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Authorisation and Restriction: Interplay and other Strategic Considerations

Informa Conference on REACH

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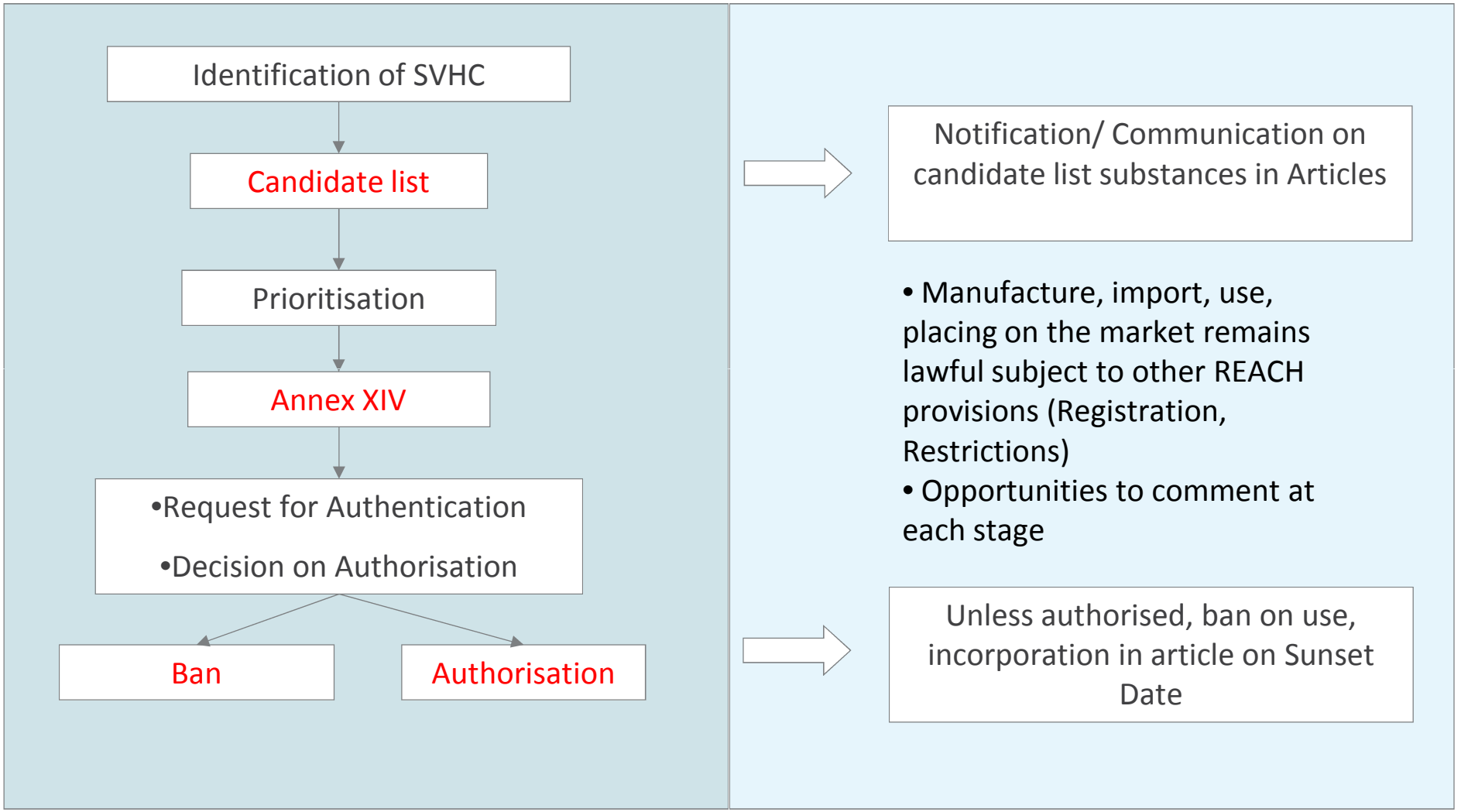
Available Risk Management Options

- The main Risk Management Options (RMOs) under REACH:
  1. Authorisation: For substances meeting the criteria of Substances of Very High Concern, i.e; CMRs 1 and 2, PBT and vPvBs, and substance of equivalent concern
  2. Restriction: For substances presenting an unacceptable risk to human health or the environment
- These are two seperate processes but overlaps exists
- Dossier and Substance Evaluation processes will be used to feed in further Autorisation and Restrictions
- Other RMOs exist:
  - Harmonized Classification & Labelling under the CLP
  - Restrictions under sector specific legislation, e.g. RoHS

Authorisation under REACH

- The Authorisation process applies to SVHC that have been identified and prioritized for review
- It involves Member States Authorities, ECHA, the Commission and Industry
- Authorisation is a “company specific” process addressed to the applicant but that can also be relied upon by its supply chain
- Applications may be submitted by one or more manufacturer(s), importer(s) and/or downstream user(s)
- A fee has to be paid for each application: Base 50 000 EUR
- The undeclared aim of the Authorisation process is to ban the use of most SVHC. So Authorisation will be difficult to obtain!
- Today 73 substances are on the Candidate list and 14 are listed on Annex XIV. 136 expected by end 2012 and all by 2020

Authorisation Process in summary



Content of Authorisation Dossier

- Application to the Agency to include:
  - Mandatory:
    - Identity information (applicant/substance)
    - Chemical Safety Report (CSR)
    - Analysis of alternatives and, if any alternative exists, a substitution plan
  - Optional:
    - Socio-eco analysis
    - Justifications to not include risks from authorised emissions and discharges

Analysis of Alternatives/Substitution Plans

- Suitable alternative is available if there is an alternative substance or technology that:
  - provides an equivalent function as the substance
  - reduces overall risks to human health and the environment
  - is technically feasible for the applicant
  - is economically feasible & reasonably accessible for the applicant
- If suitable alternative is available → Substitution plan
- If suitable alternative is not available → Applicant may provide:
  - list of actions needed to make an alternative technically or economically feasible
  - research and development activities needed to develop alternatives
- Information on R&D activities by the applicant may be included. No obligation to initiate new research

Criteria for Granting Authorisations

- Authorisations will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. This should be documented in the CSR using CSR methodology
- The “adequate control route” does not apply for:
  - Substances (e.g. CMRs) for which it is not possible to determine a threshold
  - Substances with PBT or vPvB properties or equivalent.
- If the risk is not adequately controlled, an authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternative substance or technology

Consequences of an Authorisation

- The company to whom the Authorisation is granted can continue to use or market the substance for uses which have been authorized. It must include the Authorisation number on a label
- DU can use the substance supplied by the authorized supplier only and only in accordance to the conditions indicated in the Authorisation
- DU must notify ECHA within 3 months of their first use of an authorized substance. The Agency keeps a register
- DU's may also apply for authorisations for their own uses (not included by supplier's application)

Strategic Considerations

- Autorisation will be costly and difficult and companies should only engage if no other solution and if sustainable
- If Authorisation is necessary, it is important to:
  - Start as early as possible to prepare the case (CSR; Exemptions; Identification/analysis of alternatives & substitution plans; Socio-economic analysis)
  - Possibly engage into discussion with other industry players (but antitrust risk)
- DU should consider whether to submit a DU application for authorisation or ask their M/I to do so. Relevant factors:
  - High authorisation costs/expected price increases as a result of internalisation of M/I authorisation costs
  - Confidentiality of uses
  - Need for M/I to obtain authorisation for their own uses
  - Number of DU supplied by that M/I

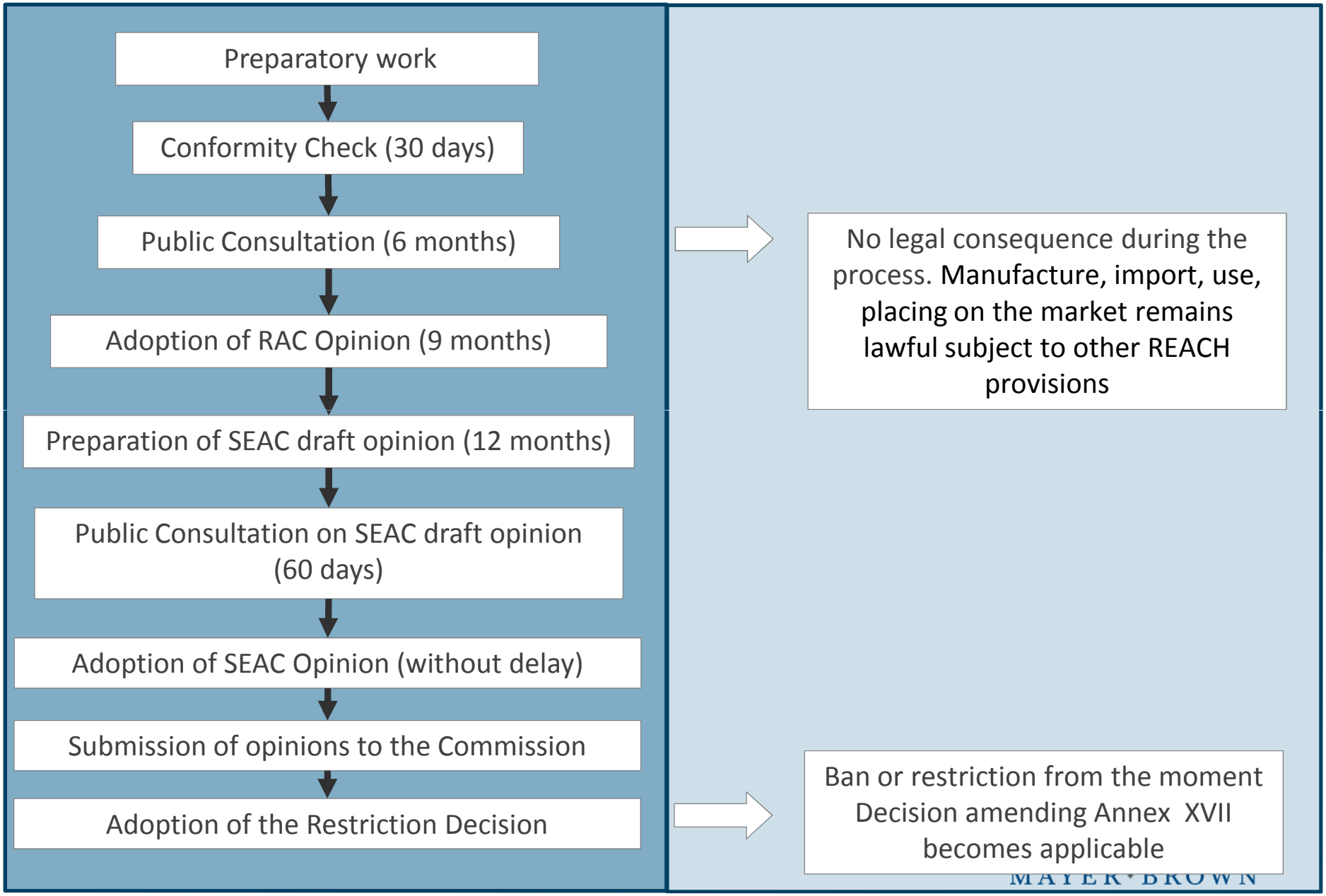
Antitrust Considerations

- Unlike for Registration, REACH does not require/organise cooperation between companies to submit a joint dossier on Authorisation
- Involves critical decision to apply for authorisation or substitute.
- Companies can contemplate working together to prepare an Authorisation dossier, but this raises complex antitrust issues:
  - Whether to pursue authorisation/substitute, should always remain an individual decision and companies should be free to change at any time
  - Exchange of sensitive information (as part of the substitution plans, socio-economic analysis, research plans) must be controlled
  - Possible collusion (express or tacit) on market conduct may result from decisions on authorisation/substitution (e.g. to “protect” the investment).
  - Possible abuse of dominant position if market leader(s) use their power to discriminate uses and/or force competitors out of the market
- General CEFIC guidance exist. But specific legal advice and very careful handling needed

The Restriction Process

- Restrictions may apply to any substance presenting an unacceptable risk to human health or the environment arising from their manufacture, use of placing on the market, which need to be addressed on a Community-wide basis, not only SVHC
- The restriction process is not company specific as it leads to measures of general application, but companies have opportunities to comment during the process (as do NGOs)
- Reach provides for two procedures:
  - *Expediate* (Article 68.2): May apply to CMRs category 1 and 2 used in consumer products and for which restrictions to consumer products are proposed by the Commission. Commission may adopt restriction under Comitology
  - *Normal*: Outside these particular circumstances, the normal procedure in Articles 69-73 applies

(Normal) Restriction Process in Summary



Interplay between Authorisation or Restriction

- General perception that Authorisation and Restrictions are “either-or”, but this is not entirely true
- For authorities, a choice exist: ECHA Workshop on the Candidate List and Authorisation as Risk Management Instruments (January 2009) aimed at a common understanding of the legal and practical implications of the choice between Authorisation and Restriction
- For companies, listing of their substance in Annex XIV requires them to seek Authorisation (unless they have an alternative)
- If a substance is subject to a proposed restrictions, they can only provide comment
- Unexpectedly, sometimes, they will have to fight the two battles in parallel!

Interplay: View of Authorities (1)

Practical Considerations	Authorisation	Restriction
Risks	• Only risks related to Article 57 (CMR, PBT and equivalent concern) • Risk from manufacturing process not covered	• Risk emanating from almost any specific hazards • Covers the manufacturing process as well as the substance in articles
Consumer uses	• Nothing specific	• Simplified procedure for consumer uses of CMRs 1-2
Use of the substance in articles	• Can cover only the "incorporation" of the substance into an article when made in the EU	• Broader: Can cover the "use" of substances in articles, or their importation or placing on the EU market

Interplay: View of Authorities (2)

Practical Considerations MSs	Authorisation	Restriction
Existence of Alternatives	• No need to provide information on suitable alternatives to include a substance in the candidate list, but existence of alternatives is part of the review	• Information on alternatives, is required as part of Annex XV dossier
Costs	• Less costs to authorities to prepare an Annex XV SVHC dossier	• Higher costs for authorities to prepare an Annex XV dossier for restriction
Timing	• Longer timeframe from inclusion in the candidate list to sunset date	• Shorter timeframe • Even shorter if expediate procedure is applied to consumer uses
Enforcement	• Difficult to enforce: applicant -specific (and its supply-chain)	• Easier to enforce : all actors at the same time

Interplay: Implications for Industry

Practical Considerations Industry	Authorisation	Restriction
Costs	• Fee: 50,000 € + Expenses from authorisation application	• Less expenses for industry (participation in public consultation).
Involvement	• Direct involvement/active role	• Reaction to public consultation
Different effects	• Legal requirements start from inclusion in Candidate List • If granted, Authorisation allows continue use but only for some time	• No legal requirements during the restriction process • If adopted, restriction or ban may no longer allow continued use
Existence of Alternatives	• Industry to provide information on alternatives • Existence of alternatives (or not) has more direct legal consequences	• Information provided by authorities • Industry can comment on this is during consultation process
Right of Appeal	• Authorisation decisions can more easily be challenged before the EU Courts as there are addressed to the applicant	• More difficult to challenge before the EU Courts

Autorisation – Restrictions: Exemptions

Autorisation (Title VII)	Restrictions (Title VIII)
• Medicinal products, food and feed, biocides, plant protection products, motor fuels and fuels in closed systems • Cosmetics and food contact materials with respect to human health hazards (CMRs) • On site and transported isolated intermediates • Monomers (as intermediates), but polymers are not exempt	• Cosmetics (with respect to restrictions addressing the risks to human health within the scope of the Cosmetics Regulation)
• R&D (PPORD can be exempted only during Annex XIV process) • Substances in mixtures below concentration limit 0,1% or specific concentration limit • Uses and categories of uses can be exempt from authorisation through listing in Annex XIV if subject to specific EU legislation imposing minimum requirements to protect health and environment	• R&D (Manufacture, placing on the market or use of a substance in scientific research and development) • The restriction in Annex XVII must specify whether it applies to PPORD, as well as the maximum quantities exempted

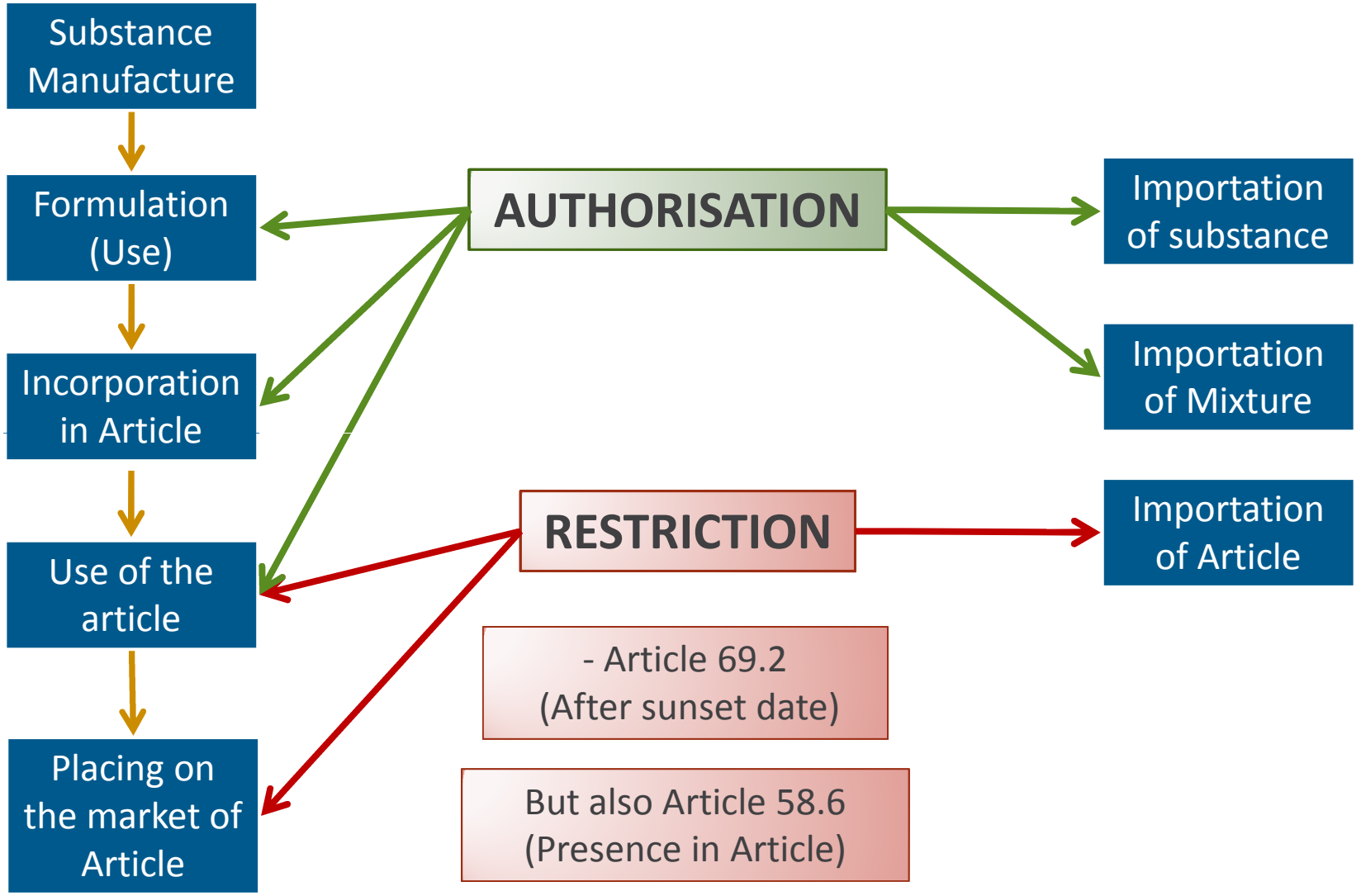
Authorisation- Restriction: The Provisions

- Article 56.1 prohibits the placing on the market/use of Annex XIV substances as such or in preparations or their incorporation in articles unless authorised or exempted after the sunset date.
- Article 58.5 prevents Annex XIV substances from being subject to restriction covering risks from the “use” of the substances as such or in preparations or “incorporation” of the substances in an article.
- Article 58.6 allows Annex XIV substances to be subject to restriction to cover risks from the “presence” of the substances in articles.
- Article 58.7 provides that substances for which all uses have been prohibited under a restriction process or other EU law, then it shall not be included or must be removed from Annex XIV
- Article 60.6 excludes the granting of authorisations to restricted substances if such authorisations would relax the existing restrictions
- Article 69.2 enables ECHA to start the restriction process after the sunset dates for Annex XIV substances, if the risk from their “use” in articles is considered inadequately controlled.

The case of LMW Phthalates

- LMW phthalates are listed on Annex XIV since 17 February 2011
- Companies are preparing submissions for their authorisation under REACH (Application date: 21/08/2013; Sunset date: 21/02/2015)
- In the meantime, DK submitted an Annex XV dossier to restrict the use of 4 LMW phthalates in articles intended for use indoor and articles that may come into contact with the skin above 0,1% by weight of plasticised material. ECHA accepted proposal on the basis of Article 58.6 of REACH
- Public consultation started and process should be over by end 2014, i.e. BEFORE the end of the Authorisation process
- Main concerns:
  - DEHP is subject to 2 separate REACH processes working in parallel
  - Denmark bases its dossier on the combination effects of chemicals
  - Restriction process will in effect prevent autorisation for DEHP
  - Denmark has now also notified a national restriction to the Commission

Interplay for Substances in Articles



Interplay: Authorisation- Restriction

- The use of the restriction process seriously limits the possible use of the authorisation process for the same substance:
  - Article 58(7): where all uses of a substance are restricted, that substance cannot be subject to authorisation or be removed from Annex XIV
  - Article 60.6: excludes the granting of authorisations to restricted substances if such authorisations would relax the existing restrictions
  - Even for uses that would not be directly affected by the restriction, the restriction will have a determinative influence on the final outcome of the authorisation process (authorities will seek to avoid diverging opinions)
  - If the use/presence of a substance in an article is prohibited by a restriction, autorisation to incorporate it in that article is useless
- Basically, the adoption of a prior restriction would in many cases *de jure* or *de facto* prevent the authorisation process to be carried out, a situation that would certainly trigger legal challenges, as well as confusion among the supply chain

Conclusions

- The REACH Autorisation and Restriction processes, as such, represent significant challenges and may cause delisting of chemicals in key industrial applications
- The practice so far reveals additional unexpected difficulties, e.g.
  - The REACH Regulation unfortunately seem to allow both Authorisation and Restrictions to run at the same time in some cases
  - MS have an increasing influence on REACH processes, and it is not clear that the Commission is ready to stand firm to protect the single market
- This warrants a review of the applicable provisions (REACH Review)
- At a minimum, ECHA/European Commission should adopt the necessary policies to ensure that RMOs are selected and applied consistently and in such a way that each process is applied in full respect of its fundamental underlying principles, including those of sound science and due process
- In the meantime, companies must roll up their sleaves to face the complex challenges ahead

Thank you for your attention!