APRIL 24, 2024

Understanding Evolving European Chemicals Policies – Part 2

This webinar is being hosted by:

- Sustainable Chemistry Catalyst at UMass Lowell
- Change Chemistry
- FIPRA

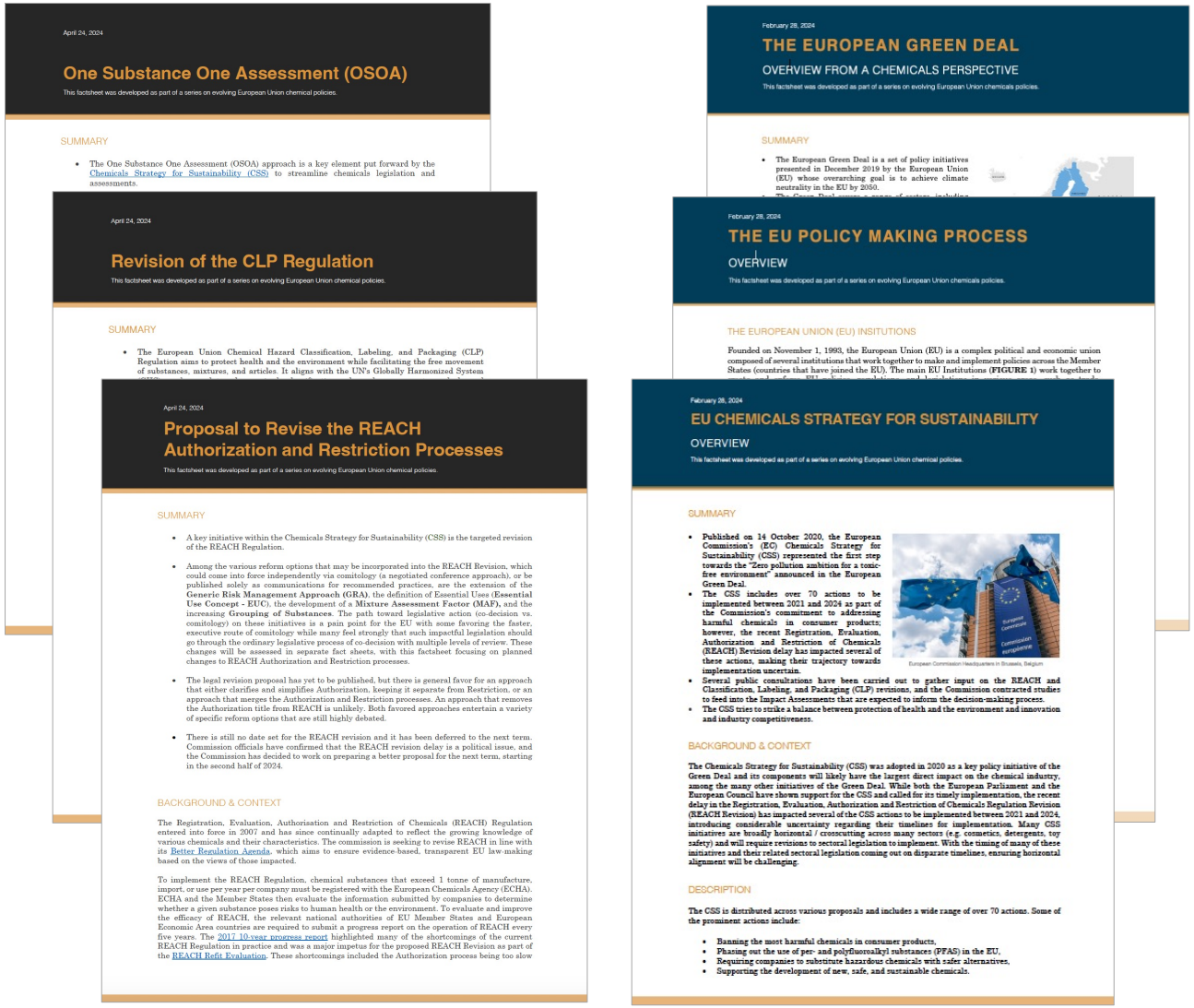
Ground Rules

- Please keep your lines muted and your videos off.
- Use “speaker view” in Zoom – it offers the best viewing experience.
- If you have a question or comment, please type it in the “Chat” box located in the control panel or use the raise hand function.
- Questions will be answered during and at the end of the presentation.

Factsheets Available!

Factsheets were developed as part of a series on evolving European Union chemical policies. To download this information, please visit:

www.sustainablechemistrycatalyst.org/eu-chemical-policy



Next Webinar

Coming up **22nd May 2024** – Understanding Evolving European Chemicals Policies Part 3 (Safe and Sustainable by Design framework, Ecodesign for Sustainable Products Regulation, Digital Product Passport, Taxonomy Regulation, Corporate Sustainability Reporting Directive and more…)

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Upcoming Events

2024 European Forum

(Limited space available)

2024 US Innovators Roundtable

Today's Speaker

FIPRA

Jan Ahlskog

Senior Director at FIPRA and Secretary General of the European Regulation and Innovation Forum

UNDERSTANDING EVOLVING EUROPEAN CHEMICALS POLICIES (OSOA, CLP & REACH REVISION)

Webinar series – Part 2

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Agenda

1. One Substance One Assessment
   - ECHA Proposal
   - OSOA Package
   - Guiding principles
   - Indicative timeline
2. CLP/New Hazard Classes
3. REACH Revision

ONE SUBSTANCE ONE ASSESSMENT (OSOA)

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One Substance One Assessment (OSOA)

- The One Substance One Assessment (OSOA) approach is a key item put forward by the Chemicals Strategy for Sustainability (CSS) adopted in 2020 to streamline chemicals legislation and assessments.
- It is an **approach, not a legislation**, meant to ensure consistent assessment outcomes for similar chemicals and help the EU and Member States governing bodies work together to assess chemicals just once.
- Implementation is supported by three main proposals published by the Commission in December 2023:
  - Proposal to establish a common data platform on chemicals
  - Proposal to establish a founding regulation for ECHA
  - Proposal to reallocate work across EU agencies

1. PROPOSAL FOR A REGULATION ESTABLISHING A COMMON DATA PLATFORM ON CHEMICALS`

1. The data platform will increase transparency on chemical data.
    - Increased awareness from civil society and potential pressure on industry to phase out certain substances.
2. The Regulation will support the reuse of chemical data and information collected for regulatory action.
    - This might lead to wrong regulatory decisions if regulators use the data platform to make (quick) regulatory decisions.
3. The Regulation proposes that studies commissioned or carried out by businesses are notified.
    - Industries are concerned about increased administrative burdens and costs associated with the notification procedure.
    - Additionally, they fear a loss of competitiveness against non-EU actors due to the application of notification requirements to EU-located laboratories

ECHA will be responsible for managing the platform.

2. PROPOSAL FOR A BASIC REGULATION OF THE EUROPEAN CHEMICALS AGENCY (ECHA)

- This proposal will provide a legal framework for ECHA, clarifying its tasks, financing model and governance.
- It aims to prepare the agency for its future role, and the complexities that the CSS implementation may bring.
- The regulation will allow ECHA to adapt to the additional technical, scientific and administrative tasks the agency has been taking over throughout the years.
- Clarify how the agency works with other agencies also involved in chemical safety assessments (e.g., EFSA & EMA).

➢ Linked to the One Substance One Assessment process to coordinate the hazard/risk assessment on chemicals across chemical legislation.

➢ ECHA faces challenges in terms of manpower and funding to assess complex restriction cases (e.g. universal PFAS Restriction) and to deal with upcoming new responsibilities (e.g. batteries).

3. PROPOSAL TO REALLOCATE THE AGENCIES' TECHNICAL AND SCIENTIFIC WORK (OSOA PACKAGE)

- **Form:** An "omnibus regulation" amending provisions on the allocation of tasks and responsibilities. Specific sectorial legislation will need to be amended to adapt to the omnibus regulation.
- The Commission is considering reallocating work under 34 legislations, such as RoHS, WFD, or Cosmetics across 5 agencies: ECHA, EFSA, EMA, EEA, OSHA.
- This proposal introduces relevant changes for businesses as it focuses on amending the RoHS (Restriction of Hazardous Substances) Directive (namely articles 5 and 6), giving ECHA the responsibility for the assessment of restricted substances under RoHS, and for reviewing and assessing exemptions.

➢ The new responsibility given by ECHA would allow for more transparency in the process and better involvement of stakeholders, giving industry better predictability in RoHS restrictions and exemptions processes.

Implications of OSOA

1. Proposal for a Regulation establishing a common data platform on chemicals.

- Industry stakeholders have raised concerns about the potential impact of the regulations on the confidentiality of shared and utilized information, which could pose a threat to competitiveness and innovation.
- If data is assessed by groups of chemicals, it might lead to more substances being classified as SVHCs and subject to authorization or restriction.

2. Proposal for a basic regulation of the European Chemicals Agency (ECHA)

- ECHA may need to be reorganized to deal with the increased workload. ECHA's RAC committee would absorb the tasks of various other scientific committees now under the Commission (e.g. cosmetics) or EFSA. This raises questions as to whether RAC will still deal with hazard and risk assessment or whether it can be divided into two sub-committees, one for hazards and one for risks.
- If no new budget from the EU is allocated, ECHA may need to increase or create new fees.

3. Proposal to reallocate the agencies' technical and scientific work (OSOA package)

- The possible concentration and separation of functions across agencies can lead to EMA having the competence for medicinal products, including the assessment of substances. This could be beneficial as it would allow for tailored assessments under specific legislations/uses and a more specific focus on the health and essentiality aspect of medicinal products.

Guiding principles for (re-)attribution of tasks

Consider attributing the work to one of the agencies that are mandated to perform such work

ECHA (European Chemicals Agency)

- Hazard, exposure and risk assessment of chemicals (except plant protection products and medicinal products) in all products except in food and feed and related products (food contact materials);
- Management of committees;
- Data collection, management and IT tools

efsa (European Food Safety Authority)

- Hazard, exposure and risk assessment of plant protection products and chemicals in relation to food and feed safety;
- Management of committees and panels
- Data collection, management and IT tools

European Medicines Agency (Science Medicines Health)

- Hazard, exposure and risk assessment of medicinal products and of their residues in food;
- Management of committees and panels
- Data collection, management and IT tools

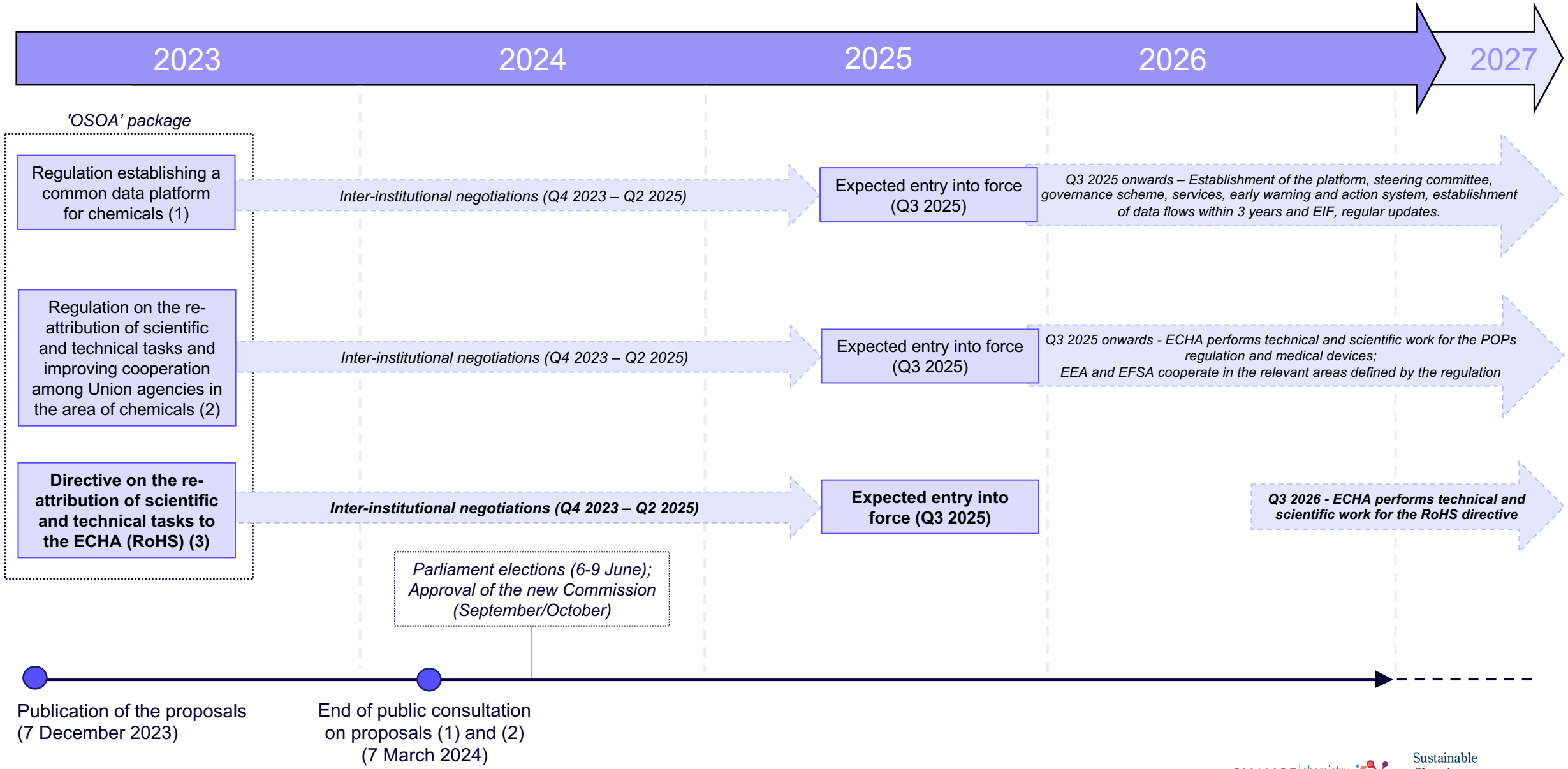
European Environment Agency

- Collection and management of chemical occurrence data in the environment and emission data
- Assessment of state of environment
- Management of network of experts
- Data collection, management and IT tools

European Agency for Safety and Health at Work

- Information on chemicals risks
- Tools for employers

Indicative OSOA timeline



Q&A Session

CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES (CLP)

Classification, labelling and packaging of substances and mixtures (CLP) reform

- The EU, through the Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008, requires companies to classify, label and package their chemicals before placing them into the market, to ensure that the risks that chemicals pose are indicated throughout the supply chain. The objective is to protect workers, consumers, and the environment, and to allow for free movement of substances, mixtures, and articles.
- The Regulation includes the classification criteria and labelling rules agreed at the UN level: the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).
- The CLP outlines legally binding hazard identification and classification rules, and specific criteria for labelling, including pictograms, signal words, and standard statements addressing hazards, prevention, response, storage, and disposal. Additionally, it establishes general packaging standards to guarantee the safe distribution of hazardous substances and mixtures.

Classification, labelling and packaging of substances and mixtures (CLP) reform

The revision is composed of two different pieces of legislation Proposal for a revision of the CLP (Art.294 TFEU) and a Delegated Act (Art. 290 TFEU) establishing new hazard classes.

Targeted revision to clarify, strengthen or complement some provisions:

- Introducing new hazard classes and criteria
- Addressing practical issues with labelling
- **Article 37** to extend the right of initiative to initiate harmonised classification and labelling over to the Commission
- **Article 36** to prioritise harmonised classification and labelling of substances which are endocrine disruptors (EDs)
- **Articles 40 and 42** to allow companies to have better access to information and ease their duty to 'self-classify' their substance

Amendments via delegated act: New hazard classes:

- Endocrine disruptors (ED),
- Persistent bioaccumulative toxic (PBT),
- Very persistent and very bio-accumulative (vPvB),
- Persistent and mobile in the aquatic environment (PMT, vPvM)

Proposal: *19 December 2022*
Adoption of new hazard classes: *Q1 2023*
UN GHS discussions: *2023-2024*
Guidance document on the new hazard classes: *Q1 2024*
Plenary vote: *23 April 2024*

Classification, labelling and packaging of substances and mixtures (CLP) reform

Implications

- New hazard classes can trigger more communication of hazards through workers' protection, handling, packaging, labelling requirements, transport, etc. due to the obligation to act on the basis of the hazard class.
- CLP classification is also the basis for **legislative provisions on the risk management of chemicals**, meaning it can trigger requirements under REACH, especially relevant in light of the more generic approach to risk (GRA) to be extended in REACH which has been delayed.
- The inclusion of new hazard classes which are not provided for by the UN GHS will have important consequences on internal and international markets.

Q&A Session

REACH REVISION

Proposal to revise the REACH Authorization and Restriction processes

Proposal: *Initially planned for Q3 2024, it was postponed to the next Commission. Possible date of publication: second half of 2024 or 2025.*

- Targeted revision of the REACH Authorization and Restriction processes introducing new elements:
- A mixture assessment factor (**MAF**) to account for combination effects
- Extending the generic risk management approach (**GRA**) to:
  - Restrictions on EDs, PBT/vPvBs, immunotoxicants, neurotoxicants, respiratory sensitisers, and substances that affect specific organs
  - Products marketed for professional use (those similar to consumer uses rather than industrial)
  - Restrictions/bans by default with the possibility of derogations ONLY for **essential uses**
  - **Grouping** of substances
  - Adding EDs and PMT & vPvMs to the **SVHC** list

OPTION 1

Keep authorizations with clarifications and simplifications

OPTION 2 AND 2A

2: Merge authorizations and restrictions

2A: Keep SVHC and restriction titles separate, but introduce the possibility for derogation requests

OPTION 3

Remove the authorization title from REACH

Proposal to revise the REACH Authorization and Restriction processes

Implications

- It will allow for bigger and more generic restrictions and derogations, making restrictions feasible and reasonable.
- It could offer an opportunity to simplify REACH through an Essential Uses process.
- Increasing numbers of substances could end up subject to restriction and may result in some groups of substances becoming no longer available even for essential uses. The REACH revision will enshrine most of the CSS initiatives, which will then be translated into further sectoral legislation (e.g., toys, food contact materials or cosmetics).

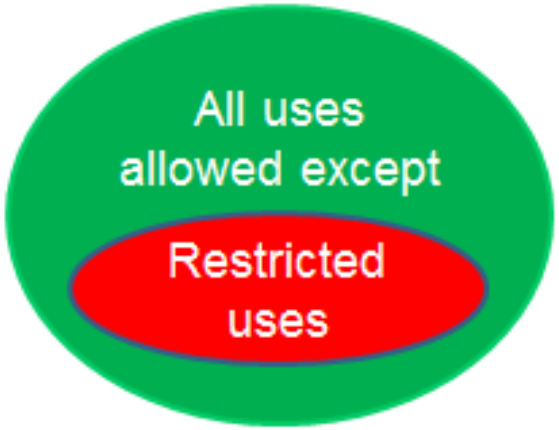
Authorization vs. Restriction

Authorization: No supply/use without permission

- REACH Annex XIV
- Applies to all uses unless exempt
- Must seek and gain positive permission for use
- No general tonnage threshold
- Substitution the focus, approval time-limited
- Applications require significant resources and time

Restriction: Specified supply/use not allowed

- REACH Annex XVII
- Applies to specific uses
- No general tonnage thresholds
- Not always an outright ban



Application and exemptions

Broad exemptions (non- exhaustive list):

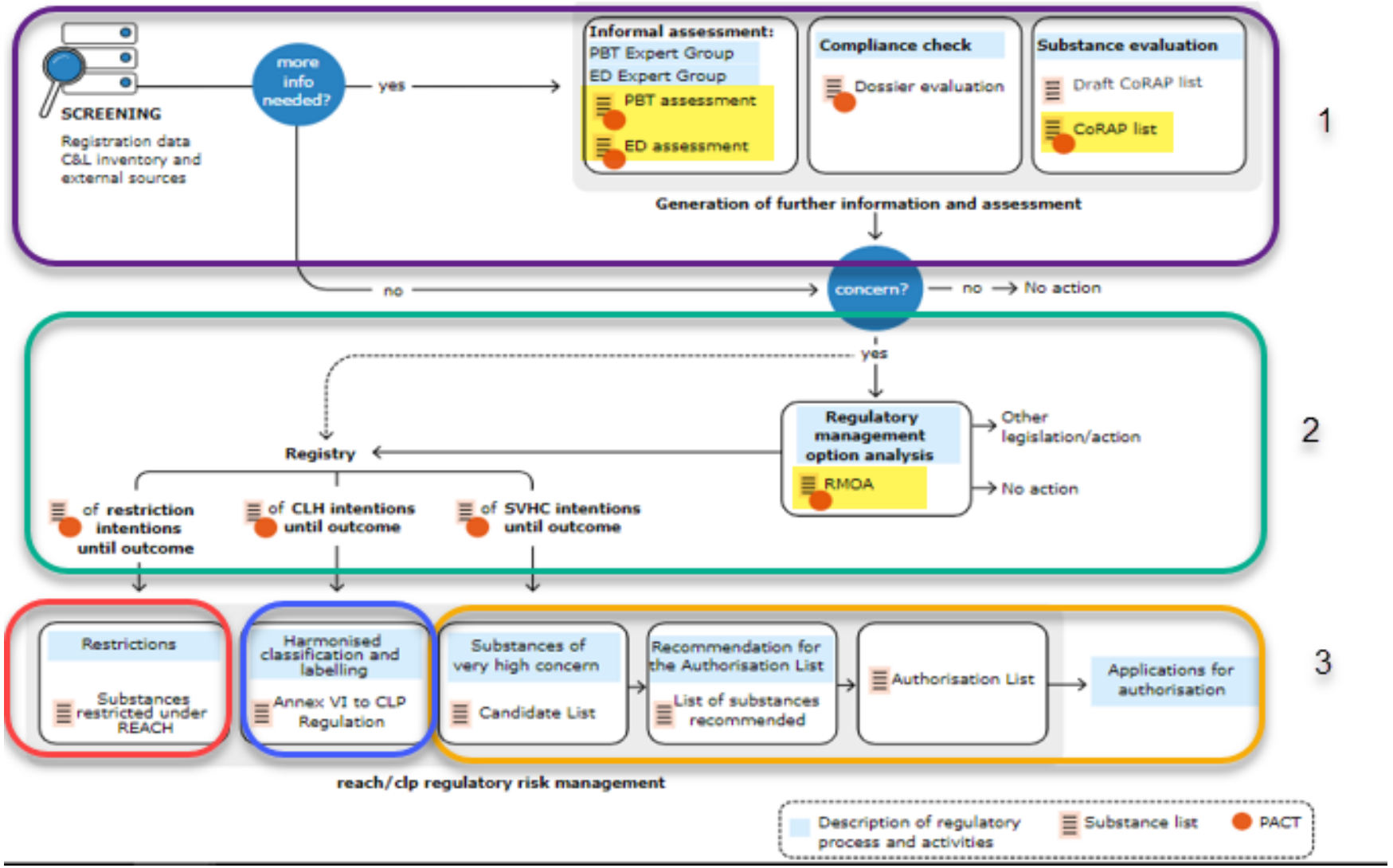
- Under Customs supervision
- Defense
- Non-isolated intermediates
- Wastes
- SR&D exemption

Specific exemptions from *selected* REACH obligations:

- For regulated products, e.g., medical products, veterinary products, cosmetics, etc.
- Medicinal products exemption includes the use as an API, excipients, finished formulations and products

Substances used in/as	Exemption Registration	Exemption, Evaluation	Exemption Authorisation	Exemption Restrictions
•Medicinal Products*	Yes	Yes	Yes	No
•Medical Devices	No	No	HH	No

Process for addressing chemicals of potential concern



1 – Screening & assessment

2 – Regulatory Management Options Analysis and Intentions

3 – Risk Management Implementation

Source: European Chemicals Agency, http://echa.europa.eu/

What are the most hazardous substances?

Article 57 of REACH: Substances of Very High Concern (SVHCs)

- A Carcinogen, Mutagen or Reprotoxic (Category I & II)
- A persistent bioaccumulative toxic (PBT)
- Very persistent very bioaccumulative toxic (vPvB)
- Substances of equivalent level of concern (ELoC), e.g. endocrine disruptors, respiratory sensitizers, case by case

➢ Please keep in mind that **data on chemicals** hazards **evolves** over **time** and varies across **regions** around the world. This is why it is important to keep monitoring the development of new hazard classes in the EU/globally, and to keep an eye on development related to e.g. carcinogenicity of chemicals (e.g. IARC) or regulatory action at global level (e.g. POPs) as this will in many ways influence decision- and policy-making in the EU.

Restrictions (Annex XVII of REACH)

- Restrictions limit or ban the manufacture, placing on the market or use of certain substances that pose an unacceptable risk to human health and the environment
- A list of substances whose use is restricted - Annex XVII
- Restrictions may **involve**:
  - a complete ban or restricted categories of use
- A restriction may **apply to**:
  - any substance on its own;
  - any substance in a mixture;
  - any substance in an article;
  - substances including those that do not require registration, e.g. substances manufactured or imported below one tonne per year or certain polymers
- There are select exemptions from restriction but examine carefully
- Mentioned in section 15 (regulatory information) of the Safety Data Sheet (SDS)

REACH Restriction Process (General)

I Phase

Preparation and submission of a restriction proposal

- Starting the restriction process
- Notification of intention to submit a restriction proposal
- Registry of Intentions
- Preparing the restriction dossier
- Submission and conformity check

II-A Phase

Public consultations

- Public consultation on the restriction report
- Public consultation on SEAC's draft opinion

II-B Phase

Opinion development

- Advice from the Forum
- RAC's opinion
- SEAC's opinion

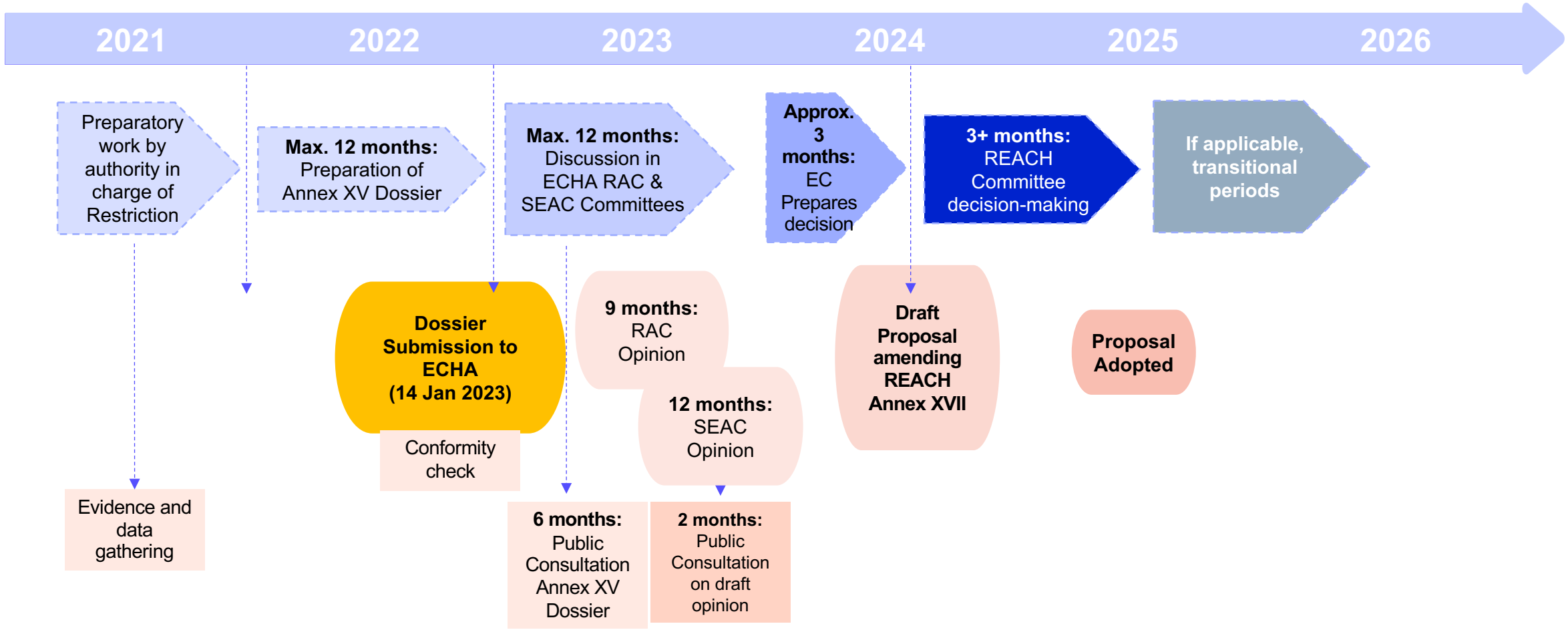
III Phase

Decision and follow-up

- Commission decision on restriction
- Complying with restriction
- Enforcing the restriction

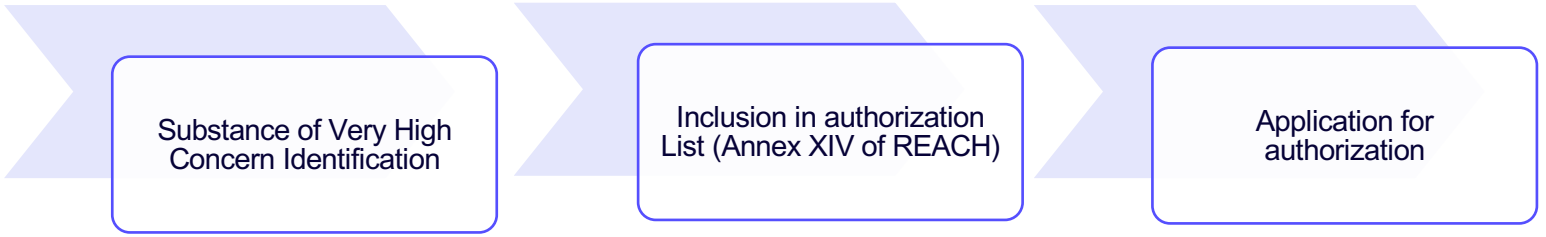
➢ Please keep in mind that **the timelines of restrictions under REACH might be subject to delays depending on several factors (e.g. complexity of the dossier, number of inputs received during public consultation).**

REACH Restriction Process (Timeline)



Authorization

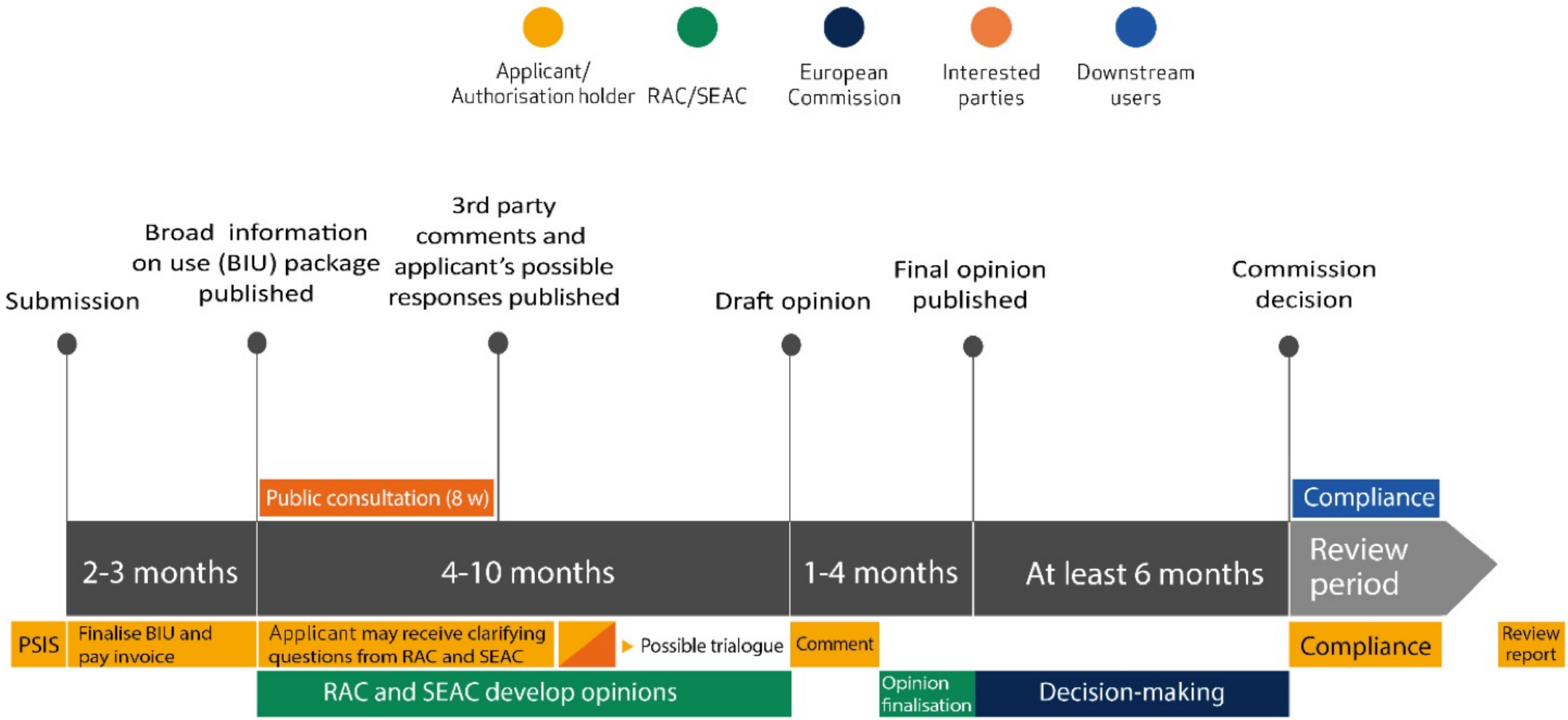
- Applies to substances on “The authorization List” - Annex XIV
- Authorization is the **mechanism** though which REACH will **phase out use** of the **most hazardous chemicals.**
- **Industry must justify the continued use** of substances that are subject to the authorization regime and replace with safer alternatives.
- **Use of the substance must cease** by specified date called ***The Sunset Date*** unless an application has been submitted to European Chemicals Agency (ECHA).
- Substances are **selected (prioritised) for inclusion based on a scoring system:**
  - Intrinsic properties/hazards
  - Wide Dispersive Uses
  - Tonnage



Authorization (continued)

- General Exemptions:
  - Scientific Research & Development < 1 tonne per year under controlled conditions
  - All intermediates
  - Covered by other relevant Community legislation (medicinal products, veterinary products, partial for medical devices when a substance is listed for human health hazards)
  - Use of the substance at a concentration less than 0.1%
- Authorizations are **specific to** the company for a specific use/uses of a substance
- Authorizations are **limited in time**
  - Granted for a specific period – 4, 7 or 12 years – based on your substitution plan timeline
- **The authorization number** should be included on the SDS
- Authorization applications require **significant resources and time**
- **A bridge to allow to continue to use the substance until you can find a safer substance**

Authorization (Timeline)



Q&A Session

Thank you for your attention!

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Annex – Implications of the REACH revision delay for CSS initiatives

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Context – REACH revision delay and CSS

The Chemicals Strategy was announced in October 2020 and outlines several actions to strike a balance between innovation and competitiveness in the industry and protecting the health and the environment. It also sets an indicative timing for the implementation of these actions. As the new mandate of the European Commission approaches, the REACH revision delay has left several uncertainties as to how certain tools introduced by the CSS would be implemented across legislation and sectors. The table below aims to provide an update on these initiatives (e.g., Essential Use, Generic Approach to Risk Management), which can be used to assess the situation, what to expect and to discuss upcoming advocacy strategies in the context of the REACH revision which is now delayed.

CSS Initiative	Form	Next Steps & remarks	Timing	Impact on veterinary medicinal products sector
Develop EU Safe and Sustainable-by-Design (SSbD) criteria for chemicals	Commission Recommendation	Ongoing technical work by EU services for criteria definition and first case studies. 5th stakeholder workshop planned for December 2023. Guidance report expected in Q1 2024. SSbD is not a regulatory action but will act as a complement to REACH. It is intended as a driver for better chemistries and intends to offer predictability and incentives to investors. Thus, it will not result in new obligations for companies.	Adopted in December 2022	No legal obligations, but might include criteria and performance indicators to measure the transition to more sustainable manufacturing in the pharmaceuticals sector. Frontrunner companies might be rewarded by certification schemes thus attracting investments.
Introduce legal requirements on the presence of substances of concern in products, including PFAS, through the initiative on sustainable products	Legal proposal (Ecodesign for Sustainable Products regulation - ESPR)	The Commission is expected to adopt its working plan setting priority products in Q1 2024. Work will continue at the technical level before the second 'trilogue', the date of which has yet to be set. The ESPR defines 'Substances of Concern' (SoC) in products and can lead to the restriction of substances if they are hindering recycling activities. It can also prevent environmental claims under the Green Claims directive.	Adoption expected in Q1 2024	Medicinal products are out of scope of ESPR. However, the definition of SoC puts increased scrutiny on hazardous substances and can lead to restrictions.
Restrictions Roadmap (prioritisation of CMRs, PBTs, etc)	Staff Working Document (REACH implementation)	The Roadmap is regularly reviewed and updated by the European Commission. It will continue to be used until the REACH revision enters into force, which does not provide the sufficient predictability for users and manufacturers, as substances listed in the Roadmap would be subject to the same complexities of current authorizations and restriction processes.	Roadmap published in April 2022	The Roadmap shows which upcoming REACH restrictions are expected and allow to anticipate whether veterinary medicines would be affected.
Extend the Generic Approach to Risk management (GRA)	Legal proposal – fragmented per file (REACH revision, FCM, Cosmetics and Toys)	REACH revision and FCM revision delayed. Toys and Cosmetics legislation in progress. Uncertainties remain as the GRA is a key action of the REACH revision which has been delayed. It also depends on the introduction of new hazard classes under the CLP.	Next Commission 2024	It would group uses, hazard and exposure data into a few use scenarios based on worst case assumptions, thereby often overestimating risk. It would fail to consider the importance of critical substances for essential uses like medicines.
Define an 'Essential Use Criteria' (EUC)	To be integrated in the REACH revision or published separately. To be implemented in other legislation.	Study completed in May 2023. DG ENV working on final changes. Delays in the publication of the EUC leads to uncertainties for a number of sectors which do not know if their uses will be derogated or not. This could drive investments away from Europe in the short term. The EUC should clearly define what is considered essential for society and put aside the assessment of viable alternatives which can take years.	Q1 2024	Draft versions of the EUC fall short of addressing the complexities of the assessment of alternatives for critical uses subject to complex testing and approval processes like veterinary medicines.
Proposal to revise the REACH authorization and restriction processes	Legal proposal (REACH revision - codecision)	Part of REACH revision and Impact Assessment. Until the revised authorizations and restrictions processes come into force, substances listed in the SVHC list would be subject to current REACH processes, creating a lot of ucnertainties for users. The simplifications a reform would bring also rely on the Essential Use Concept that has not been yet published.	Next Commission 2024	Increasing numbers of substances could end up subject to authorization or restriction because of the revised process. Even if medicines are exempt, some groups of substances might still become no longer available even for essential uses.
Proposal to amend REACH Article 68(2) to include professional users	Legal proposal (REACH revision - codecision)	Part of REACH revision and Impact Assessment.	Next Commission 2024	Could introduce simplified restriction procedures for professional uses which could affect various steps of the sector's value chain if pharmaceuticals fall within scope.

CSS Initiative	Form	Next Steps & remarks	Timing	Impact on veterinary medicinal products sector
Update information requirements to allow the identification of endocrine disruptors in relevant legislation, particularly under REACH, legislation on cosmetic products, food contact materials, plant protection products and biocidal products	REACH revision - comitology BPR - Delegated Regulation Active substances and Plant protection - Commission Communications Legal proposal - revision Food Contact Materials regulation Legal proposal - revision Cosmetic Products regulation	REACH revision delayed, FCM delayed, BPR?, Plant protection? Cosmetics in progress. Consistency between the inclusion of the requirements under separate legislations is needed, in particular as these legislative proposals do not have the same timeline and might have different provisions when finally adopted. This rely on the new hazard classes introduced via the CLP delegated act. Endocrine Diruptors will also be prioritised for harmonised classification and labelling under the revised CLP regulation.	Next Commission 2024	Could put stricter information requirements for substances used by the sector (e.g., biocides) and possibly trigger additional regulatory measures under REACH for substances classified as endocrine disruptors.
Proposal to amend REACH Art. 57 to add endocrine disruptors, persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances to the list of substances of very high concern	Legal proposal (REACH revision - codecision)	Part of REACH revision and Impact Assessment; Study launched, consultations ongoing.	Q4 2022	This amendment will lead to an increasing number of substances to be listed as candidate for authorization due to their classification under CLP.
Introduce (a) mixture assessment factor(s) (MAF) in Annex I of REACH	Legal proposal (REACH revision - comitology)	Could be launched separately to REACH revision. The MAF may lead to unintended consequences in downstream legislation and compromise the ability to accurately assess the risk to consumers, and indirectly impact the availability of chemicals for which there is no risk. The MAF will be taken into account in the reformed authorizations and restrictions processes.	Unknown	Similarly to the GRA, the MAF would fail to consider the importance of critical substances for essential uses like medicines and lead to increasing authorization and restriction cases.

CSS Initiative	Form	Next Steps & remarks	Timing	Impact on veterinary medicinal products sector
Review of the definition of nanomaterial	Staff Working Document on the review of the Recommendation 2011/696/EU and a new Commission Recommendation (2022/C 229/ 01) on the definition of nanomaterial, replacing 2011/696/EU	Individual sectors are updating their internal definition according to the revised definition, in accordance with their own timetables. Nanoform definition expected as part of the REACH revision proposal, now delayed.	Next Commission 2024	A modification of the definition could lead to adjustments in the regulatory requirements for substances falling within the scope, as well as how information is communicated throughout the supply chain.
Proposal to amend CLP Regulation to give the Commission the mandate to initiate harmonised classification	Legal proposal (CLP revision)	The CLP revised regulation is expected to have various effects on REACH. For instance, harmonised classification being the starting basis to extend the generic approach to risk management. In addition, extension of data requirements under the REACH revision needs to be made available for classification under the new CLP regulation. In summary, the two revisions are expected to work together.	Possible adoption before May 2024	CLP classification is the basis for legislative provisions on the risk management of chemicals, meaning it can trigger requirements under REACH, especially relevant in light of the GRA.
Proposal to amend the CLP Regulation to introduce new hazard classes on endocrine disruptors, PBTs/vPvBs and persistent and mobile substances, and apply them across all legislation	Legal proposals (CLP revision)	Proposal adopted but some parts may remain unclear due to delay in REACH restriction. Until the new REACH is in place, new hazard classes would possibly trigger new authorizations and restricitons under the current procedure.	Adopted March 2024	CLP classification is the basis for legislative provisions on the risk management of chemicals, meaning it can trigger requirements under REACH, which is particularly relevant in light of the GRA.
Proposal at the UN GHS level to introduce, adapt or clarify criteria/hazard classes in line with the CLP Regulation	New hazard classes in GHS	Dependent on CLP regulation revision.	2022-2024	Introduction of CLP hazard classes at the UN level would extend the challenges faced at EU level to the global level, which might be concerning for international supply chains like for pharmaceuticals.
Proposals under the Stockholm Convention and the Basel Convention to address PFAS concerns at a global scale	Decisions from the COP and amendment of EU legislation, when relevant (i.e. POPs Regulation).	PFHxS inclusion in the Stockholm Convention to be discussed at next COP face to face meeting (foreseen in June 2022). A party is preparing a nomination dossier for C9-C14 PFCAs. Two parallel tracks are being taken on PFAS, as the most toxic group of PFAS are targeted at POP level and as the EU is proposing to restrict the whole group of substances with derogations under the 'universal' PFAS restriction. Coherence between these two tracks is critical to ensure predictability for businesses.	2023- 2024	This could affect the affordability and availability of certain PFAS critical to medicinal products on a global scale. Under the Stockholm convention, PFAS might be subject to further international bans; under the Basel convention, to stricter measures for transboundary movements of PFAS-containing wastes and their disposal.

CSS Initiative	Form	Next Steps & remarks	Timing	Impact on veterinary medicinal products sector
Horizontal proposal for reallocation of EU technical and scientific work on chemicals to the EU agencies (OSOA)	Legal proposal	Draft Regulation published by the European Commission in December 2023. Parliament and Council will now work on the file.	2023	The possible concentration and separation of functions across agencies can lead to EMA having the competence for medicinal products, including the assessment of substances. This could be beneficial as it would allow for tailored assessments under specific legislations/uses and a more specific focus on the health and essentiality aspect of medicinal products and ultimately support a full exemption of the sector from REACH, including packaging and manufacturing of APIs.
Grouping of chemicals	REACH revision	Use and acceptation of grouping of chemicals should be further facilitated. Grouping of substances rely on other measures in the REACH revision (e.g., the identification of polymers requiring registration that will elaborate on grouping principles to be established, and the new authorization and restriction processes).	Next Commission 2024	May lead to more chemicals being classified as SVHCs, requiring authorization or restriction without carefully considering their use in critical sectors like medicines.
Information on environmental footprint of chemicals	REACH revision	Relates also to SSbD.	Next Commission 2024	Manufacturers and importers of substances might be required to include information related to the environmental footprint of their substances as part of REACH registrations (e.g. for polymers used to produce medicinal products).
Registration of Polymers	REACH revision	Registration will provide basic information on the quantities, uses, hazards and risks of polymers. The number of polymers to be identified for registration requirement is unknown until the REACH revision is published.	Next Commission 2024	Measures related to the introduction of regisration requirements for polymers could increase the burden for sectors using a significant amount of polymers.
Registration of low volume substances	REACH revision	Could lead to a merger of ANNEX VII & VIII	Next Commission 2024	Information requirements for substances at all tonnage levels could be increased, therefore affecting communication on substances used throughout the supply chain.

CSS Initiative	Form	Next Steps & remarks	Timing	Impact on veterinary medicinal products sector
Proposal for a founding regulation for the European Chemicals Agency (OSOA)	Legal proposal (new Regulation)	Consultation September – October 2022. First expected to be published in July 2023, the proposal has been delayed since. The Belgian Presidency of the Council of the EU has committed to make it a priority once the Commisison publishes it. The new proposal is expected to prepare ECHA for the complexities of the CSS implementation, which has already started.	Unknown	ECHA may need to be reorganised to deal with increased workload. Greater resources for ECHA would allow the agency to better assess REACH authorizations and restrictions and better manage large restrictions (e.g., PFAS) while better assessing industries' concerns which are numerous in the case of medicines.
Regulation to establish a Common data platform for Chemicals (OSOA)	Legal proposal (new Regulation)	Draft Regulation published by the European Commission in December 2023. Parliament and Council will now work on the file.	Published 2023, possible final adoption in 2024 or 2025	Information on certain chemicals might be reused inappropriately and not take into account the specific purposes and uses of the chemical, for instances if data is being used by regulators to take (quick) regulatory actions affecting veterinary medicinal products.
Substitution Framework study	Study to be used to define the regulatory tool	Could replace the Essential Use Concept on the long run	Study conducted throughout 2024, with two stakeholder workshops including the first on 1 March 2024	The tool would allow derogations from restrictions taking into account substitution plans bringing together industry wide planning and individual commitments. Positive development for complex uses as it would ensure continued use where no alternatives are available.
Substitution Centre	Pilot project	Aims to support businesses, especially SMEs in choosing safer alternatives for hazardous chemicals.	2024-2025	The centre is expected to play an important role in the assessment of alternatives and in the substitution framework of the European Commission to financially support companies.

Final Questions?

Call to Action!

Change Chemistry members who would like to take part in the European Advocacy Working Group.

Please reach out to Asli Tamer Vestlund via email at asli@changechemistry.org.

We also welcome other stakeholders and organisations to help build a strong and diverse stakeholder coalition.

Thank you!

Please contact us for further information.

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