ECHA
EUROPEAN CHEMICALS AGENCY

In brief

ECHA-21-FS-01-EN

SVHC Roadmap 2020 – achievements and extended aims

Roadmap to address substances of very high concern (SVHCs)

KEY ACHIEVEMENTS

- All relevant, currently known substances of very high concern (SVHCs) identified and action taken where needed to manage their risks. The substances include all relevant, currently known carcinogenic, mutagenic and toxic to reproduction substances (CMRs), persistent, bioaccumulative and toxic or very persistent and very bioaccumulative substances (PBTs/vPvBs) as well as endocrine disruptors (EDs).
- The need for regulatory risk management assessed through regulatory management option analysis (RMOA) for around 220 chemicals. Regulatory actions proposed for around 80 % of them.
- Faster identification of new substances of concern by focusing on groups of chemically similar substances instead of one substance at a time.
- Increased transparency and predictability on the work on substances of concern.

INTRODUCTION

Since 2013, ECHA, Member State authorities and the European Commission have worked together under the SVHC Roadmap 2020 to identify substances of very high concern (SVHCs) and put measures in place to manage their risks where required.

The roadmap was set up by the Council of the European Union with the goal of having all relevant currently known SVHCs identified and included on the Candidate List by 2020.

The key to achieving this goal was to establish a consistent, transparent and efficient approach for identifying and addressing substances of concern.

As part of this approach, ECHA and Member States began to systematically screen registered substances and use a new way called regulatory management option analysis (RMOA) to decide whether regulatory actions were needed and what would be the most appropriate ways to manage their risks.

CORE ACHIEVEMENTS

1. **All relevant, currently known substances of very high concern (SVHCs) identified.** By 2017, all relevant, currently known carcinogenic, mutagenic and reprotoxic and persistent, bioaccumulative and environmentally toxic substances (CMRs, PBT/vPvBs) as well as endocrine disruptors (EDs) were included in the Candidate List for authorisation, identified for other regulatory risk management measures (e.g. restriction), or considered to not currently require further regulatory risk management.

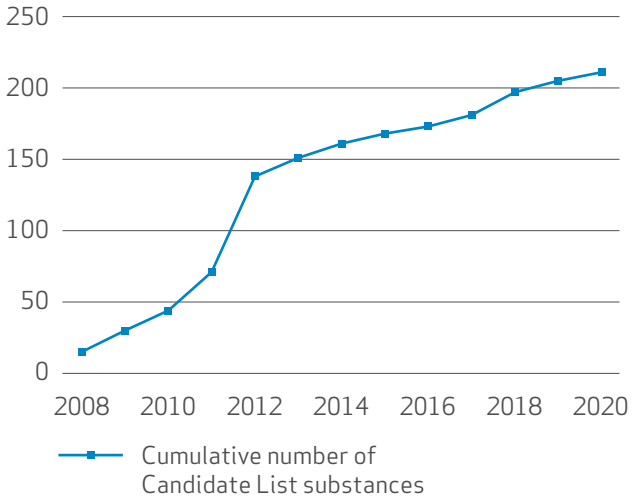


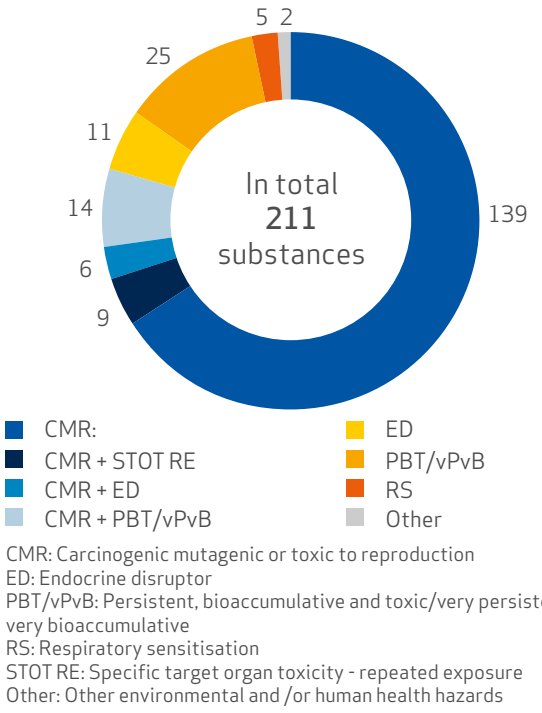
FIGURE 1.A CUMULATIVE NUMBER OF SUBSTANCES OR GROUPS OF SUBSTANCES INCLUDED IN THE CANDIDATE LIST.

SVHC ROADMAP DEFINITIONS

Relevant substances are those that have been registered for uses within the scope of authorisation under REACH. This definition gives priority to substances that are used by consumers and professionals or that have non-intermediate industrial uses in the EU. To discourage regrettable substitution, other types of substances (non-registered or registered as intermediates only) that were structurally similar to prioritised substances could also be considered.

Currently known substances cover those for which hazard properties have been clarified and that have been concluded as being carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBTs/vPvBs) or endocrine disruptors (EDs).

By the end of 2020, 211 substances or groups of substances have been included in the Candidate List (Fig. 1A and 1B). More SVHCs are expected to be identified from substances that did not have adequate information to be able to conclude on their hazard properties. These substances are undergoing substance or dossier evaluation to generate hazard information.



CMR: Carcinogenic mutagenic or toxic to reproduction
ED: Endocrine disruptor
PBT/vPvB: Persistent, bioaccumulative and toxic/very persistent, very bioaccumulative
RS: Respiratory sensitisation
STOT RE: Specific target organ toxicity - repeated exposure
Other: Other environmental and /or human health hazards

FIGURE 1.B OVERVIEW OF THE HAZARD PROPERTIES OF ALL SUBSTANCES OR GROUPS OF SUBSTANCES IN THE CANDIDATE LIST.

2. **Efficient processes established to identify and address new substances of concern.** Screening and regulatory management option analysis (RMOA) have helped to identify new substances of concern and address them effectively with the most appropriate regulatory actions.

Since 2014, ECHA and Member States have systematically screened the hazard, use and exposure information that companies have provided on registered substances. The RMOA approach has promoted early discussions and sharing of information between authorities and stakeholders.

Through the RMOA, other regulatory management actions than including substances in the Candidate List were also investigated. By the end of 2020, authorities had concluded RMOAs for approximately 220 substances and proposed regulatory action for around 80 % of them (Fig. 2).

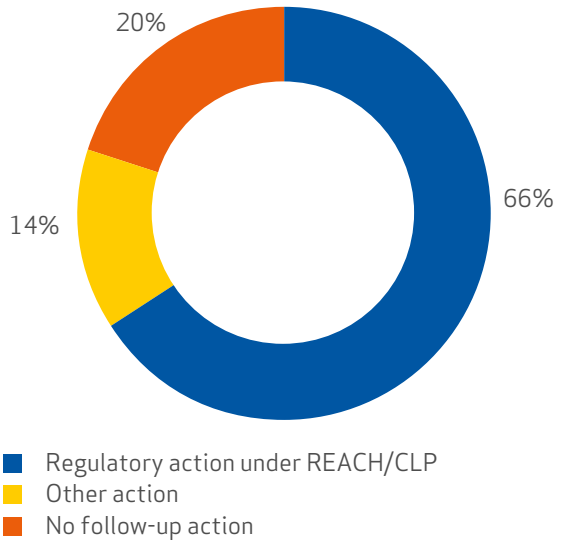


FIGURE 2 PROPORTION OF RMOAS CONCLUDED WITH REGULATORY ACTION UNDER REACH/CLP, OTHER ACTION OR WITH NO FOLLOW-UP ACTION.

3. **Grouping to identify substances of concern faster.** ECHA and Member States started working on groups of chemically related substances to speed up the identification of chemicals that need regulatory action. Grouping:

- Makes it possible for authorities to use all of the available data and cover a bigger share of registered substances, including those lacking hazard and exposure information. This can be seen in the increased amount of substances screened in 2019 – 2020 (Fig. 3);
- Improves regulatory consistency when addressing similar substances and increases the predictability of authorities' actions;
- Supports industry in moving towards better-informed substitution by considering potential substitutes for known substances of concern; and
- Makes the early identification of substances that do not require further action possible.

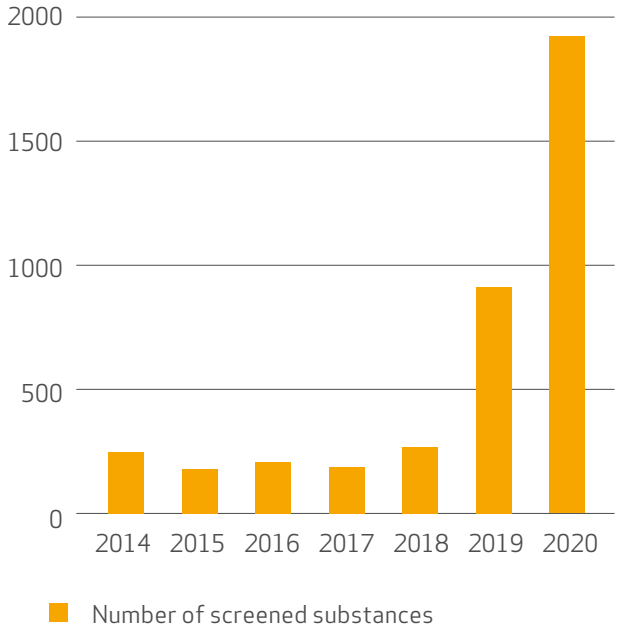


FIGURE 3 NUMBER OF SUBSTANCES SCREENED BY MEMBER STATE AUTHORITIES AND ECHA DURING 2014 – 2020.

4. **Action taken on petroleum and coal stream substances.** Defining and assessing petroleum and coal stream substances is challenging because of their very complex and variable compositions and has postponed regulatory actions on them. Under the Roadmap, Member States, the European Commission, ECHA and industry stakeholders developed an approach to prioritise and address petroleum and coal stream substances.

Based on the gained experience authorities are now defining which regulatory actions would be effective and efficient in managing substances containing constituents of concern and initiating them.

5. **Scientific advice on endocrine disrupting substances and PBTs.** The assessment of endocrine-disrupting substances was supported by the scientific advice given by the Expert Group on EDs, which was established under the Roadmap. Also, the **work of the Expert Group for Persistent, Bioaccumulative and Toxic substances (PBT Expert Group) has continued** providing scientific advice on the identification of persistent, bioaccumulative and toxic (PBT) and very persistent, very bioaccumulative (vPvB) properties of chemicals.

6. **Increased transparency and predictability.** ECHA launched the public activities coordination tool (PACT) to increase the transparency and predictability of authorities' work on substances of concern covered by different REACH and CLP processes. PACT provides stakeholders with information on planned, ongoing and completed activities in the areas of data generation and assessment, RMOAs and regulatory risk management.

ON THE HORIZON

The work that was kicked off as part of the SVHC Roadmap now continues under ECHA's Integrated Regulatory Strategy. The next goal has been set for 2027. By then, the aim is to conclude on all registered substances whether they are of:

- High priority for EU level regulatory risk management;
- High priority for data generation; or
- Currently of low priority for further EU level regulatory action.

On a global level, this work contributes to the United Nation's 2030 Sustainable Development Goals concerning chemicals.

LINKS TO KEY BACKGROUND MATERIAL

SVHC Roadmap to 2020
» https://data.consilium.europa.eu/doc/document/ST%205867%202013%20INIT/EN/pdf

SVHC Roadmap Annual Reports
» https://echa.europa.eu/svhc-roadmap-to-2020-implementation

Integrated Regulatory Strategy Annual Reports
» https://echa.europa.eu/report-archive-specific-reports

Candidate List of substances of very high concern for Authorisation
» https://echa.europa.eu/candidate-list-table

The approach on how to address PetCo substances
» https://echa.europa.eu/documents/10162/19126370/approach_on_how_to_address_petco_substances_en.pdf

Endocrine disruptor assessment list
» https://echa.europa.eu/ed-assessment

PBT assessment list
» https://echa.europa.eu/pbt

Universe of registered substances
» https://echa.europa.eu/universe-of-registered-substances

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