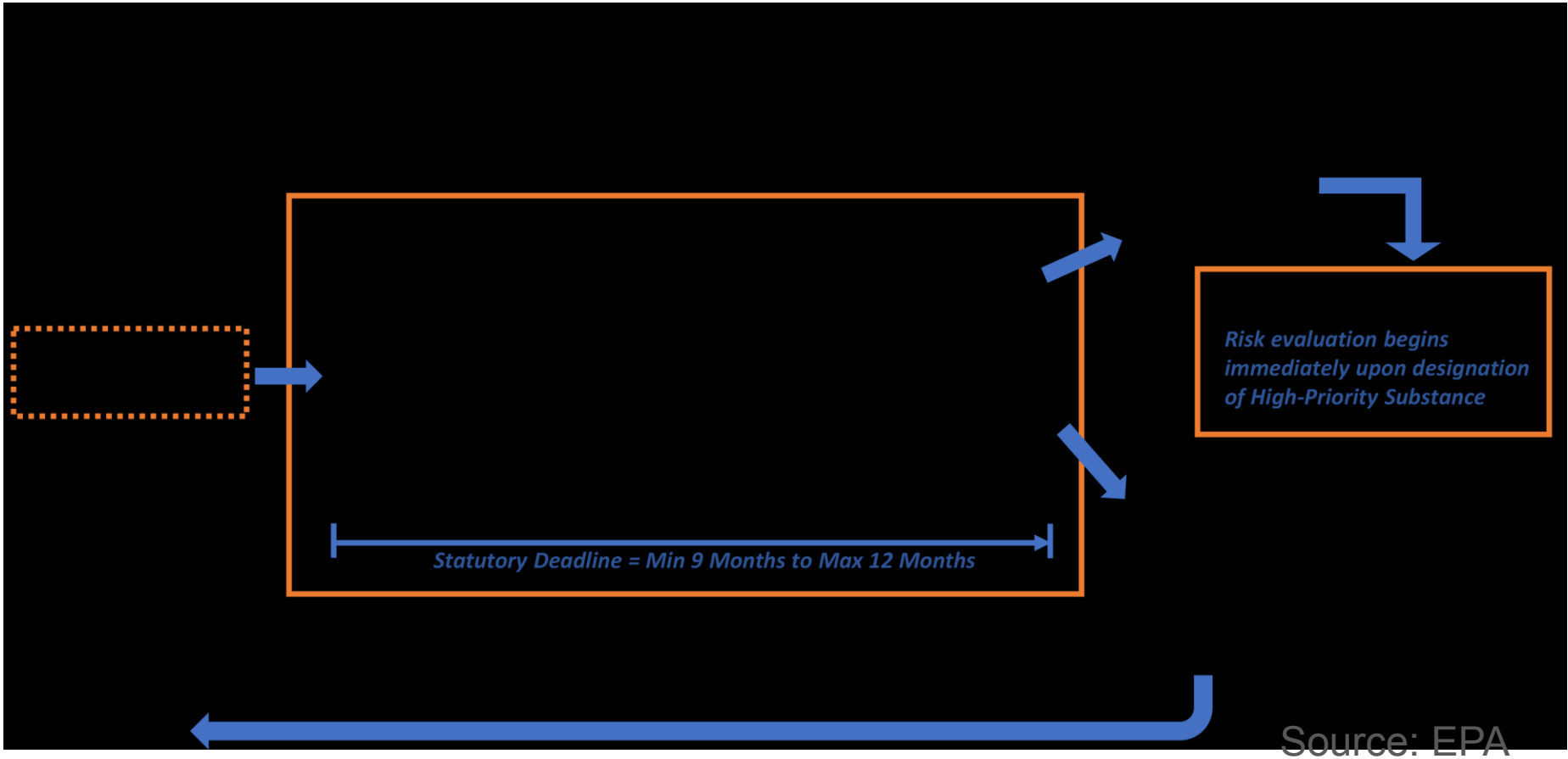
Reference: METI, Recent Progress of CSCL (FY 2014)

TSCA - Safety evaluation of existing chemicals



Source: EPA

TSCA - Safety evaluation of existing chemicals



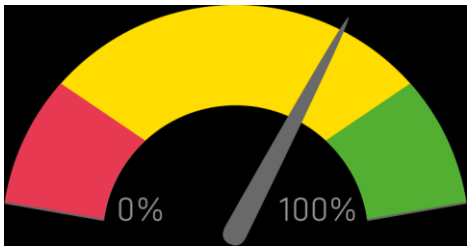
Source: EPA

TSCA - Substances of High Concern

- In the PMN process if risk of a concern substance is mitigated *in a particular use* the EPA may allow a new substance in commerce under strictly controlled conditions
  - These conditions are defined in a **Significant New Use Rule (SNUR)** which typically contains some or all of the following requirements as conditions:

  - Use of specific worker personal protective equipment
  - New Chemical Exposure Limits (NCELs) for worker protection
  - Specific Hazard communication language in the SDS
  - Distribution and use restrictions
  - Restrictions on releases to water, air and/or land, and
  - Recordkeeping

  → Which shows some similarities to an authorization under EU REACH



Benchmarking
„risk assessment and SVHCs“

- The procedures under EU REACH are very transparent, well documented and quite sophisticated

- Other jurisdictions have different procedures, but there is a clear tendency towards a REACH like procedure:
  - Identify, prioritize and assess potential SVHCs
  - Find appropriate Risk Management Options (Authorizations, Restrictions, Bans)

Summary

- Some regulations are more REACH like than others
- There is no „harmonized“ approach for registration
- BUT there is a clear tendency towards an alignment of general procedures such as
  - Registration
  - Evaluation
  - Authorization
  - Restriction

- Other countries do not simply „copy“ EU REACH (except Turkish KKDIK), but are to some extent in alignment with general procedures.

Thus, to a considerable extent, (the idea behind) REACH goes global !

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Thank you for your attention!

Dr. Michael Cleuvers
Managing Director Industrial Chemicals & Biocides (ICB)
mcleuvers@knoell.com