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Ecosystems I: Chemicals, Food, Retail
F1. REACH

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B2. Safe and Sustainable Chemicals

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Concerns: **Update on CLP revision - procedure**

Agenda Point: **3 CLP**

Action Requested: **For information**

REVISION OF THE REGULATION ON CLASSIFICATION AND LABELLING OF CHEMICALS (CLP) – PROCEDURE

Introduction

One of the actions listed under the **Chemicals Strategy for Sustainability** under the European Green Deal is the targeted revision of the Regulation on classification, labelling, and packaging of substances and mixtures (CLP)[1]. The Commission has had a critical look at that Regulation to assess where improvements are needed, based on an Impact Assessment and taking into account comments and suggestions from experts and stakeholders.

The revision is expected to cover a number of issues as e.g. introducing new hazard classes (e.g. for endocrine disruptors) but also addressing practical issues with labelling or notification of information to poison centres (the latter: to ensure they have all necessary information to provide emergency health response), procedural issues (e.g. giving the mandate to the Commission to initiate procedures for harmonised classification and labelling to complement the Member States' and industry's right of initiative). The planned revisions aim at **improving certain aspects of CLP, allowing even better fulfilment of its main objectives, i.e. to ensure a high level of protection of human health and the environment and a well-functioning internal market.**

Legal framework

The CLP is a Regulation of the European Parliament and the Council, adopted in co-decision in 2008. Hence, amendments to that Regulation should in principle be adopted via the ordinary legislative procedure. However, **as it is often the case with legislation of a technical nature, the co-legislators have empowered the Commission to amend certain parts of that Regulation**. Hence, according to Article 53(1) of CLP, the Commission can amend the annexes and some articles via delegated act instead of ordinary legislative procedure to adapt that Regulation to technical and scientific progress. Such adaptation to technical and scientific progress allows keeping up with the rapid evolution of scientific knowledge and the decisions taken reflect the conclusions of scientific experts. In practice, such adaptation occurs on a regular basis via Commission Delegated Regulations amending the annexes to CLP, under the scrutiny of the Council and the European Parliament.

The Commission is planning to adopt the upcoming revision of CLP under the ordinary legislative procedure, except for those amendments to its Annexes which aim at adding the new hazard classes in CLP.

a) The legislative proposal

As in general the CLP Regulation functions well, the amendments to be included in the legislative proposal do not aim to introduce major changes, but they constitute a targeted revision with a view to clarify, strengthen or complement some provisions – taking into

[1] Regulation EU No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p. 1.

account the experience from authorities and stakeholders in applying and complying with the Regulation and the major findings of the Fitness Check on chemicals (except REACH) which evaluated the CLP Regulation.

By way of example, amendments via ordinary legislative procedure could concern Article 36 (to prioritise e.g. harmonised classification and labelling of substances which are endocrine disruptors), Article 37 (to extend the right of initiative to initiate the harmonised classification and labelling procedure, currently limited to Member States and industry, to the Commission). Articles 40 and 42 (to allow companies to have better access to information and ease their duty to 'self-classify' their substance), Article 48 (to ensure a level-playing field of on-line sales of EU and third country chemicals). They could also introduce a framework for digital labelling.

b) The delegated act

The Commission plans to adopt certain amendments within the scope of its empowerment in the framework of the CLP revision via Delegated act. The amendments envisaged to be adopted via delegated act pertain mainly to Annex I. That Annex sets out the criteria and methodologies to classify and label substances and mixtures that are hazardous for human health (e.g. carcinogens) or the environment (e.g. aquatic toxic) or which present physical hazards (e.g. explosives).

These amendments aim at introducing new hazard classes and criteria to assess some additional hazards to human health and the environment displayed by chemical substances and mixtures. They are of a purely scientific nature. The amendments concern the following hazard classes: (a) for human health: endocrine disruptors, (b) for the environment: endocrine disruptors (ED), persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB), persistent, mobile, and toxic (PMT) and very persistent and very mobile (vPvM).

For the amendments aiming at including the new hazard classes and criteria, as e.g. endocrine disruptors, in CLP, the question was raised whether the Commission is empowered to adopt such amendments under the current provisions of CLP. A detailed legal analysis is included in Annex. In essence, in the Commission's opinion, the empowerment clearly covers all non-essential amendments to the Annexes, as there is no limitation in the legal provision. The main criterion to judge whether the adoption via delegated act is justified, is therefore whether the amendment pertains to an 'essential element' of the legislation or not. An element is considered non-essential when its amendment does not involve a political choice. As the draft amendments to include new hazard classes and criteria are the result of a scientific assessment not involving a political choice, they should be considered as modifying 'non-essential' elements and hence can be adopted via delegated act[2]. To the contrary, the amendment of e.g. Article 36 of CLP defining the hazard classes for which harmonised classification and

[2] See Recital 77 of CLP which confirms that conclusion: '*In particular, the Commission should be empowered to adapt this Regulation to technical and scientific progress, including incorporating amendments made at UN level to the GHS, in particular any such UN amendments relating to the use of information on similar mixtures. In carrying out such adaptations to technical and scientific progress the biannual working rhythm at UN level should be taken into account. Furthermore, the Commission should be empowered to decide on the harmonised classification and labelling of specific substances. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC*.'

labelling should be prioritised, involves a political choice and will be adopted via the ordinary legislative procedure.

To be noted that the European Parliament was adamant on having the hazard class and criteria for endocrine disruptors in place swiftly and has called the Commission for action, e.g. in its Resolution of 18 of April 2019[3] on endocrine-disrupting chemicals, to '*swiftly take all necessary action to ensure a high level of protection of human health and the environment against EDs*'. The Resolution also '*Calls on the Commission to ensure that data requirements are continuously updated in all the relevant legislation in order to take account of the latest technical and scientific progress, so that EDCs can be properly identified*.' It further '*Considers that EDCs are a class of chemicals that is of equivalent concern to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR substances), and should therefore be treated identically in Union legislation'*. In its Conclusions of June 2019[4], the Council stated amongst others that it '*URGES the Commission to develop a horizontal approach for the hazard-based identification and risk management of endocrine disruptors taking into account the uncertainties as regards identifying hazards and assessment of risks for chemicals with endocrine disrupting properties…*'. Also the Council Conclusions of 15 March 2021[5], which expressed explicit support to introduce the new hazard criteria, called for full implementation of the CSS 'without undue delay'.

Having those hazard classes and criteria set in a swift way will not only increase protection of human health and the environment in Europe sooner, but it will also allow to avoid market fragmentation given the concrete risk that certain Member States would regulate alone on the issue. Also, in order to steer discussions at UN GHS level and keep the overall objective in mind, it would be very convenient to have a finalised and adopted version ready before starting the negotiations and technical work at UN GHS level as of January 2023[6].

[3] European Parliament resolution of 18 April 2019 on a comprehensive European Union framework on endocrine disruptors (2019/2683(RSP), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52019IP0441

[4] "Towards a Sustainable Chemicals Policy Strategy of the Union-Council conclusions", 26 June 2019, https://data.consilium.europa.eu/doc/document/ST-10713-2019-INIT/en/pdf

[5] "Sustainable Chemicals Strategy of the Union: Time to Deliver-Council conclusions", 15 March 2021, https://www.consilium.europa.eu/media/48827/st06941-en21.pdf

[6] Pending approval by the UN ECOSOC Sub-Committee on GHS

ANNEX: LEGAL ANALYSIS

Article 290 TFEU provides for the conditions for using the delegated acts procedure. According to Article 290(1) a delegated act is a non-legislative act 'of general application' and should 'supplement or amend certain non-essential elements of the legislative act'.

As flows from **recital 3 of CLP**, the objective of that Regulation to ensure a high level of human health and environmental protection should be ensured in the approximation of legislation on the criteria for classification and labelling of substances and mixtures. The enacting terms of the CLP (**Article 3, first paragraph**) refer in this respect to three general types of hazards: physical hazards, health hazards and environmental hazards laid down in Parts 2 to 5 of Annex I and a classification in relation to the respective hazard classes provided for in that Annex. The CLP Regulation's enacting terms do not go into the specific characteristics of the hazard classes, but leave this specification for Annex I to provide.

The scope of the Commission's empowerment in **Article 53 of CLP** is to amend some Articles and the Annexes in order to adapt them to technical and scientific progress. Article 53 refers to 'amending' these provisions of the CLP Regulation, which does not prevent the Commission from adding new criteria and new hazard classes into Annex I, as Article 53 does not limit or enumerate specific elements which can or cannot be amended.

The Court's definition of the delegation of a **power to 'amend**' a legislative act as set out in the judgment of case C-286/14[7] ('*...to modify or repeal non-essential elements laid down by the legislature in that act*') does not exclude the possibility for the co-legislators to empower the Commission to amend a legislative act by adding new non-essential elements to it. This is also reflected in the Non-Binding Criteria for the application of Articles 290 and 291 of the Treaty on the Functioning of the European Union[8]. The addition of new non-essential elements to the legislative act itself must be seen as a form of modification and this power is conferred by using the verb 'amend'. This applies regardless of whether the non-essential elements are added to articles or to annexes of the legislative acts.

The most important question is, in our view, whether adding new hazard classes (such as endocrine disruptors and Persistent Bioavailable and Toxic (PBTs)) can be considered a **non-essential element** of the CLP Regulation that could be amended by the Commission.

Recital (77) of CLP – on the Commission's empowerment – clearly stipulates that '*Since those measures are of general scope and designed to* ***amend non-essential elements*** *of this Regulation…*' [bold added].

Deciding whether a matter must be categorised as essential must be based on objective factors amenable to judicial review[9]. Account must be taken of the characteristics and particular features of the field concerned. An element is essential within the meaning of the second sentence of the second subparagraph of Article 290(1) TFEU in particular ***if, in order to be adopted, it requires political choices falling within the responsibilities of the EU legislature, in that it requires the conflicting interests at issue to be weighed up on the basis of a***

[7] Judgment of the Court of 17 March 2016 in case C-286/14, *Parliament v Council*, para 42.
[8] Section II, B 2 of the delineation criteria, OJ C 223, 3.7.2019, p. 1.
[9] Judgment of the Court of 5 September 2012 in case C-355/10, *Parliament v Council*, para 67.

number of assessments, or if it means that the fundamental rights of the persons concerned may be interfered with to such an extent that the involvement of the EU legislature is required[10]. An annex to a legislative act can contain an essential element[11].

The development of new hazard criteria and classes within the three types of hazards defined in the CLP Regulation (physical, human health and environmental) can be considered an **adaptation to scientific and technical progress**, based on scientific data and does not include any political choice. The scientific nature of the determination of the hazard criteria for substances and mixtures is a characteristic and a particular feature of the legislation in the chemicals field. Several technical discussions have taken place with experts from Member States to agree on the scientific criteria for classification in the new hazard classes, as defining such criteria requires a **significant level of scientific expertise**. There are no conflicting political interests at issue to be weighed up on the basis of a number of assessments for determining a hazard of a chemical (intrinsic property of a chemical). This seems to be confirmed by the similar approach adopted under the **Biocidal Products Regulation**[12] and **Plant Protection Products Regulation**[13] for specifying scientific criteria for the determination of endocrine-disrupting properties under those pieces of chemicals legislation.

The endocrine disruptor criteria in the Biocidal Products Regulation (2017) and those in the Plant Protection Products Regulation (2018) were respectively adopted via a delegated act and an implementing act (in accordance with a specific empowerment provided for in Article 5(3) of the Biocidal Products Regulation and the second paragraph of point 3.6.5. of Annex II to the Plant Protection Products Regulation). This specific empowerment shows that the legislator viewed such definitions of a hazard endpoint newly added by them as a non-essential element of the Biocidal Products Regulation and there would be a serious inconsistency if scientific criteria of the same nature were to be considered as essential elements under the CLP Regulation.

Adopting the criteria for endocrine disruptors and PBTs via delegated act would allow **keeping consistency,** both procedurally – as explained above – and in terms of content, with the existing criteria adopted in the framework of other EU legislation as e.g., the Biocidal Products Regulation and the Plant Protection Products Regulation. Indeed, **as the CLP applies to the products covered by both these Regulations,** it is important to align as far as possible the criteria used across sectorial legislation.

It may be argued that the legislator considered as essential elements of the CLP Regulation, inter alia, the provisions of Article 3 (with reference to the three general types of hazards to be communicated) and Article 9 on how actors in the supply chain shall evaluate hazard information for substances and mixtures by applying the criteria for classification for each hazard class or differentiation in Parts 2 to 5 of Annex I. **The actual determination of the hazard classes and criteria for classification was considered as a scientific and technical element**, **subject to scientific and technical progress over time and considered**

[10] Judgment of the Court of 26 July 2017 in case C-696/15 P, *Czech Republic v Commission*, paras 77 and 78.
[11] Judgment of the General Court of 13 December 2018 in joined cases *Ville de Paris v Commission*, T-339/16; *Ville de Bruxelles v Commission*, T-352/16; *Ayuntamiento de Madrid v Commission*, T-391/16.
[12] Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1.
[13] Point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1.

appropriate to be set out in the Annex, in line with recital 32 of the CLP Regulation[14]. It was further considered appropriate to empower the Commission to amend that Annex to adapt it to technical and scientific progress. The definition of criteria for new hazard classes follows the best available scientific data and evidence without any political choice being involved. Indeed, such scientific criteria could clearly be considered '*technical and detailed elements which develop a legislative act or subsequently amend certain aspects of the legislative act itself*'[15].

It could be argued that if the legislator had considered adding new hazard classes and criteria as an essential element of the CLP Regulation, it would have explicitly limited the empowerment in Article 53 of the CLP Regulation for the Commission, as it had done in some other pieces of Union legislation in terms of limiting the Commission's empowerment to amend certain annexes. However, **the legislator has not limited the empowerment in this particular way**. Point V.5 of the Annex to the Omnibus Regulation[16] does not suggest any such limitation of the Commission empowerment when the CLP Regulation was recently 'Lisbonised'.

Article 53 of CLP does not expressly limit or enumerate which elements may be amended in Annex I by the Commission. It also does not limit the empowerment to adapt the Annexes to technical and scientific progress to the developments specifically listed, i.e., developments at UNGHS (which should be '*duly taken into account*') or developments in internationally recognised chemical programmes[17] and the data from accident databases (which should be '*considered*'). Hence, **amendments may result from a broad spectrum of technical and scientific progress**. Peer reviewed results of a number of convincing and widely circulated scientific analyses may, for example, be a sufficient basis to update one of the Annexes to the CLP. In the case at hand, the key characteristics of endocrine-disrupting chemicals and some other hazard classes, as a basis for hazard identification, have gone through **several years of detailed examination and acceptance by the relevant experts.** As a result, these criteria are nowadays considered to constitute a hazard similar to those typically addressed by CLP. It is hence logical that this reason for amending the Annexes to CLP must be considered as 'scientific and technical progress'.

It has been argued that introducing the new hazard classes and criteria via delegated act entails a political choice in so far as the EU would regulate hazard classes that are not yet included at the level of UN GHS. However, it is to be noted that the decision whether to act at one level or the other first is not the same as the decision at EU level to adopt amendments via one or the other procedure.

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[14] Recital (32): '*The criteria for classification in different hazard classes and differentiations should be set out in an annex, which should also contain additional provisions as to how the criteria may be met*.'

[15] See Opinion of Advocate General Jääskinen in Case C-286/14, *Parliament v. Commission*, para 38 and the references cited therein.

[16] Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union, OJ L 198, 25.7.2019.

[17] Regarding the specific case of endocrine disruptor criteria for human health, it must be underlined that the draft EU criteria are in line with the WHO definition, hereby fulfilling in our view, the condition in Article 53(1) of 'considering the developments in internationally recognised chemical programmes': '*An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations. A potential endocrine disruptor is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations*.'

Moreover, it should be noted that the Commission has already introduced a new hazard class 'Hazardous to the ozone layer' under Part 5 in Annex I before its adoption at UN GHS. Even if ozone depletion substances had been covered in the Dangerous Substances Directive[18] and had not been taken over into the basic act of CLP, they are still a new hazard class which was introduced via comitology (regulatory procedure with scrutiny) without an explicit reference to that hazard class in the enacting terms.

As mentioned above, **modifying Annex I to adapt the CLP Regulation to scientific and technical progress can go beyond the developments at UN GHS**, while it needs to be recognised that it was the primary, though not exclusive, intention of the legislator that the CLP Regulation reflects the GHS. On the other hand, Article 53(2) of the CLP Regulation provides that the Commission and Member States shall promote the harmonisation of the criteria for classification and labelling of PBT and vPvB substances at the level of the UN. It should be noted that the implementation of amendments to CLP which result from amendments to UN GHS are also performed via Delegated Act, as this is clearly in the scope of the Commission's empowerment, in accordance with Article 53 of CLP.

Discussions on new hazard classes and their criteria at UN GHS are planned to take place starting the next biennium (2023-2024). Ideally, the new hazard classes and criteria at EU level should already be defined as much as possible by then, so that discussions in the international fora can be steered and aligned to the EU ones. A preliminary discussion should take place at the UN GHS Sub-Committee session in July 2022. The formal proposal to include the classes as a work item in the programme of the next biennium 2023-2024 is planned for the UN GHS Sub-Committee session in December 2022.

[18] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 196, 16.8.1967.