

CALL FOR EVIDENCE FOR AN EVALUATION AND IMPACT ASSESSMENT RUN IN PARALLEL

TITLE OF THE INITIATIVE	Hazardous chemicals – prohibiting production for export of chemicals banned in the European Union
LEAD DG – RESPONSIBLE UNIT	ENV.B2
LIKELY TYPE OF INITIATIVE	Legislative initiative
INDICATIVE PLANNING	Q4 2023
ADDITIONAL INFORMATION	https://environment.ec.europa.eu/strategy/chemicals-strategy_en

A. Political context, evaluation, problem definition & subsidiarity check

Political context

The [Chemicals Strategy for Sustainability](#) adopted on 14 October 2020 is a key action in the European Green Deal and the move towards a toxic-free environment. The strategy aims to protect people and the environment against hazardous chemicals and encourage innovation to develop safe and sustainable alternatives, within the EU and globally. In line with the Chemicals Strategy¹, this initiative aims to ensure more consistency between internal and external policies and thus improve the international standing of the EU, strengthening the credibility of our values and actions and most importantly improving protection for human health and the environment globally.

The initiative is linked to several EU Regulations which are instrumental in deciding whether chemicals are considered banned or severely restricted, in particular in the context of the [PIC Regulation](#). These include the:

- **REACH Regulation** ([Regulation 1907/2006](#) on the registration, evaluation, authorisation and restriction of chemicals)
- **PIC Regulation** ([Regulation 649/2012](#) on the export and import of hazardous chemicals)
- **Plant Protection Products Regulation** ([Regulation 1107/2009](#) on the placing of plant protection products on the market)
- **Biocides Regulation** ([Regulation 528/2012](#) on the making available on the market and use of biocidal products).

Evaluation

The international trade in hazardous chemicals is regulated through the UN's [Rotterdam Convention on the Prior Informed Consent](#) (PIC) Procedure for certain hazardous chemicals and pesticides in international trade.

The EU and all its Member States are Parties to the convention, which currently has 165 Parties.

The EU's PIC Regulation implements the Rotterdam Convention and is in line with the core elements of the convention:

- the export notification requirement;

¹ See section 2.5.2 of the Chemicals Strategy for Sustainability

- the PIC procedure – which is built on the principle that it is for importing countries to decide whether to consent to the import of certain chemicals (including pesticides) and that exporting countries must respect those decisions.

As the revision of the PIC Regulation is considered among the possible measures (see below) under this initiative, it is necessary to evaluate in a targeted way certain requirements in the PIC Regulation since its entry into force in 2012.

This evaluation will provide information on whether the current rules continue to meet the PIC Regulation's objectives and where improvements to the current system may be needed, to increase efficiency and effectiveness.

The Regulation will also be assessed on the criteria of relevance, coherence (consistency) and 'EU added value' (value that is additional to what would otherwise have been created by EU countries acting alone). The results will feed into the envisaged back-to-back evaluation and impact assessment.

Problem the initiative aims to tackle

Under EU law, chemicals are regulated in different manners, to ensure a high level of protection for human health and the environment.

The precise regulatory approach taken depends on the context: chemicals may be banned (not allowed for use in the EU):

- because they did not meet the regulatory requirements for human health, animal health or environmental protection;
- because there was no application for approval in the EU, or;
- because an operator withdrew its application before a decision was taken by the authorities.

In other cases, manufacturing, and all (or just specific) uses of chemicals, are explicitly restricted for safety reasons.

The overall EU system of chemicals regulation represents a comprehensive legal system, based on the best available science. It delivers a high level of protection for human health and the environment. However, in most cases the regulations only concern placing chemicals on the market and using them in the EU, and it is possible to produce chemicals that are not authorised to be used in the EU and export them outside the EU.

In many cases the very same concerns that justified restriction or non-authorisation in the EU would have the same negative effects on human health or the environment in other countries. Moreover, adverse environmental and health impacts may have a global impact, for example in the case of POP substances (Persistent Organic Pollutants).

The EU's chemicals strategy strives for a toxic-free environment where chemicals are produced and used in a way that maximises their contribution to society, including achieving the green and digital transition, while avoiding harm to the planet and to current and future generations.

The EU is not able to attain these goals unless action is taken to address the production of hazardous chemicals that are not allowed for use in the EU but still can be produced and then exported.

Basis for EU action (legal basis and subsidiarity check)

The initiative concerns an area where the EU has 'shared competence', according to Article 114 of the Treaty on the Functioning of the European Union, as it is related to health, safety, environmental protection and consumer protection.

'Shared competence' means that both the EU and its Member States can adopt legally binding acts in the area concerned. However, the Member States can do this only where the EU has not exercised its right to

do this or has explicitly ceased to do so.

The total amount of exported chemicals that are subject to the PIC Regulation (without necessarily being banned in the EU) was around 667,000 tonnes in 2020 (as reported by EU Member States).

Action at EU-level is necessary to increase protection for human health and the environment globally.

In addition, this initiative is deployed in the context of the Chemicals Strategy for Sustainability, which promotes safe and sustainable chemicals management globally.

Certain Member States have already adopted national laws to restrict the export of certain hazardous chemicals. But tackling the measures at EU-level is more efficient and effective and contributes to the integrity of the EU's environmental policies and the single market.

B. Objectives and policy options

The objectives of the initiatives are to increase protection for human health and the environment globally and to apply uniform measures in all EU countries.

The impact assessment will consider non-regulatory and regulatory measures, compared to a baseline scenario. This analysis will identify the most likely response to the options by various parties and quantify the costs and benefits of possible changes to one or more pieces of EU law regulating chemicals, compared to its current implementation. It will also analyse the impact on EU customs legislation, procedures and systems.

The measures that will be examined through options could include, for example:

- Increasing the amount of information made available to non-EU countries under the PIC Regulation, to enable them to better act on the risks identified under EU law by restricting or banning the chemicals concerned in the same way as in the EU.
- Revising the current requirements for export under the PIC Regulation, to offer a higher level of protection from unwanted imports of hazardous chemicals that are banned in the EU.
- Introducing a prohibition to produce hazardous chemicals that are not approved or prohibited for placing on the market and/or use in the EU.
- Taking an approach that combines the above options.

The described objectives and policy options are preliminary and will evolve throughout the impact assessment.

C. Likely impacts

The initiative will strengthen the credibility of the EU at international level.

Hazardous chemicals that are banned in the EU due to their hazardous properties and/or unacceptable risks to human health or the environment are still produced in the EU and then exported to countries outside the EU. However, these chemicals can potentially cause the same human health and environment concerns regardless of where they are used.

The EU, in line with its environmental policy objectives, does not wish products produced within the EU to contribute to such harm.

The initiative also has the potential to improve protection for human health and the environment in the EU, by preventing the use of chemicals in non-EU countries that have persistent and mobile properties with the capacity of having transboundary effects.

It is expected that there will be direct economic impacts on EU companies, including small and medium

firms, who are currently exporting hazardous chemicals banned at EU-level, as those companies will no longer be able to produce/export their products. This will result in a loss of sales and market share and a possible relocation of production outside the EU.

However, in the long term, this change is expected to reinforce the reliability of EU products as regards safety and quality and thus their image on the global market.

The initiative is in line with Articles 31, 35 and 37 of the EU Charter of Fundamental Rights, which require EU policies to ensure healthy and safe working conditions, a high level of human health and environmental protection and an improved quality of the environment.

This initiative is closely linked to Sustainable Development Goals (SDG), in particular SDG 3 (“Good Health and Well-Being”), SDG 6 (“Clean Water and Sanitation”) and SDG 12 (“Responsible Consumption and Production”).

D. Better Regulation instruments

Impact assessment and evaluation

An evaluation and an impact assessment will be carried out from March 2023 until October 2023.

The evaluation will provide a targeted assessment of the effectiveness, efficiency, coherence (consistency), relevance and EU added value of the PIC Regulation.

The objective of the impact assessment is to identify and assess, both quantitatively and qualitatively, which effects (positive and negative) the various options are expected to have in terms of improved protection for human health and the environment, as well as the economic costs, the impact on the single market and social impacts – including, where feasible, effects in non-EU countries and the implications for customs.

Consultation strategy

Consultations are planned, to gather data to support the targeted evaluation of the PIC Regulation and to inform the impact assessment process. They will complement other information gathered while formulating the Chemicals Strategy for Sustainability.

The purpose of the consultations is to obtain feedback from the public by way of:

1. This call for evidence and an online public consultation in all 24 EU languages, which will be open for 12 weeks.
2. Existing Commission expert groups under the main EU chemicals laws concerned by the initiative (i.e. REACH, PIC, biocides).
3. At least one workshop with stakeholders.

A factual summary report of the online public consultation will be published after its closure on the [Have your say portal](#). A synopsis report summarising and analysing all consultation results will also be prepared and included in the impact assessment.

Why we are consulting?

This consultation aims to seek views from different stakeholders and citizens on the commitment of the Chemicals Strategy for Sustainability (adopted on 14 October 2020) to prohibit the production for export of hazardous chemicals banned in the EU.

Target audience

We would like to hear the views of stakeholders, including citizens, researchers, businesses including small and medium-sized firms, industry, industrial associations and trade bodies, governmental and non-

governmental organisation (international, European, national and more local), employers' groups, trade unions and social bodies.