

Cefic views on the European Commission initiative “Hazardous chemicals – prohibiting production for export of chemicals banned in the European Union”

This view paper highlights Cefic’s views on the Chemical Strategy for Sustainability (CSS) action to ensure that certain hazardous chemicals banned in the European Union (EU) are not produced for export. Cefic understands the reasons and the intent behind this action, that is why it is important to address it through the most effective policy instrument. We ask that the action is implemented in a way that substantially contributes to both the protection of health and the environment, particularly in third countries while ensuring a global level playing field. The following suggestions and recommendations can help to achieve these goals:

Key elements:

- 1. Global issues should be tackled with global solutions:** given the global nature of trade, only global initiatives like the better implementation of the Rotterdam Convention can tackle the issue. This will help to ensure adequate regulation while providing a level playing field.
- 2. Cefic supports the review and improvement of the EU Prior Informed Consent (PIC) regulation**
- 3. Production and export bans should be considered as measures of last resort for chemical substances banned in the EU**
- 4. There is a need for clear definitions, processes, and case-by-case decisions**
- 5. Compliance with World Trade Organisation (WTO) law and the Rotterdam Convention needs to be ensured**

International solution as the most effective route to achieve the CSS ambition

Cefic considers that an international policy solution like better implementation and enforcement of the Rotterdam Convention would be the most effective and WTO-law-compatible option to achieve stated policy goals of the CSS action. As a first step, Cefic believes that ways to make better use of the legal provisions under the Rotterdam Convention should be examined. Due to the global nature of the issue, only global rules will ensure adequate regulation while providing for a global level playing field. A unilateral EU measure risks being ineffective as third countries have also production capacities to supply the same chemical substances and thus generating an unlevel playing field.

Any international action should be supplemented by capacity-building initiatives especially in developing third countries to improve the implementation of the Rotterdam Convention. This would promote legal certainty, infrastructure, safe processing and handling of certain hazardous substances, and training of the designated authorities and users.

PIC review and improvement

In case the European Commission finds that additional measures should be taken at the European level, Cefic asks to consider first how the PIC regulation¹ could be improved. It is the obvious policy instrument to consider as it was designed to implement the Rotterdam Convention aiming to regulate the trade of certain hazardous chemicals.

To this end, Cefic welcomes the European Commission's efforts to evaluate the PIC regulation. However, we believe that the current scope of the evaluation is too limited. We would therefore support a more comprehensive exercise. This would help to achieve a holistic understanding of the functioning of the regulation and help to identify potential improvement areas.²

In general, our view is that the PIC regulation delivers on its stated policy objectives as it regulates and monitors import and export of PIC listed substances. However, further improvements are possible. Next to the areas that are already under consideration by the targeted evaluation, additional improvements areas may entail:

- (1) Improve harmonization of the notification and reporting processes among Member States,
- (2) increase flexibility and address complexity of data requirements in global supply chains and foresee simplification,
- (3) apply PIC notification obligation to non-EU established entities operating within the EU,
- (4) improve the listing process for new substances in the Annexes via more transparent public consultations and
- (5) improve transparency measures. We support exploring the possibility to link every PIC-listed substance to a dedicated Combined Nomenclature (CN) code. This will help to monitor, evaluate and enforce the effectiveness of the new measures.

We therefore support the adaptation (i.e., review and improvement) of the EU PIC regulation to further improve the protection of human health and the environment. Eventually, an obligation should be on the importing country to grant explicit consent for the import of all chemicals banned in the EU. Furthermore, a reference to safe use practices being applied in the importing country should be included into the explicit consent form. Potentially, this should also include an obligation to track and manage severe incidents.

Production ban/Export ban option

In case the European Commission would decide to adopt a ban, we would like to better understand how such ban would prevent existing or new non-EU suppliers from replacing banned EU substances. Our concern remains that a unilateral ban on EU exports would not solve the issue at hand, since non-EU suppliers would be able to step in and supply the respective substances.

¹ Regulation (EU) 649/2012 concerning the export and import of hazardous chemicals

² ECHA has also raised issues in this regard:

https://echa.europa.eu/documents/10162/1244645/report_pic_art_22_2020_en.pdf/2775f5de-4d54-f8fc-49d4-d99bb60e7768?t=1598863292234

These non-EU originating supplies risk to be produced and used in certain cases under health and environmental production standards that do not meet the standards applied in the EU.

Regarding the design of any measure, Cefic advocates for clear definitions and dedicated procedures that allow for case-by-case decisions. In our view, these are essential requirements for any instrument to deliver precise, proportionate, and science-based results which are key elements to ensure predictability for stakeholders.

WTO Compliance

It is fundamental that any export measure taken by the EU adheres to WTO law. As any EU measure banning the export and/or production—however structured under EU law—faces a significant risk of violating General Agreement on Tariffs and Trade (GATT) Article XI, the EU would need to justify the measure via the general exception clause provided under GATT Article XX. To be able justify the measure, the following principles were drawn from the analysis of the legal requirements regarding Article I of GATT and most importantly Articles XX(b), XX(g) and the chapeau of Article XX:

I. Justification of Risk to Health and Environment

Any type of measure to implement the CSS action as well as any specific substance listed by such a measure would need to be formally justified regarding the health and environmental risks in the importing country that the measure(s) intends to protect against. These justifications would have to be backed by qualified and respected sources. This justification requirement also implies that it would be insufficient to simply rely on the precautionary principle.

II. Consideration of Third Country Conditions and Impacts

Any type of measure to implement the CSS action as well as any specific substance listed by such a measure would need to consider the impact on third countries. In doing so, it would have to consider the specific conditions in third countries (e.g., the use of certain EU-produced plant protection products for agricultural production). This third country assessment should at least consider the most important economic and trade effects. Crucially, this third country assessment should also assess alternatives that achieve the same level of protection but are less trade restrictive.

III. Non-Discrimination

Any type of measure to implement the CSS action would need to ensure that there is no discrimination either between third countries and the EU, or between third countries themselves. In practical terms, this would be particularly difficult if the EU were to continue to

allow for production and certain uses in the EU that are banned from export. Any exceptions raise the risk of discriminatory treatment.

IV. Due Process

Any type of measure to implement the CSS action would need to provide for due process, in particular a consultation of stakeholders in which third countries can participate, and public reason-giving for its regulatory choices. This due process requirement would apply not only to the adoption of the general legal framework but also to the listing of specific substances.

V. Non-Coercive / Flexible

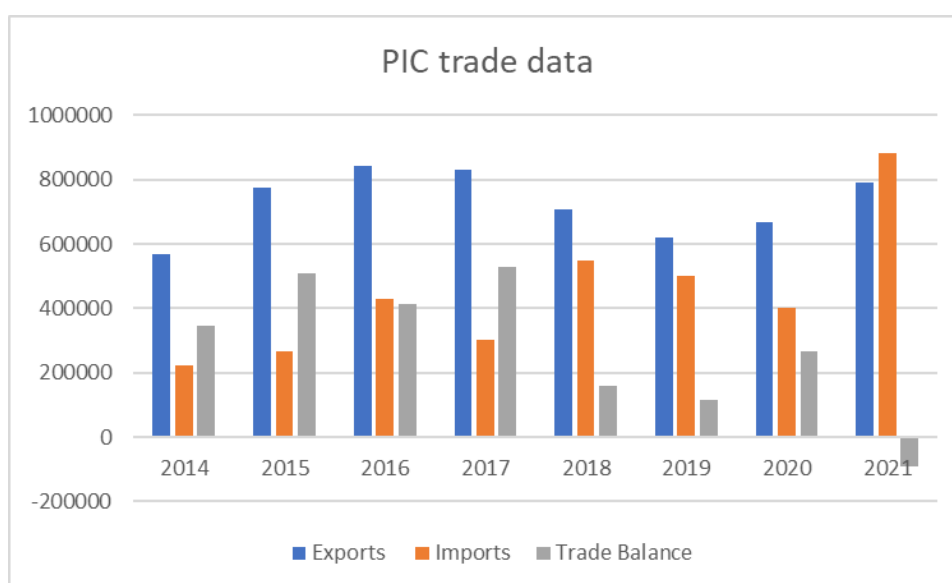
Any type of measure to implement the CSS action would need to address the perception that an EU measure would effectively force other countries to adopt the EU's policy choices on what substances to use (or not to use). Therefore, any measure should provide for some flexibility for emergency or other exigent use applications. The design of this "emergency use" mechanism would have to be tailored to ensure that the EU can also satisfy the other Article XX chapeau requirements concerning the justification of the measure, non-discrimination, and due process.

Further details can be found in the three annexes that can be consulted in the following pages.

Annex I: Analysis of PIC exports

General overview: trade flows of PIC registered chemicals

In the period between 2014 (when the PIC regulation became applicable) and 2021 (last year of currently available data) the EU exported in total 5.007.134 tonnes of PIC registered substances.³ At the same time the EU imported 3.551.299 tonnes of registered PIC registered substances leaving a total positive trade balance of 1.455.835 tonnes for the EU. The yearly EU exports totalled on average 715.305 tonnes and the imports 443.912 tonnes. This means that there was a positive average trade balance for the EU of 280.926 tonnes.



The main outlier to this trend was 2021, when for the first time the EU had a negative trade balance. This corresponds with an increase in volumes especially for imports, +120 %, and exports, +19% compared to 2020. As European Chemicals Agency (ECHA) explains in its report⁴ that this increase in exports was mostly due to newly reported trade with the United Kingdom (UK)⁵ which in turn was related to 85% to export of benzene to the UK.⁶ 2021 was the first year that in which the UK was considered a third country following the end of the transition period on 31 December 2020. Hence, it needs to be seen if 2021 remains an anomaly or whether this is the start of a new

³ All data was taken from the annual ECHA reporting on PIC exports and imports: <https://echa.europa.eu/regulations/prior-informed-consent/annual-reporting-on-pic-exports-and-imports>

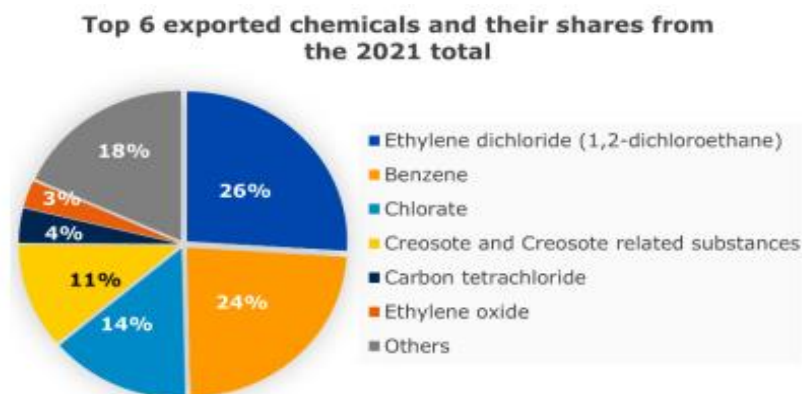
⁴ https://echa.europa.eu/documents/10162/1244645/pic_article_10-2021_en.pdf/b56b1552-9a2b-5572-5f19-640bba01b008?t=1671440822534

⁵ In line with the Northern Ireland protocol, Northern Ireland is considered part of the EU Single Market. However, in 2021 there were no PIC relevant exports or imports notified.

⁶ https://echa.europa.eu/documents/10162/1244645/pic_article_10-2021_en.pdf/b56b1552-9a2b-5572-5f19-640bba01b008?t=1671440822534, page 5.

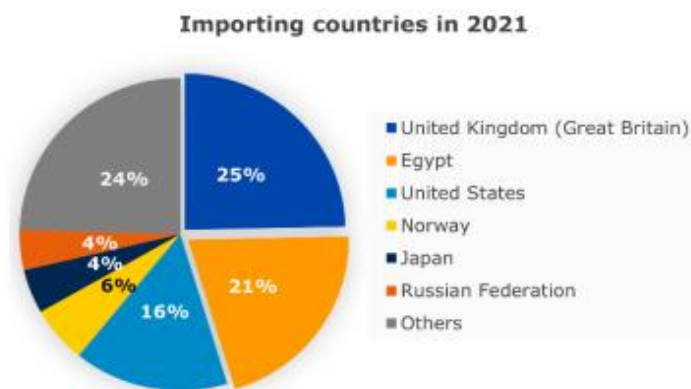
trend. Moreover, it is noteworthy that EU exports did not increase substantially during the observed period even though additional substances were added on a regular basis.

PIC-related EU Exports



According to ECHA data, in 2021, PIC registered substances listed in six entries of the PIC Regulation were responsible for 82% of the EU PIC exports. In tonnage this means that the six entries were responsible for 649.093tonnes of the grand total of 791.576 tonnes. In total, substances belonging to 101 PIC entries were exported in 2021. This means that exports were reported for ~35% of the PIC entries.

PIC-related Export Destinations



According to ECHA data, in 2021, six countries were responsible for 76% of all EU PIC-related exports. In tonnage this means that the six countries imported 601.598 tonnes of the total of 791.576 tonnes. The UK, Egypt and the United States covered 62% alone. Of the six importing countries, only Egypt belongs to the lower middle-income group according to the World Bank. Russia is considered as an upper middle-income country and the other four are considered as high-income countries.

Annex II: Case study: impact of potential production/export ban on benzene

This case study analyses the impact on benzene of a scenario under which a potential EU manufacturing ban on all substances listed in Annex I to the PIC regulation would be implemented. The scenario was chosen based on the assumption that a hypothetical production and/or export ban would require a total ban on all uses to avoid discrimination and thus remain WTO compliant.

The case study shows that such a ban would have serious negative impacts on the entire European petrochemical industry, with significant ripple effects on upstream and downstream industries. This case is therefore exemplary for many other PIC-listed substances that have important uses both in the EU and globally. We therefore advocate for caution when to adopting restrictive measures with regards to the substances listed in Annex I to the PIC regulation to avoid undesired consequences especially when considering the scope of any potential EU unilateral measure.

Benzene is a chemical substance that is severely restricted due to its properties of concern⁷ but not totally banned for use in the EU. It is therefore also listed in Annex I, Part 1 of the PIC Regulation as a severely restricted substance for industrial chemical uses. Benzene is an important industrial intermediate and also present as impurity in substances/mixtures containing benzene >0.1% are present in petrochemical feedstocks (i.e., crude oil, naphtha)/ intermediates/ products. It is inherently impossible to refine crude oil without the presence of any benzene. A production ban would challenge the entire operation of the related manufacturing facilities (i.e., steam crackers & refineries) in Europe. This would mean that Europe would be severely constrained to produce fuels and petrochemicals domestically.

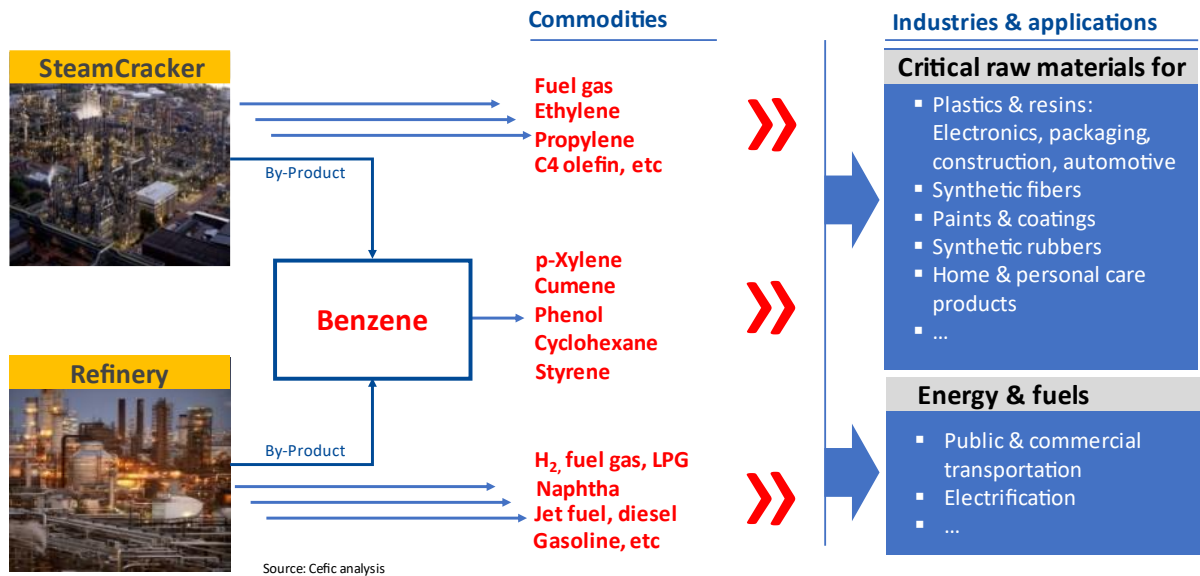
The reason is that benzene is an unavoidable byproduct of refining and petrochemical processes, e.g., as part of a so-called pygas mixture which comprises also other essential commodities (e.g., toluenes, xylenes, olefins). The by-products including benzene serve various material supply chains in Europe (e.g., in construction, automotive, packaging). The EU is mainly a producer and importer of benzene. The limited production surplus is exported globally.

Benzene is mainly produced and imported in Asia, Europe and North America. Major importing countries are developed countries with established regulatory, safety and trade control infrastructure such as South Korea, United States, China, or Taiwan. Moreover, while benzene represents 24% of overall PIC related exports in 2021 The EU remains mainly an importing region of benzene as also detailed in ECHA's 2021 annual report where benzene accounted for 57% of all imports⁸. As benzene is a commodity traded globally, an EU production and/or export ban would have little effect to achieve the envisioned global goals on human health and environmental protection.

⁷ <https://echa.europa.eu/substance-information/-/substanceinfo/100.000.685>

⁸ https://echa.europa.eu/documents/10162/1244645/pic_article_10-2021_en.pdf/b56b1552-9a2b-5572-5f19-640bba01b008?t=1671440822534 page 109.

**Benzene is an unavoidable byproduct –
A ban impacts also major commodities and critical raw material supply chains**



The potential ban would therefore result in an “avoidance” strategy of benzene as a by-product (~8.2 mio. tonnes in Europe in 2022) by reducing the refinery and petrochemical operation capacities. This means that the by-products (including benzene) as well as the main products in the refinery (transportation fuels, heating oil) and petrochemical (i.e., olefins) operations would be throttled, something which would also constrain the supplies of large-scale commodities (e.g., production of plastics and other materials). Also, critical supplies for energy and fuel consumption such as hydrogen and gasoline would be impacted, and this in turn would hamper the EU ambitions on electrification.

In case, the EU would adopt a unilateral production ban on benzene, this would imply that the EU would become import dependent on third countries for these essential materials, with serious knock-on effects for EU policies like EU Green Deal. This goes against the EU principle of strategic autonomy, on a commodity that has strategic applications for the EU.

Moreover, as benzene is a globally trade commodity, importing countries could switch to non-EU suppliers. It would therefore merely shift production geographically while not addressing the CSS goal. Depending on where these substances are manufactured, another impact may be that due to a potentially lower standard of chemical control regulations in these locations (less stringent, or completely unregulated), manufacturing operations would be less safe, have more emissions or result in increased exposure to users across the supply chain.

Annex III: A non-approval for a biocide has many reasons

This annex explains why non-approval decisions, be it under the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) or other chemical legislations, can have many reasons and are not exclusively linked to the hazard profile of a substance. These other reasons are detailed below:

1. In the case of biocides, active substances (AS) can be used for different uses, the so-called Product Types (PT). There are 22 PTs⁹. Each of these AS/PT combinations is evaluated separately and gets a separate approval decision. Thus, it is possible that a substance will be approved for one or several PTs, but due to a specific reason not necessarily connected to the hazard profile of the substance (e.g., efficacy, exposure...) one or more PTs would not be approved. The non-approval for one AS/PT combination would trigger PIC listing, but for the other approved AS/PT combination(s) the substance would be allowed to be used as biocide. An example would be PHMB (1415; 4.7) (CAS 32289-58-0 and 1802181-67-4) which is approved for PT 2 and PT 4, but not approved for PT 1, PT 5, and PT 6 (for more info, see their corresponding BPC Opinions on the ECHA website¹⁰).

An additional layer of complexity is added by the fact that the “Review Programme to examine existing biocide active substances” is highly delayed. It was intended to be concluded in 2010 and has since then already twice prolonged (to 2014 and then 2024). It is currently up for an extension until the end of 2030¹¹. At the moment, only 45% of the Review Programme¹² is completed, meaning that 65% is still under evaluation. This means that the different conclusions on different AS/PT combinations can come at different points in times. Concretely, a non-approval for one AS/PT combination, not necessarily linked to the hazard profile, could already exist, but the decision to approve the substance for another AS/PT combination might only come in the future.

2. In the case of biocides, we noticed that of the already approved active substances which are coming up for renewal, in more than 30% of the cases applicants do not submit applications for renewal (see overview from DG SANTE¹³). In a substantial amount of these cases, it can be assumed that the reasons for not applying for renewal are purely of economic nature. The costs and the regulatory burden to maintain substances alive in the EU under the BPR is very high, so it is likely that a company would leave the EU market and focus on other markets in the world. However, such an “expiration” of an already existing approval could also be seen as

⁹ [Product-types - ECHA \(europa.eu\)](#)

¹⁰ [Biocidal Products Committee opinions on active substance approval - ECHA \(europa.eu\)](#)

¹¹ [Circabc \(europa.eu\)](#)

¹² [Circabc \(europa.eu\)](#)

¹³ [Circabc \(europa.eu\)](#)

a non-approval, and if this would result in the substance ending up on the PIC list, it could close the doors to the market in the rest of the world, which would create a rather obstinate situation.

3. Cholecalciferol (Vitamin D3) (CAS 67-97-0) is on the PIC list because it is prohibited as a Plant Protection Product (PPP). But it is a widely used food supplement and approved as biocide active substance. It is identified through an EU-wide comparative assessment conducted by ECHA as an alternative for a group of other biocide active substances that are candidates for substitution (see the ECHA BPC Opinion of 07/06/2023¹⁴). So, even though the substance is listed on the PIC list, it is approved and used as a biocide and therefore it would not be justified to have a complete ban of the substance solely based on the PIC listing. There are many more such cases of substances that are used both as PPP and as biocides where the PIC listing comes from PPP, but the substance is also formally approved and used under biocides. Examples are *inter alia*: Permethrin (CAS 52645-53-1), Didecyldimethylammonium chloride (DDAC) (CAS 7173-51-5), Imidacloprid (CAS 138261-41-3), Propiconazole (CAS 60207-90-1).
4. Under the BPR, there are examples where an AS is not approved because at a certain moment a certain data request was not fulfilled by the applicant. Depending on at what moment in the approval process this happens, the procedure would describe either that the substance is no longer supported, or that the substance is proposed for non-approval. It is not unusual that the applicant is then advised to re-submit his dossier as a new application for approval once the additional data would be available.

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About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for 15% of world chemicals production.

¹⁴ <https://echa.europa.eu/en/regulations/biocidal-products-regulation/approval-of-active-substances/opinions-on-article-75-1-g>