HIGH LEVEL ROUNDTABLE
ON THE CHEMICALS STRATEGY FOR SUSTAINABILITY
25 NOVEMBER 2021

Background document 2: A zero tolerance approach to non-compliance

[The 2nd meeting of the High Level Roundtable on the Chemicals Strategy will focus on enforcement and compliance of chemicals legislation. This document serves as background for the members of the Roundtable to produce a joint report, which will be adopted at the meeting.]

1. Background

The Chemicals Strategy for Sustainability aims at to step up enforcement of EU chemicals legislation and to reduce non-compliance. Enforcement[1] is essential to accomplish the objectives of the legislation. Therefore, strengthening enforcement and increasing compliance are priorities for ensuring the highest protection of health and the environment from hazardous chemicals and providing a level playing field both within the EU and between EU and non-EU players. Considering that EU standards are not always necessarily mirrored globally, it is also important that enforcement activities become more effective in order to tackle the higher risk of non-compliance from chemical products or articles containing chemicals imported from outside the EU.

To ensure the highest protection of EU citizens and the environment, it is vital that EU chemicals legislation is applied by all economic operators (manufacturers, importers, downstream users…) in all Member States and with the same level of scrutiny and effectiveness.

Enforcement of EU chemicals legislation is mainly a Member States' competence and the Commission oversees and supports their enforcement activities. There is wide experience with enforcement of chemical legislation and information and intelligence has been collected for more than 10 years.

Some key data on enforcement activities on chemicals

- *More than 67 000 and 72 000 controls per year are carried out on REACH and CLP respectively in the EU+EEA*

- *82 % has been the average level of compliance in REACH and CLP in the last 10 years but lower levels of compliance have been reported in last years in more targeted enforcement projects and only about a third of REACH registrations dossiers are fully compliant*

- *13 % of the notifications by Member States on dangerous non-food products in the EU market in the past years is related to chemicals. A large proportion of these products were coming from outside the EU*

- *In average, 24 Member States participate every year in EU-wide enforcement projects*

More information and details in the Annex to this document.

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2. How to move to zero tolerance to non-compliance?

The Chemicals Strategy announces a set of actions for all relevant players to work together to step up enforcement of the EU rules on chemicals nationally and at the EU borders, and to promote compliance. The following gives a state of the ongoing activities:

a) Being more effective at the borders and on e-commerce

The Commission is currently working on a new strategic approach on customs enforcement of non-fiscal legislation that relates to environment, health, product safety, security, etc., with a particular attention to the enforcement of chemicals legislation at the EU borders. The contribution of all stakeholders in this reflection will be key to help develop new approaches via which competent authorities for chemicals legislation and customs authorities can jointly strengthen border enforcement.

Strengthening the enforcement of REACH at the EU borders is one of the, key challenges for a successful implementation of REACH in the EU – and perhaps even the most important one. The Commission is currently carrying out a study on how to integrate REACH requirements into customs' processes. The study, which is currently in its final stage, - focusses on bringing concrete improvements within the existing legal and operational framework and will present a number of recommendations. Issues under consideration range from increasing the knowledge of relevant stakeholders regarding REACH requirements and addressing the information needs of importers about the goods concerned, to including specific data elements on customs declaration, to enhancing customs risk assessment and more. Existing IT-systems, such as the integrated Tariff of the European Union[2] and the EU Single Window Environment for Customs[3], might also represent important tools. Ultimately, this may lead to consider changes to the REACH legislation and of the Union Customs Code (UCC) in order to step up the enforcement of REACH at the EU borders.

Recent years have seen a massive increase of online sales of goods including products containing chemical substances. Controlling and ensuring compliance with EU chemicals legislation of such online purchases, in particular through online platforms established in third countries, has become increasingly challenging. The growing import of products, including consumers' direct purchases, requires additional enforcement efforts with new tools. In this regard, the Chemicals Strategy already points out to online sales and imported articles as elements to be addressed. The e-commerce Directive, the Digital Services Act and the digital products passport planned under the revision of the Ecodesign Directive will be instrumental to address those concerns. However, EU legislation alone will not be sufficient to tackle the challenges, further efforts of online platforms, businesses and enforcement authorities will be also needed.

Up to 28% of imports have been found non-compliant and therefore a successful collaboration with the EU's external partners is key. The Commission will identify the most appropriate fora at international level (e.g. OECD) or bilateral meetings (e.g. regular discussions under Free Trade

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[2] TARIC, https://ec.europa.eu/taxation_customs/business/calculation-customs-duties/customs-tariff/eu-customs-tariff-taric_en

[3] https://ec.europa.eu/taxation_customs/eu-single-window-environment-customs_en

Agreements) to discuss with third-countries how they can best contribute to ensure compliance of products entering the EU market.

#	Main actions	Timeline
1	Integration of REACH requirements into customs processes – study	Study delivered and REACH revision
2	Revision of the Union Customs Code and Strategic overhaul of border enforcement of non-fiscal, including chemicals, legislation	Medium term
3	Explore the use of Digital Product Passport	Medium term
4	Engage with third countries to ensure compliance of products entering the EU	Medium term

b) Reinforce the support to Member States and strengthen the role of the ECHA Forum

The control and enforcement activities are not equally effective in all Member States. The availability of resources, structure of the enforcement administrations and enforcement policies affect the effectiveness of national control systems. Moreover, the resources of enforcement authorities seem to be limited and therefore need to be allocated to such areas where they can be most effective. Within the framework of the REACH revision, the Commission is considering to establish a European Audit Capacity in order to verify and strengthen the effectiveness of the Member States control systems.

The new market surveillance Regulation[4] will be instrumental in considerably increasing effective enforcement, as it provides additional tools to reinforce the market surveillance of relevant product legislation, including chemicals legislation. Some of its instruments (e.g. activities under the product compliance network (EUPCN)[5], Implementing Acts) can be used as they already provide tools to enhance enforcement, at the borders or in the internal market.

Although the European Chemicals Agency's Forum[6] for exchange of information on enforcement has proven effective in advancing towards the harmonisation of enforcement of five[7] chemical Regulations throughout Member States, e.g. through standards and common enforcement campaigns, there is much room for improvement. In the framework of the REACH revision, the Commission is exploring how to improve the existing provisions that task the Forum. Options include establishing minimum requirements for national controls and enforcement. Setting clearer requirements for stronger resourcing of enforcement can support the Member States in contributing more to the Forum and in exploring mechanisms for supporting enforcement activities (e.g. more testing, exchange of inspectors). In addition, the Forum is envisaging cooperation with other existing enforcement networks, which needs to be formalised. For example, significant benefits

Enforcement authorities are generally not involved in the development of legislation. However, in the case of restrictions, the Forum plays the role to give advice on the enforceability of proposed restrictions.

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[4] Regulation (EU) 2019/1020
[5] EU Product Compliance Network | Internal Market, Industry, Entrepreneurship and SMEs (europa.eu)
[6] *Forum* for Exchange of Information on Enforcement, a network of authorities responsible for the enforcement of the REACH, CLP, PIC, POPs and Biocidal Products regulations in the EU, Norway, Iceland and Liechtenstein.
[7] REACH, CLP, PIC, POP and Biocides

and synergies could be achieved by cooperating with the expert group on customs[8], the Senior Labour inspectors' Committee[9] and the Environmental Compliance and Governance Forum[10]. At the same time, the Commission is considering to expand the current exchange of inspectors programme set up for REACH and CLP[11] to promote training and harmonise enforcement in the Member States.

The activities of the European Anti-Fraud Office (OLAF) are currently limited to coordinating the relevant national authorities to prevent exports from or imports into the EU of illicit chemicals. In that respect, OLAF can rely on a wide network of partners in the EU and beyond and use its analytical capacities. However, OLAF disposes of a broader range of investigative tools that include forensic capacities, ability to conduct investigative missions or to carry out on the spot checks. This tool box could be used to complement the Member States' actions, to tackle more effectively the traffic of illicit chemicals from third countries and also to fight complex intra-EU cross border fraud cases, in close cooperation with the relevant national authorities. To this end, a legal base for this new responsibility of OLAF may be created within the enforcement chapter of REACH, in the framework of the REACH revision. It would empower OLAF to undertake this new supportive role to the benefit of Member States' activity. Within the revision of the Environmental Crime Directive, the Commission is also exploring the option of adding a new criminal offence for certain serious breaches of chemicals legislation. This could help bring closer harmonisation of the sanction system of Member States as well as more effective prosecution procedures, avoid unequal penalties for the same behaviours, increase the probability for perpetrators of being caught and fight legal dumping[12], eventually reducing illicit trade of chemicals into the EU and within the EU.

#	Main actions	Timeline
1	Establish a European Auditing Capacity	REACH revision, 2022
2	Strengthening the Forum and its cooperation with other enforcement networks (PARCS, SLIC and ECG Forum)	Ongoing
3	Extend the mandate of OLAF to tackle the circulation of illicit chemical products in the EU	REACH revision, 2022
4	Introduce a criminal offence for breaches of chemicals legislation	Revision of the Environmental Crime Directive, 2021-2022

c) Prioritise areas for enforcement

Resources of Member States for enforcement are also tight and therefore activities need to be prioritised. The experience from the last decade on the enforcement of REACH and CLP can be used

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[8] PARCS is the expert group on the protection of health, cultural heritage, the environment and nature https://ec.europa.eu/taxation_customs/business/customs-controls/safety-health-environment-customs-controls/cooperation-between-member-states_en
[9] The Senior Labour Inspectors' Committee (SLIC) promotes effective enforcement of EU occupational safety and health legislation at the national level
https://ec.europa.eu/social/main.jsp?catId=148&intPageId=685&langId=en
[10] The Environmental Compliance and Governance Forum (ECG Forum) brings together Member States' representatives and representatives of top practitioners' bodies, such as IMPEL (Inspectors), EnviCrimeNet (Police), ENPE (Prosecutors), and EUFJE (Judges), in order to work more closely together on compliance assurance and wider environmental governance issues.
[11] n.b. non-chemical inspectors supporting REACH and CLP enforcement can also benefit of the programme
[12] E.g. more incompliant imports entering the EU via Member States with less stringent enforcement

to identify the most relevant cases, for example a list of products and areas having the highest risk of non-compliance. The Commission, with the support of the ECHA Forum and other Administrative Cooperation Groups[13], is identifying such products and areas. Such information will be vital to decide where and how to act. In this regard, the Chemicals Strategy already identifies some areas, in particular classification, labelling and restrictions of chemicals (e.g. cheap jewellery has high risk to contain heavy metals above restricted limits, online sales of chemicals, flow of information in the supply on hazardous substances and their safe use) In addition, the Commission wants to continue supporting the Member States to prioritise integrated enforcement through multi-legislation checks,[14] and the market surveillance networks can play an important role.

With regard to the compliance of information requirements, ECHA and the Commission have developed in 2019 a joint action plan to address the lack of compliance in registration dossiers and encourage industry to improve their safety data on chemicals.[15] As part of the commitments in the Chemicals Strategy, tThe Commission is currently exploring various options in the framework of the REACH revision to ensure that the registration dossiers[16] of the substances registered under REACH are in compliance and that sufficient information for identifying their hazard properties and potential risks is timely available. These include the possibility to revoke registration numbers for non-compliant registrations and to allow authorities to commission tests to obtain additional hazard information.

#	Main actions	Timeline
1	Identification of areas of concern of non-compliance and addressing them through implementation of legislation (e.g. REACH, market surveillance, customs …)	Medium term
2	Develop integrated approaches with other sectors to increase controls	Medium term
3	Revocation of registration numbers	REACH revision

d) Strengthen the use of IT enforcement platforms and other digital tools

IT tools are also fundamental for enforcement. They can play an important role to improve the quality of data as well as to interconnect the different systems used by authorities[17]. The Commission and the Member States are equipped with IT tools that support and enhance enforcement activities. Often, these platforms are limited to some enforcement authorities (e.g., customs authorities, chemical inspectors, market surveillance inspectors). The Chemicals Strategy calls for a harmonised EU-wide response and coordinated exchange of information on enforcement of chemical legislation, as well as for exploring the use of digital tools (e.g. artificial intelligence) to support market surveillance and customs authorities.

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[13] Administrative Cooperation Groups (AdCos) https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en
[14] i.e. products are controlled for chemical compliance at the same time that checks are carried out for other non-chemical requirements (e.g. product safety).
[15] All news - ECHA (europa.eu)
[16] Industry has spent around4.8 billion EUR to comply with REACH registration requirements
[17] See also the examples provided in sections 2a and 2b (e.g. Digital Product Passport, Single Window).

The Commission is currently assessing the possibility to enlarge the capacity of the IT tools used for the enforcement of chemicals legislation (e.g., the ICSMS[18] developed under the market surveillance Regulation). Moreover, it is exploring the possibility to connect the different IT tools (e.g. by giving targeted access to customs authorities to the REACH IT tools) and to take advantage of the Single Window project[19]. In this context, and in line with the Commission proposalon the Digital Services Act, the role of online intermediaries (e.g., e-commerce platforms, search engines, domain name ecosystem[20], etc.) is also explored.

#	Main actions	Timeline
1	Integration/connections between current IT tools used for enforcement	Medium term

e) Allow civil society and businesses to contribute to enforcement

Actions to empower consumers and consumer organisations will also be key, as consumers can be important partners in ensuring compliance with legislation, and consumer behaviour can also be a powerful driver to the industrial transition to safer and more sustainable chemicals.

The implementation of consumer protection rules[21] is a key mechanism in this sense. However, information on the chemical content of products is also key to allow consumers to make informed choices. In the context of the revision of the Ecodesign Directive,[22] the Commission is currently working on a digital product passport, which will ensure availability of information on the chemical content of products, in addition to other safety and sustainability information. All information should be electronically accessible to consumers already at the point of sale.

In addition, civil society organisations and businesses have and develop information for their associates on how to comply with chemicals legislation[23]. The ECHA Forum is sometimes informed of these activities, but a more proactive way to provide the information to enforcement authorities would be beneficial. Active initiatives by stakeholders aiming to identify breaches in the law are very important to achieve the goal of full compliance.

#	Main actions	Timeline
1	Mobilise civil society and businesses	Medium term

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[18] Information and Communication System on Market Surveillance, https://ec.europa.eu/growth/single-market/goods/building-blocks/icsms_en

[19] https://ec.europa.eu/taxation_customs/eu-single-window-environment-customs_en

[20] Provides a high level view of the relationship between different parties within the Domain Name Industry (registry service providers, registry operators, registrars, resellers etc.), and how the Industry relates to the ICT Sector (ISPs etc.) and groups involved in internet coordination.

[21] e.g. as Directive COM(2020) 1828 of 25 November 2020 on representative actions for the protection of the collective interests of consumers

[22] https://ec.europa.eu/growth/industry/sustainability/product-policy-and-ecodesign_en

[23] Some examples are REACH for textiles, SDS for ACEA associates, etc …

3. Issues for discussion

In the previous section, five clusters of actions have been identified:

2.a)   Being more effective at the borders and on e-commerce

2.b)   Reinforce the support to Member States and strengthen the role of the ECHA Forum

2.c)   Prioritise areas for enforcement

2.d)   Strengthen the use of IT enforcement platforms and other digital tools

2.e)   Allow civil society and businesses to contribute to enforcement

- Are there further actions or tools to enhance enforcement (both at the national, EU and global level) that are not addressed in the Chemicals Strategy or in this document?

- Having in mind the limited resources available, what are the top three issues (activities included in the clusters) we should address as a priority to have a more effective and efficient enforcement of chemical legislation?

- How can we use digital tools to further support the supervision and monitoring of compliance of chemicals legislation? How can digital instruments enhance the better exchange of data among authorities?

- Non-compliance in imports from non-EU countries and online sales remain a matter of concern, what additional actions may be possible?

- What complementary role can consumers, civil society, and business have to enhance enforcement?

- Do we need to take enforceability better into account when developing new legislation and measures?

Annex. List of some enforcement facts gathered in the last 10 years

Issue	Data	Comments
Number of national enforcement authorities (NEAs) enforcing REACH/CLP in each Member States	1 – 5	It is common that every NEA is responsible for a different area of REACH and/or CLP (e.g. restrictions, registration, safety data sheets). In some cases, NEAs can also be located and act at regional or local level.
Number of controls per year carried out by MSs	REACH: 67 343 CLP: 72 586	Average for period 2007-2019 for REACH Average for period 2009-2019 for CLP
Range of annual level of compliance reported by MS	REACH: 76 - 88 % CLP: 73 - 97 %	2007-2019 for REACH 2008-2019 for CLP
Range of annual level of compliance for REACH and CLP duties of imports reported by MS	72 – 94 %	2008 -2019
Range of annual level of REACH and CLP compliance experienced by ECHA	58 – 79 %	2008 – 2019 This level of compliance takes into account specific dossier compliance issues (e.g. intermediates, substance identification, SME status,) but also evaluation decisions followed up by NEA
Range of the ratio between the penalties and the compliance cost	44 – 57 %	2008 - 2019 Values calculated only with data for registration and authorisation
Chemical inspectors trained per year	2897	Average number of inspectors trained on REACH and/or CLP in the period from 2008-2019
Percentage of Safety Gate (former RAPEX) notifications related to REACH and CLP	5 – 20 %	Range for the period 2008 - 2019
Number of complaints received annually by the Commission related to enforcement matters	Average: 1.6 Range: 0 - 6	Period 2008 - 2019
Average number of EU enforcement projects organised by the Forum per year	Average: 1.8	Period 2008 - 2019
Average number of Member States participating in EU Forum projects	REF: 24.2 Pilot projects: 13.6	Period 2008 – 2019 REF projects are major EU enforcement projects organised by the Forum. Pilot projects are smaller projects organised by the Forum as well. One REF project is organised per year but pilot projects are less frequent.

References:
- Enforcement indicators report (2018) https://op.europa.eu/en/publication-detail/-/publication/199c348e-00e9-11ec-8f47-01aa75ed71a1/language-en
- Enforcement indicators report (2021) https://op.europa.eu/en/publication-detail/-/publication/e5c3e461-0f85-11ec-9151-01aa75ed71a1/language-en/format-PDF/source-230270611
- Member States reports: Chemicals - Environment - European Commission (europa.eu)
- ECHA Forum: https://echa.europa.eu/about-us/who-we-are/enforcement-forum