SOLVAY

REACH

Authorization at large including the issue of Candidate and Priority Listing process

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Agenda

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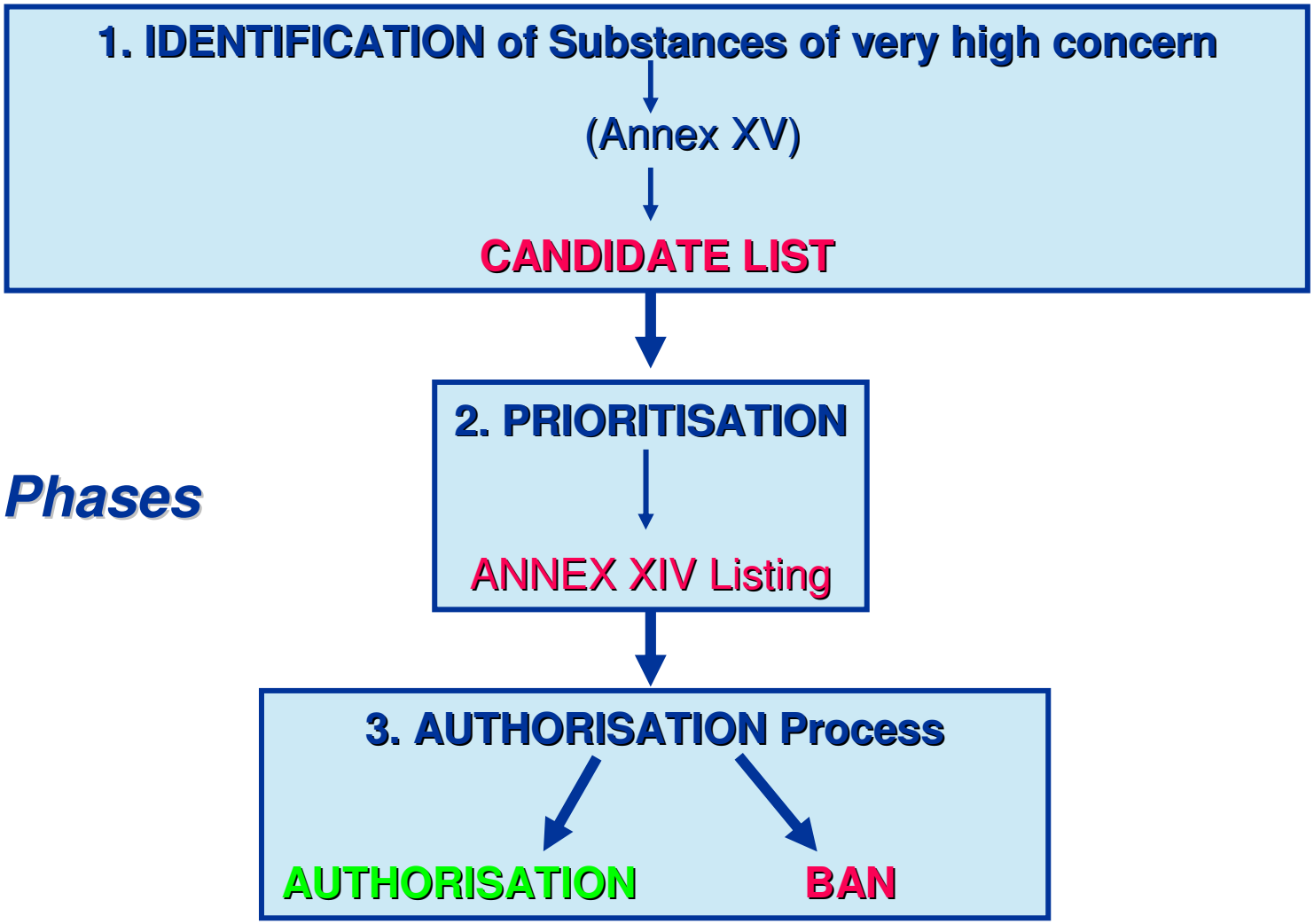
Regulatory Background

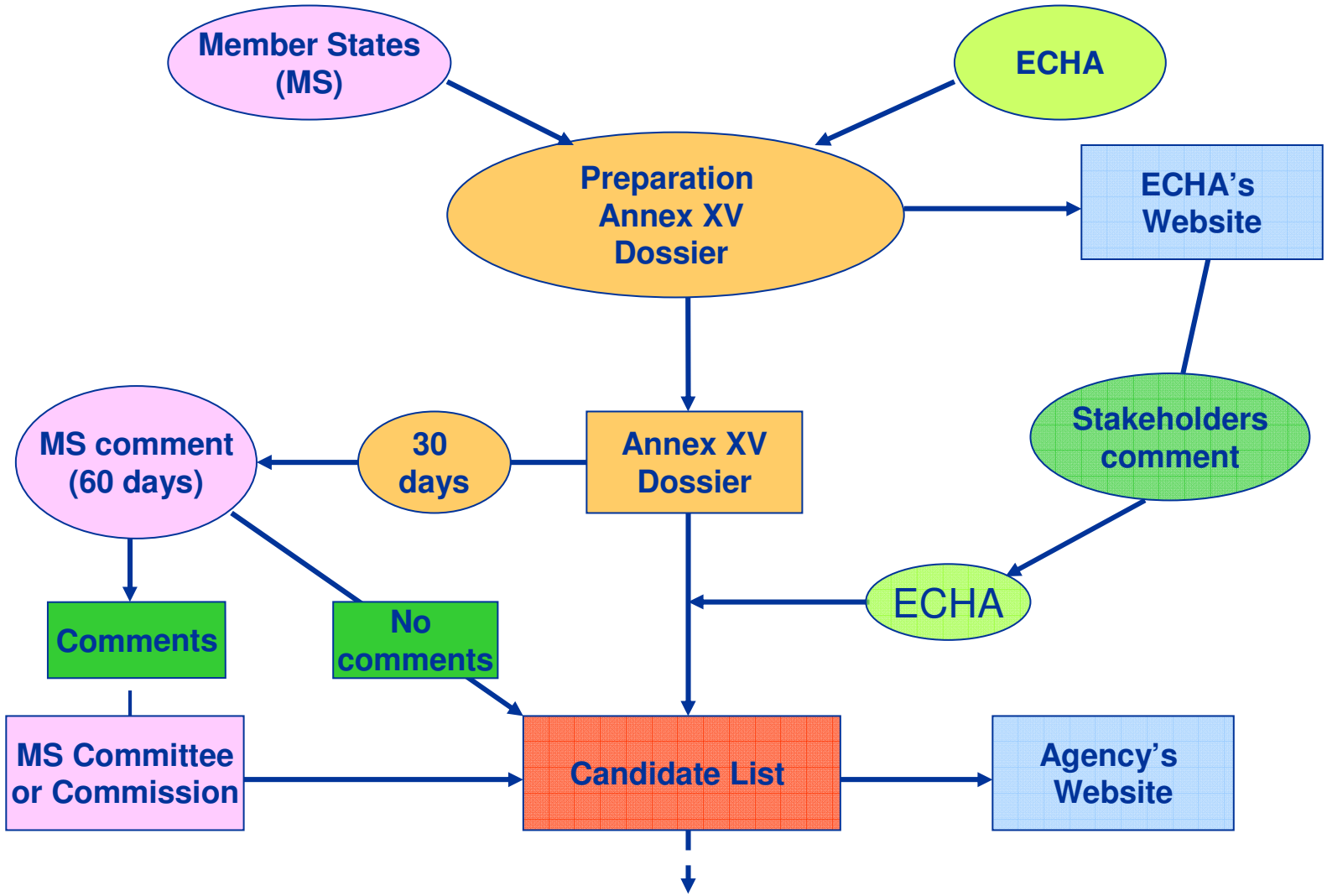
- The new REACH Regulation entered into force in June 2007 after years of debate
- Companies are preparing for (Pre-)Registration, certainly a priority under REACH.
- REACH also requires Authorisation of “substances of very high concern”, a process that includes the elaboration of a “candidate list” of these substances
- The presence of a substance on the candidate list will trigger several consequences, regulatory and others, that are worrying and may cause product delistings and bans earlier than expected
- Anticipating these effects should also be a priority for companies

Regulatory Process Leading to Authorization

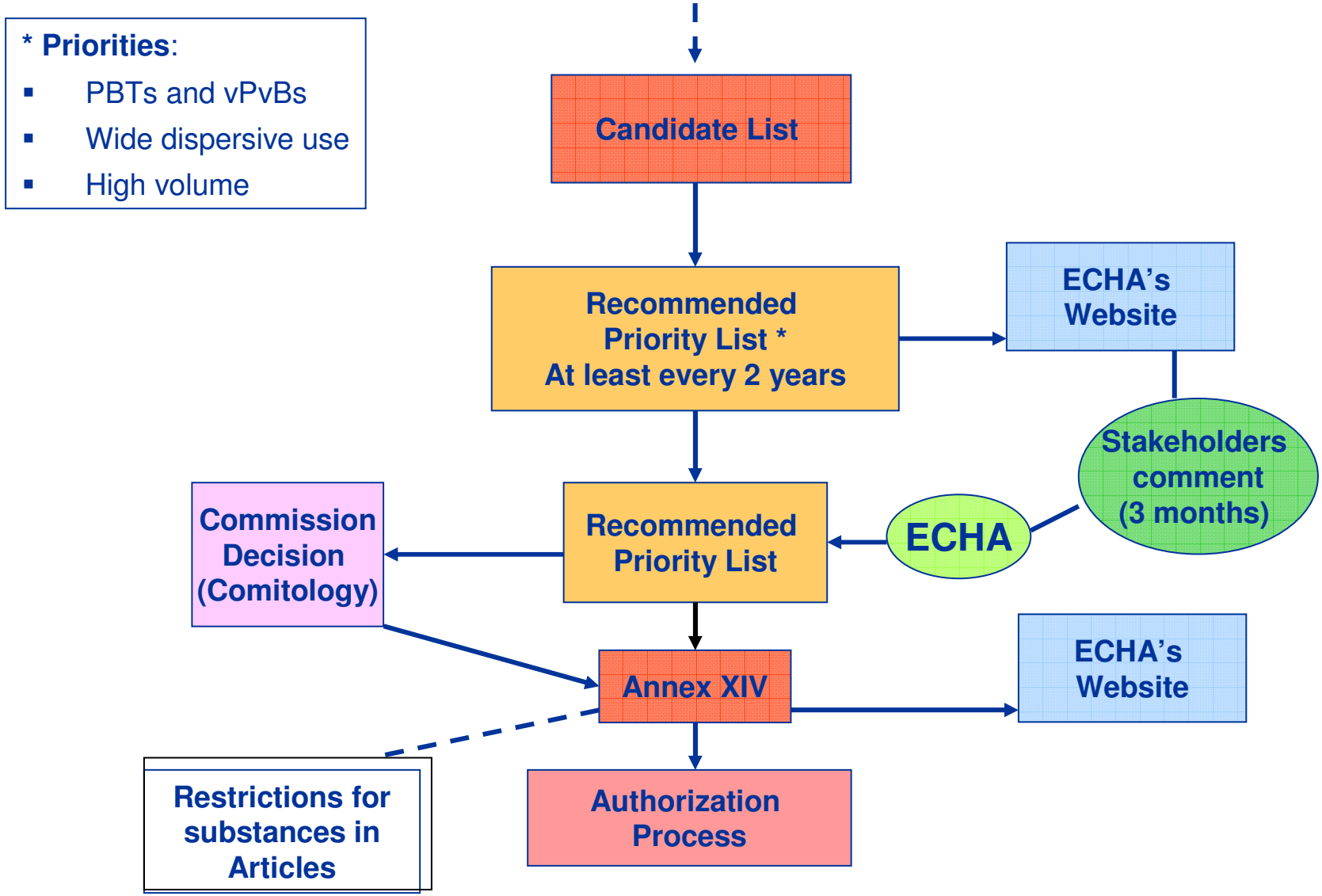


3 Phases

Identification of SVHC



Prioritisation of SVHC



Which Substances will be listed?

- **Substances "meeting the criteria" of :**
  - Carcinogenic Substances, Cat. 1 and 2
  - Mutagenic Substances, Cat. 1 and 2
  - Reprotoxic substances, Cat. 1 and 2

  CMRs
  - Persistent, Bioaccumulative and Toxic Substances - PBTs (Annex XII Criteria)
  - Very Persistant, Very Bioaccumulative Substances - vPvBs (Annex XII Criteria
  - Substances of "equivalent concern"

Which substances will be listed?
CMRs

- **Annex 1 DSD: Lists CMRs of categories 1 and 2**
- **These substances are either proven CMRs in human or highly suspected to be CMRs and already restricted/banned (e.g. prohibition of CMRs 1 and 2 above 0,1% in preparations for the general public)**
- **But new CMRs may be identified**
  - GHS will create new catergories : CMRs 1a, 1b and 2
  - Implementation of GHS may lead to new chemicals being identified as CMRs (e.g. Japanese report)

Which substances will be listed ?
PBT and vPvBs

- While the criteria to classify CMRs are well established, this is not the case for PBTs in the EU and even less so for vPvBs
- Newly developed PBT and vPvB criteria in Annex XIII of REACH are still under review. Possibility of non harmonized criteria
- PBT/vPvBs are to be treated in priority among SVHC for Annex XIV listing (before CMRs)
- History shows (e.g. Water Framework Directive and the POPs Regulation) that authorities seek flexibility in applying the P+B+T criteria even when the legislation does not contain a provision on « equivalent concern »

Which substances will be listed ?
Substances of Equivalent Concern

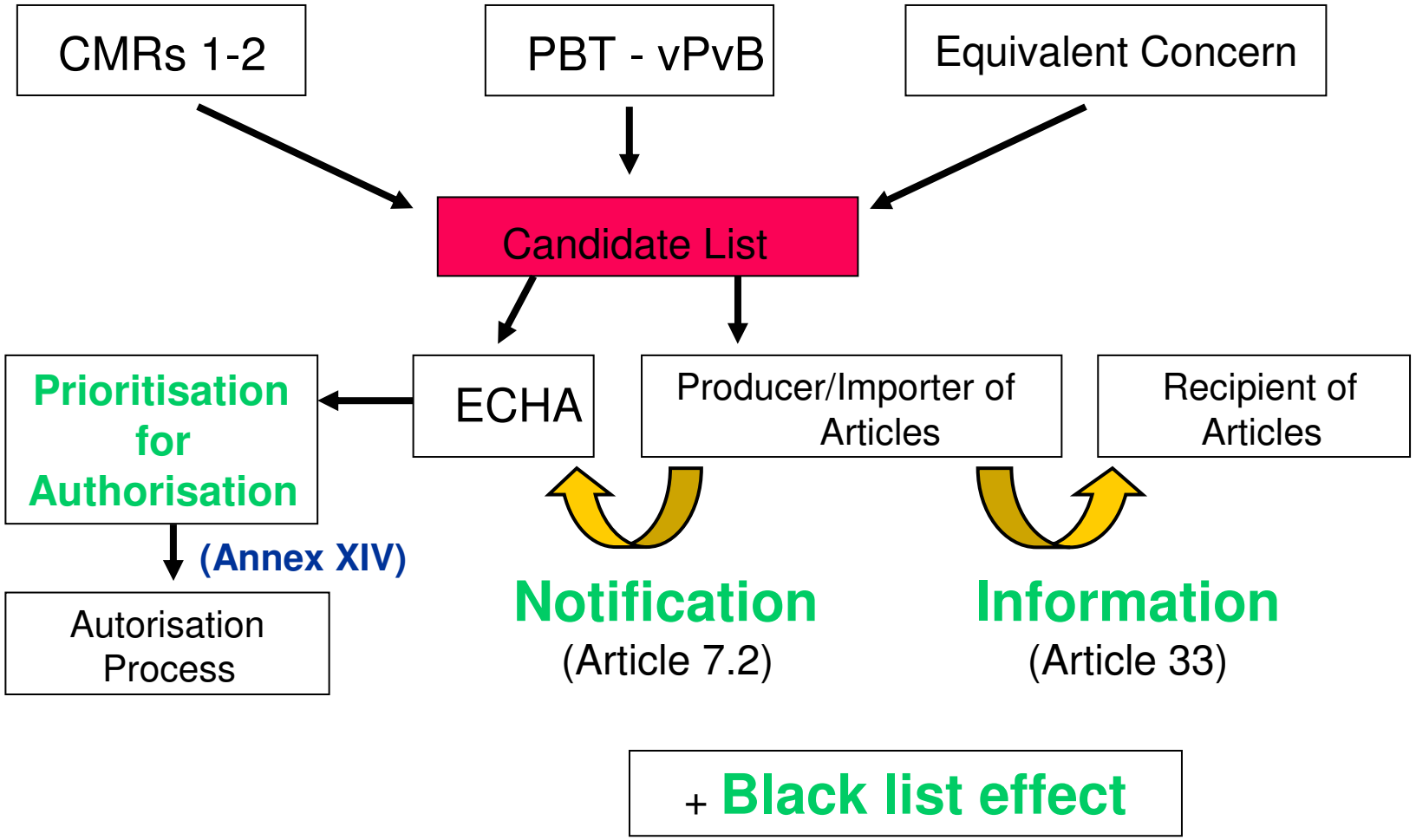
- **Article 57.f : "Substances - such as those having endocrine disrupting properties or those having PBT or vPVB properties, which do not fulfil the [other SVHC] criteria - for which there is** *scientific evidence of probable serious effects* **to human health or the environment which give rise to an** *equivalent level of concern* **to those of other substances [of VHC] and which are identified on a case-by-case basis […]"**

- **Legislative history during the legislative trial**
  - **Commission: «***Causing* **serious and irreversible effects to humans or the environment wich are equivalent…»**
  - **Parliament: « giving rise to a** *similar level of concern***…»**

Equivalent Concern: A Political Decision

- **Experience shows that decisions are often political**
  - CMR classification discussions
  - Decision taken despite scientific conclusions (e.g. phtalates), but many others
- **The same is likely to apply under REACH**
  - The term «*concern*» has no substantial/precise meaning and allows political decisions despite the need to provide scientific evidence of «*probable serious effects to human health or the environment*»
  - RIP 4.4 Report (Guidance for ECHA and national authorities on SVHC identification) confirms that there are no specific criteria to identify SoEC and only indicates an open-ended list of « factors » that « *may* » be taken into account
  - RIP 3.2.2: PBT Assessment under CSR

Consequences of *Candidate List* listing



Notification of Candidate List Substances (art. 7.2) which may be present in Articles

- **Notification to the ECHA of Candidate list substances present in articles:**
  - ≥ 0.1% w/w
  - 1 ton per producer/importer
- **Unless:**
  - Producer/Importer can exclude exposure during use and disposal
  - Substance has already been registered for that use
- **Deadline: 6 months after candidate listing from 1 June 2011**
- **ECHA can require Registration in some conditions**

Communication of Information on Articles (art. 33)

- **Suppliers of articles to:**
  - Provide “recipients” of articles with information allowing the safe use of articles containing a candidate list substance > 0,1% w/w, including the name of the substance
  - Communicate the same information to the consumers upon request

- **IMPORTANT: Communication is required regardless of:**
  - Tonnage of that candidate list substance in the articles being supplied
  - Whether the SVHC has been registered or notified

- **Communication duty applies “as soon as” the substance is on the candidate list**

Authorization of Candidate List substances

- Required for use or placing on the market for use of Annex XIV substances on their own, in a preparation or their incorporation into articles in the EU
- Only applies after prioritisation and listing in Annex XIV (C&L only does not trigger the authorisation process)
- No tonnage threshold
- Several exemptions apply (R&D, cosmetics, food contact, use of authorised substances)
- Use of articles containing Annex XIV substances does not require authorisation
- The ultimate goal of the Autorisation process is to substitute and therefore ban SVHC…

Decisions on Applications for Authorisation

- **ECHA 's Committees for Risk Assessment and Socio-economic Analysis play an important role in the authorization procedure**
- **General and applicant-specific right to know and right to comment on the Committees' draft opinions**
- **Draft decisions prepared by the Commission (Comitology)**
- **Criteria for Authorisation:**
  - Authorization granted if adequate control of the risks (Not available for PBT and vPvBs)
  - If not, it may be granted if the socio-economic benefits outweigh the risk and if there are no suitable alternative substances or technologies

Consequences of an Authorization

- The person to whom the Authorization is granted can continue to use or market the substance for uses which have been authorized. He must include the Authorization number on a label. Authorization is substance and supplier specific
- Authorization may be time limited. It may be amended or withdrawn
- Downstream users can use the substance supplied by the authorized supplier according to the conditions indicated in the Authorization
- Downstream Users must notify the Agency within 3 months of their first use of an authorized substance. The Agency keeps a register

Candidate List
Brief background history

- **The concept of generating a Candidate list appeared late in the legislative process**
- **DG Entreprise isolated opposing it**
  - About 3000 substances meet the criteria of substances of very high concern
  - ECHA will be able to process 25-50 substances per year
  - A new “burden of the past” ?
  - Unless the Candidate list is **THE** solution …

"Black List Effect" of the Candidate List

Once the Candidate List is published… it is expected that

- **NGO's / Governments to question producers and influence public opinion to require products free from "candidate list" substances**
- **Impossible for producers of consumer goods and other products, and/or for distribution outlets to justify the use of "substances of very high concern" in their products**
- **Producers will have no choice but to require supplies free from candidate list substances (or that do not contain them ≥ 0,1%)**
  - Massive product reformulations
  - De facto ban of candidate list substances in the EU
    - Only on the basis of hazard (and even less if 57 (f))
    - Years before Authorization process per se
    - While REACH allows for their lawful use
  - Global effect for products formulated for global use

Candidate List : some existing lists

- **"Pre-"Candidate lists**
  - Annex I, DSD
  - PBT Lists
    - Commission subgroup on identification of PBTs and vPvBs – initial list of 125 countries
    - Stockholm Convention : POPs
    - OSPAR Convention
    - Others, USA, Canada, Japan, etc
  - Others, for example
    - Eucomed lists 3000 substances with indicators (Annex 1, IARC, California Prop 65, EU PBT, etc.). Many substances are petroleum products
    - GIFAS (Aerospace) lists 4000 substances, includes subtances just because they have a biocidal application and are up for review

When will the first Candidate List be published ?

- No specification in the REACH text on publication of first candidate list
- Annex XV dossier can be filed starting on 1 June 2008 (but they may be ready already)
- No dossier needed for CMRs. Only need reference to Annex 1 of the DSD
- No official statement by authorities on date of publication
- ECHA to recommend first priority list for first Annex XIV list in June 2009
- Realistic scenario: First candidate list beginning of 2009 (possibly end of 2008 ?) Big pressure on Geert Dancet to anticipace (mid 08 ?)
- But ECHA has a mandate to publish without delay if no-one comments… So the ECHA may have to publish a list earlier…
  Industry should make sure to always comment

Future of the Candidate List

- On October 11, 2007 ENDS reported that NGOs via CHEMSEC announced "*Shadow REACH Blacklist*"

- Their list of high concern substances will *shadow* the official EU "*Candidate list*" because the official candidate list will be compromised "*Weak and Vague*" inclusion criteria – they claim

Government & Public Affairs

Thanks for your attention!

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