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General Secretariat

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus VI (Chemicals) - Presentation from the Commission (24 July)

Delegations will find attached a presentation from the Commission on Omnibus VI (Chemicals) presented at the meeting of the Antici Group (Simplification) on 24 July 2025.



Proposal for an Omnibus on simplification for certain chemicals – Q&A session

DG GROW – F.2. Bioeconomy, chemicals and cosmetics

European Commission

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Disclaimer: *This document aims to support the technical discussion in the ongoing negotiations of COM(2025)531 final – Proposal for a regulation as regards simplification of certain requirements and procedures for chemical products. It is not necessarily the official position of the European Commission.*

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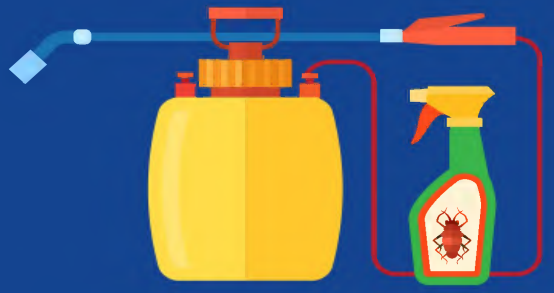
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CLP Regulation

Proposed amendments to Regulation (EC) No 1272/2008













Overview of comments/questions

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- Stop the clock
- Digital contact
- Digital labelling
- Labelling formatting rules (font size and similar provisions)
- Labelling for small packaging (< 10mL)
- Label updates
- Advertisements for consumer chemicals
- Distant-sale offers
- Other topics

Stop-the-clock: flexibility

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- **Postponed application** of some provisions from Reg. (EU) 2024/2865.
- Such provisions are proposed for **modification** in **COM(2025)531**
  - Font size and formatting requirements
  - Advertisements
  - Distance sales offers
  - Labelling of fuels at fuelling stations

What is considered digital contact? Is it enough to contact a supplier?

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- Alignment throughout legislation (Omnibus IV - COM(2025) 504 final).
- A **digital contact** should allow **a user to reach out and engage with a supplier**.
- Contact, even outside working hours, taking advantage of **diversity of digital technologies** (chats, chatbots, IA, simple emails).
- **Target is the consumer**. **Other tools** than labels for **professionals**, **industrial users**, **enforcement authorities**.
- **Flexibility** with limitations to ensure efficiency (no ‘registration or account’ for the purpose of contacting the supplier).
- Development of **more granular guidance**, in consultation with the **Forum** (enforcement).

How to foster digitalisation of CLP labels?

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- Omnibus IV and objective of ‘digital by default’.
- However, limited room for digitalisation of label elements: GHS & user/consumer behaviour.
- Requirements from various legislation for the same labelling space.
- Changes to Annex I, section 1.6: providing **information about the EU supplier once on the physical label** is enough.

How to ensure easy-to-read (CLP) labels?

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- IA 2022: **font size requirements** can be **off-set** by **increased flexibility in labelling**.
- **Reality check** & input 2024-2025: **loss of flexibility** to a very large extent.
- **Generic obligation**: labels clearly marked, clearly standing out from the background, their size and space allowing easy reading.
- **Flexibility** within CLP and other sections of labels but **parameters to consider and enforced** are listed.
- Development of **more granular guidance**, in consultation with the **Forum** (enforcement).
- The problem identified in the Fitness Check stems mainly from the **amount and complexity of information** required by different EU legal acts, including **CLP** and not only directly from the font sizes.
- Increase of the font sizes for CLP information could lead to reduction of space on the label for other (non-CLP) information, such as **use instructions**, which are read by users when they identify a pictogram (Eurobarometer 2017, p.5).

When can some or all label elements can be omitted?

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- Article 29(2) simplified (if packaging is small enough (<250mL, e.g.), derogations are possible).
- Section 1.5.2.4.1 (packaging of less than 10 mL) further clarified and simplified.
- It was modified by Reg. (EU) 2024/2865: **no additional change to the list of eligible hazard classes**.
- One **inconsistency** solved regarding **EUH208**.

How to ensure swift label updates?

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- **6-month deadline not practical** for many relabelling situations from **self-classification**.
- Reversal to '**without undue delay**' offers **flexibility**, for **shorter** deadlines where possible and **longer** ones where needed.
- **Enforcement is possible**: assessment of the situation by inspectors (similarity with Safety Data Sheet under Art. 31 of REACH).
- Development of **more granular guidance**, in consultation with the **Forum** (enforcement).

Advertisement and hazard communication

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- Advertisement is very broadly referred to as **any communication or representation to promote goods and services, without specifying its form**.
- Advertising for a hazardous chemical is **neither selling nor using this chemical**.
- **Improving consumer behaviour** toward better chemicals is possible.
- **Detailed and comprehensive information** available at the **point of sale**.
- Balance between **comprehensiveness** of information and **level of details** to ensure **fair competition**, with **REACH safety net** (only safe products on the market)
- Situation for **consumers** differ from **professional** and **industrial** ones.

Information available for distance sale offers of hazardous chemicals

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- Regulation (EU) 2024/2865 clarified what information is need for **distance sales**: **all CLP-label elements s**hould be clearly and visibly present.
- Only change is **the scope**: only for distance sales to **consumers**.
- **Simplification for B2B** as other tools are available for professionals and industrial users.
- Development of **more granular guidance**, in consultation with the **Forum** (enforcement).
- If a website offers to **both consumers and professional/industrial users**, information should be present.

Other suggestions

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- **Bridging principles**.
- **Labelling** and **notifications to poison centres** of **fragrance bespoke mixtures**.
- Similar suggestions also received during the **reality check**.

European Commission

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Cosmetics Regulation

Proposed amendments to Regulation (EC) No 1223/2009



General comments

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Why proposing the Omnibus initiative now when there is an ongoing evaluation of the CPR and an update of the CMR Guidelines?

- **Timing/urgency**: Omnibus proposes targeted changes where urgent action is needed. The revision of the CPR will end mid-2026, then an impact assessment (end 2027) followed by COM proposal (2028), negotiations and adoption (2029/2030), entry into application in 2032.
- **Legal certainty**: the CPR allows for different interpretation, the business operators need stability and legal certainty in how the law is applied.
- Experience shows that current system is detrimental for businesses that do not have time to adapt.
- **Very limited scope of changes**: the evaluation covers the whole CPR; the revision could be (potentially) comprehensive.
- **Revision of the CMR Guidelines**: will continue considering the application date of the Simplification Omnibus. This work will complement the new rules (e.g. the general conditions for suitable alternatives).

Overview of specific comments/questions

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- **General support** for suggested changes (with some clarifications/improvements):
  - ✓ Clear procedure for adding colorants, preservatives and UV filters to Annexes IV, V and VI to the CPR (new Article 14a)
  - ✓ Deletion of reporting obligations (changes in Art. 22)
  - ✓ Deletion of an obligation to adopt the glossary of common ingredient names (Art. 33 + corresponding changes in Art. 19(6) and in the headings of Annexes II to VI to CPR)
- **Some support** for deletion of prenotification of cosmetics containing nanomaterial, but some concerns were expressed.
- **Several human health/consumer safety concerns** were raised relevant to the proposed change of Art. 15 CPR that the changes will lower the current level of protection ensured by the CPR:
  - *transitional periods will allow cosmetics with CMR substances to be available to consumers much longer that it is currently the case.*
  - *changes will expand the exemption criteria.*

Comments/questions on Art. 14a

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- What happens if the SCCS does not deliver its opinion within 12 months?
  - ✓ *This process clarifies the authorisation process for colorants, preservatives and UV-filters that are **not** yet available on the market.*
  - ✓ *Industry should provide a comprehensive dossier with supporting evidence, allowing the SCCS to deliberate within 12 months.*
  - ✓ *COM may extend the deadline if additional evidence is needed (upon request from the SCCS).*
  - ✓ *The provision does not foresee a tacit approval of the use of such substances in cosmetic products, when the SCCS fails to adopt its opinion within the deadline (i.e., no conclusion = no authorisation)*
- What happens if the SCCS opinion is not conclusive?
  - *As it is a practice today, the COM will only proceed with the amendments to Annexes IV – VI of the CPR, if the SCCS concludes that the use of a substance as a colorant, preservative of UV filter is safe for human health (i.e., no conclusion = no authorisation).*
- How will the participation of the Member States be ensured?
  - ✓ *Annexes IV – VI will be changed according to Art. 31(2) CPR procedure – Member States will exercise their scrutiny over the COM via their vote in the comitology committee on the draft Commission Regulation amending the respective Annex to the CPR.*

Art. 15 – submission of derogation request

- General support to introduce a deadline for the industry to submit a derogation request: **3 months** after the **entry into force** of the harmonised classification under the CLP.
- Comments/questions:
  - The industry must begin gathering data once the RAC opinion is published.
    - ✓ *this assumption is correct; revised CMR Guidelines could encourage industry to do so.*
  - This additional time delays and shortens the time for the SCCS safety assessment.
    - ✓ *the transitional period is designed to allow time for industry to generate, gather and submit data in a comprehensive and robust scientific dossier;*
    - ✓ *The SCCS evaluation can begin as soon as a dossier is submitted – the deadline is a maximum deadline; industry can submit the dossier earlier;*
    - ✓ *The SCCS will have the same amount of time as today to review the dossier (i.e., 12 months);*
    - ✓ *It is not possible to establish an earlier legal deadline as economic operators cannot be legally required to act on the basis of an event which has no legal value (RAC opinion).*

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Art. 15 – exemption criteria

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- Compliance with food safety requirements considered as important as certain cosmetics may be ingested.

  - ✓ *Food safety criteria apply to oral ingestion under strict dietary exposure assumptions, which are not directly relevant to dermal or topical exposure routes predominant in cosmetics.*
  - ✓ *The SCCS already assesses exposure via all relevant routes, including incidental oral exposure (e.g., lipsticks or toothpaste), where relevant, route-specific exposure can and will be considered.*
  - ✓ *Retaining condition (a) across the board would be disproportionate and could prevent safe substances from being used in non-ingested cosmetic products based on irrelevant ingestion-based classifications.*

- General support to merge points (c) and (d)

Art. 15 – conditions facilitating the decision on suitable alternative

- Conditions for suitable alternative are not adequate (economic viability), can be difficult or impossible to fulfil (equivalent function to the classified substance, in a finished cosmetic product with a similar effect and the same level of efficacy) or can be considered as exhaustive or lead to unexpected consequences in the future
  - *criteria are framed **broadly**, not exhaustively, and are designed to capture the multidimensional aspects of substitution (technical, economic, availability, and sustainability)*
  - *including these criteria in the Regulation does not preclude future flexibility and can be supplemented by interpretative guidance where appropriate.*
- Conditions should be specified in the Guidelines and not in the CPR
  - *Guidance can support implementation where needed, but inclusion in the Regulation is necessary to ensure legal clarity and consistency and provide transparent and enforceable standards for decision-making.*

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Art. 15 – conditions for suitable alternative (a) and (b)

(a) Its use in cosmetic products results in reduced overall risk to human health and the environment;

Why was the environmental aspect included in condition (a)?

- *This aligns with broader EU policy goals (Green Deal, Chemical Strategy for Sustainability), which promote responsible innovation and circularity. The sustainability requirement prevents shifting from CMRs to non-viable or unsustainable substitutes,*
- *It is not an environmental hazard criterion, or a safety criterion but a supply and innovation-enabling condition*

(b) It provides an equivalent function to the classified substance, in a finished cosmetic product with a similar effect and the same level of efficacy;

The 'equivalent function' condition may be impossible to fulfil; why the reference is made to 'efficacy' which is not covered by the CPR?

- *An alternative may not act through the exact same mechanism of action - the condition refers to the functional outcome in the final product (e.g. preservation, fragrance, colour),*
- *The focus is on practical efficacy and consumer safety, not identical chemistry,*
- *This requirement is flexible in its implementation and does not hinder innovation*

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Art. 15 – conditions for suitable alternative (c) and (d)

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(c) Is technically feasible and economically viable

Economic viability is not adequate for an alternative

- *Economic viability is a well-established and legally recognised criterion under EU law, including REACH. Its inclusion in the assessment of suitable alternatives ensures a balanced, science-based and practicable approach that supports both consumer safety and the sustainable functioning of the cosmetics market.*

(d) It is not restricted, not protected by exclusive rights, and it is available on the market at scale, in quantities large enough to meet current and expected demand.

- *A suitable alternative should be accessible for the SMEs.*
- *The availability of sufficient quantities could ensure that there will be no raise of prices linked to the raised demand, and eventually a rise in prices of the relevant cosmetic products.*

Art. 15 – calculation of 15-month deadline for the COM to act

What is the justification for the long timeline for the COM to adopt an act banning/restricting CMR substances from their use in cosmetics? This timeline will delay the start of the SCCS assessment of CMR substances; the urgency procedure should be foreseen.

- *COM will have 18 months to ban/restrict a CMR substance from use in cosmetics (15 months after the **entry into application** of the ATP changes) in comparison to the current practice (15 months after the **entry into force** of the ATP changes).*
- *This additional period is necessary for those cases where a request for derogation is submitted at the latest 3 months after the entry into force of the ATP changes.*
- *In such a case, 15 months following the submission of the request will be devoted to the SCCS safety assessment and the assessment of suitable alternatives. The adoption procedure (preparation of the draft act, discussions with Member States, voting in the comitology committee, TBT notification) will require at least several months.*
- *This is a **maximum deadline for the COM** which remains free to adopt an act banning the CMR substances earlier.*
- *The current fifth subparagraph of Art. 15(2) is **not** changed – COM will still be able to use an urgency procedure on imperative grounds of urgency.*

Art. 15(5) – dermal exposure

This exception should not apply to cosmetics that may present a risk of inhalation or ingestion or oral products; how this exemption would not lower the level of protection as for most substances the CMR properties are identified via oral or inhalation exposure (the approach contradicts the precautionary principle)?

- *The provision improves proportionality without weakening safety; it aligns with risk-based regulation, avoids unnecessary bans, and allows for a more accurate safety assessment in line with actual exposure routes;*
- *The exemption will not be triggered by the way the CMR properties are identified but whether or not the route of exposure is indicated in table 3 of Annex VI of the CLP Regulation (see example of titanium dioxide on the next slide);*
- *The Member States take part in discussions on the harmonised classification and whether or not specific hazard statement should be included under the CLP Regulation;*
- *Currently very few substances bear a hazard statement e.g. H352 (suspected of causing cancer) (inhalation), and almost all are Carc. 2 (e.g. titanium dioxide); there are none with only the statement H352 (oral);*
- *According to the CLP Regulation, a route of exposure is stated (indicated) if it is conclusively proven that no other routes of exposure cause the hazard.*

Art. 15 – dermal exposure – table 3, Annex VI CLP Regulation

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Index No	Chemical Name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
'►C2 022-006-00-2 ◄	titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm]	236-675-5	13463-67-7	Carc. 2	H351 (inhalation)	GHS08 Wng	H351 (inhalation)			V, W, 10'

Art. 15(6) – approach to Natural Complex Substances

Commission should automatically send a request for the SCCS assessment when a constituent receives a harmonised classification as a CMR substance.

- *During the discussion in the Working Group on Cosmetic Products COM informed that the presence of the CMR constituent creates a concern for human health justifying the mandate to the SCCS. The use of the term 'if a potential risk to human health arises' is used in Art. 15(6) to create a link between this paragraph and Art. 31 CPR.*

How does this approach not pre-empt the outcome of the evaluation of Article 54a(1) of the CLP Regulation?

- *Art. 54a(1) requires the COM to present a scientific report which may be accompanied, if appropriate, by a legislative proposal. This legislative proposal, if presented, could propose amendments to the CPR.*

What scientific basis does the Commission have for proposing this exemption?

- *Recital 3 of the revised CLP Regulation 'Scientific data on certain substances containing more than one constituent extracted from plants have indicated that specific constituents considered in an isolated way can have hazard properties that may not be expressed in the substance as a whole (…)'.*

The SCCS should determine safe levels of classified ingredients in the final product on a case-by-case basis.

- *This aspect will be specified in the mandate to the SCCS.*

Art. 15(7) – transitional periods

General support for transitional periods but 12 and 24 months are too long as they increase consumer exposure to CMR substances, with the detriment to their health.

- The timeline balances regulatory coherence, legal clarity, and consumer safety, while enabling a smoother and fairer implementation for industry and authorities;
- The transitional periods facilitate timely and effective assessment, without compromising consumer safety or regulatory rigour;
- For the purpose of legal certainty and clarity, the transitional periods should be fixed, however, there is a flexibility to adopt the changes to the Annexes to the CPR (there is a maximum deadline for the COM);
- CMR substances are allowed in other consumer products (e.g. paints) below certain concentration specified in Part 3 of Annex VI to the CLP Regulation without any safety assessment.
- While caution around CMR exposure is warranted, it is not scientifically established that **temporary**, **low-level presence** of CMRs in cosmetics **during controlled transitional periods** poses a health risk—particularly in light of stricter cosmetic safety requirements compared to other consumer product sectors. The proposed transitional periods provide legal clarity and practical feasibility without undermining the EU's high level of protection for human health.

Art. 16 – deletion of prenotification of nanos and changes in Annex I of the CPR (Annex II to the Omnibus Act) *(part I)*

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The change would leave the safety assessment of nanomaterials to the responsible persons and competent authorities leading to potential increase of administrative burden on competent authorities.

- *The deletion of Article 16(3) does **not** remove oversight but reflects the reality that safety responsibility already lies with the responsible person under Article 4 and 10 CPR.*
- *It reduces administrative burden on CA by eliminating a process that generates early signals without legal follow-up requirements.*

Art. 16 – deletion of prenotification of nanos and changes in Annex I of the CPR (Annex II to the Omnibus Act) *(part II)*

PUBLIC

How will the data continue to be available in the future and provided for the risk assessment by the SCCS?

- *The full traceability of nanomaterials remains guaranteed via the Article 13 notification system and the CPSR as they provide comprehensive information to both the Commission and national authorities.*
- *No data will be lost, and the revision of Annex I enhances the documentation requirements for nanomaterials.*
- *Adaptions of CPNP for MSA and the SCCS access can be considered.*

The SCCS must continue assessing the safety of colorants, preservatives and UV filters in nanoforms before they can be used in cosmetics.

- *We agree – preamble to Annexes II to IV states that 'substances listed in Annexes III to VI do not cover nanomaterials, except where specifically mentioned'.*

Deletion of reporting obligation (Art. 22)

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How to organize Member States' reporting on monitoring measures?

- *The proposal to delete the reporting obligation only applies to this particular obligation laid down in the Cosmetics Regulation.*
- *The reporting of market surveillance activities should remain part of the market surveillance regulation which regulates the use of ICSMS.*
- *There is no need to duplicate the reporting obligations.*

Deletion of Art. 33 and its consequences on Art. 19

PUBLIC

The use of International Nomenclature of Cosmetic Ingredients (INCI) or a name available in the CosIng database should be prioritized to avoid confusion if any international nomenclature is allowed; How does the Commission intend to maintain market harmonization and ensure that ingredient labeling remains consistent and transparent across the EU?

- *The proposed changes maintain INCI as a **source of ingredient names**, while introducing a **flexible and controlled fallback mechanism** that avoids regulatory deadlock in cases where other internationally recognised names are available (or when such INCI name is not yet developed).*
- *This approach ensures legal clarity, supports international alignment, and continues to support consumer understanding and market surveillance integrity.*

Deletion of Art. 33 and its consequences on Art. 19

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What is a legal status of the CosIng database?

- *CosIng database will remain a point of reference for common ingredient names.*

How will CosIng database be updated?

- *The COM will continue updating CosIng regularly (once a quarter). The discussions are ongoing with the PCPC to secure automatic update of INCI names.*

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Fertilising Products Regulation

Proposed amendments to Regulation (EU) 2019/1009





Removing the extended REACH registration requirement

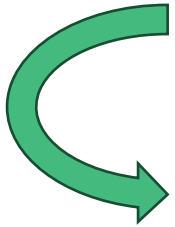
How will the safety of substances used in EU fertilising products be ensured?

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Proposal:

Deleting the requirement from the CMCs in the Fertilising Products Regulation

‘Standard’ REACH requirements apply to substances used in EU fertilising products



Information requirements are moved from the ‘pre-Single Market stage’ (where it presents an obstacle) to the ‘Single Market stage’ (once the demand for the EU fertilising product triggers registration at 10t-100t level)

How will the safety of substances used in EU fertilising products be ensured?

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- **Horizontal obligations and mechanisms under REACH**, incl. obligation to ensure safety of substances, standard registration requirements, and restriction procedure
- **Safeguards in the FPR**, incl. Article 4(2):

  "For any aspects not covered by Annex I or II, EU fertilising products shall not present a risk to human, animal or plant health, to safety or to the environment."
- **Food safety legislation**, including Regulation (EU) 2023/915 on maximum levels for certain contaminants in food and Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin
- **Moreover:** The more products are marketed as EU fertilising product, the more products are subject to the FPR requirements which are more stringent than many national rules.

Can you give specific examples of products or raw materials that would be impacted?

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Examples from position paper signed by 12 industry associations

Example 1: Colorant

- Cost: 33 €/kg
- Concentration in final product: 0.01-0.05%
- Substitution is challenging/impossible, due to specific performance requirements in terms of pH, density and viscosity
- REACH registration in the 10-100t* band would lead to a price increase by 48 €/kg, 146%, if offset over five years.

* Assuming REACH registration costs of € 240 000 and production of 9999 kg/yr

Can you give specific examples of products or raw materials that would be impacted?

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Example 2: Synthetic amino acid used as an active component

- Cost: 2.63 €/kg
- Concentration in final product: 0.04-3.5%
- Substitution is no option as other amino acids are also not registered at the required level
- REACH registration in the 10-100t* band would lead to a price increase by 3 €/kg, 117%, if offset over five years.

* Assuming REACH registration costs of € 155 000 and production of 9999 kg/yr

Can you give specific examples of products or raw materials that would be impacted?

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Examples 3 and 4: Substances used in food and feed*

- **Food dye Brilliant Blue FCF, E-133:**
  - EFSA assessment in 2010: safe intake as food ingredient of up to 6 mg/kg body weight/day → 420 mg/day for 70 kg adult
  - Concentration in fertiliser: below 0.5%
  - Application rate: 300 kg/ha
  - Area to be eaten to exceed limits: 28 m^2

- **Tartrazine, E-102:**
  - EFSA assessment in 2009: safe intake as food ingredient up of to 7.5 mg/kg body weight/day → 525 mg/day for 70 kg adult
  - Concentration in fertiliser: below 20 mg/kg
  - Application rate of 4 kg/ha
  - Area to be eaten to exceed limits: 65 000 m^2

* Assuming 100% uptake by the plant and that the consumer eats the whole plant (including stem and roots)



Adding a new COM empowerment to amend CMC 7 – Micro-organisms

Proposal for a new empowerment

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Current situation

- assessment through a technical study
- external contractor develops criteria and a methodology to assess safety and agronomic efficiency of strains
- external contractor performs assessement of new strains
- COM amends FPR and includes new strains based on conlcusions of the technical study

Proposal

- COM to assess and amend FPR including appropriate criteria and methodology, using technical study as basis
- assessement performed during conformity assessement of product by manufacturer
- notified body validates assessment results

Why the proposal does not lower the standard for risk assessment of micro-organisms

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- Future risk assessement will be performed based on methodology and criteria which will be inlcuded in FPR after consultation with Member States and experts in the field of microbial risk assessment.
- Future risk assement methodology and criteria may always be reviewed by COM and amended in case of concerns.
- Assessment based on latest state of the art and scientific evidence.
- Requirements for notified bodies set out in the Regulation: independence, confidentiality, objectivity, impartiality, professional integrity, technical competence in the specific field, capability to carry out all conformity assessment tasks for which they are notified
- Notification of conformity assessement bodies in responsibility of Member States, and notifications communicated before approval (via NANDO) to all Member States and COM for agreement.
- Any notification may be revoked by MS's notifying authority, if concerns emerge.

How MS will know which microorganisms can be used in microbial plant biostimulants?

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- Currently, no register for EU fertilising products
- Member States can require information about micro-organisms in national registers, as long as this does not impede the placing on the market of EU fertilising products.

Why now?

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- Finalisation of FPR evaluation in 2026, subsequent revision of the Regulation uncertain
- A revision of the FPR would take several years (preparation of the proposal 1-2 years + negotiations)
- Manufacturers are leaving the EU for third countries, carrying away innovation
- Need for incentives to develop new products for the single market now
- Criteria and methodology are already being developed



Digitalisation

What is meant by ‘digital contact’?

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Proposal

‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application

Examples: e-mail address, website link leading to contact form

Will the data carrier necessitate downloading additional applications on mobile devices?

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No.

- **Open format in accordance with Directive (EU) 2019/1024,** i.e. platform-independent and available to the public without any restriction that impedes the re-use of documents**.**
- **Requirements for digital labels set out in Article 11b(4), points (a)-(d), FPR:**
  - accessible free of charge;
  - easily and directly accessible through all major operating systems and browsers, without a need to register in advance, to download or install applications or to provide a password, and accessible to all potential users in the Union;
  - searchable;
  - presented in a way that also addresses the needs of vulnerable groups and supports, as relevant, the necessary adaptations to facilitate access by those groups, in particular those consisting of persons with disabilities.

- **Same digital solution as for digital label, to be determined via delegated act by 1 May 2027**

Why should the paper option be removed? How are the needs and challenges of manufacturers taken into account?

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- Market surveillance authorities and notified bodies have **divergent views and practices**, some requiring documents in **paper format** while others accept digital transmission of documents
- Manufacturers, **despite the flexibility provided by the FPR, draw up documents in paper format** to be sure that the documents will be accepted
- Handling paper documents creates **administrative burden**, is prone to **errors** and causes **waste**

→ necessary to introduce the **obligation** for such information exchange to take place electronically

- Businesses, authorities and notified bodies **should be equipped to handle electronic documents**. For those, who are not yet ready, we provide 24 months of transitional period.

Paper documents in exceptional circumstances

- **Alignment with other NLF legislation** covered by Omnibus IV, no exception foreseen in current draft.
- Any developments in that regard will be closely followed.

Extension to information exchange between manufacturers and farmers

- Information exchanges between manufacturers and farmers mainly take place via **product labels,** incl. use instructions.
- **Voluntary digital labelling** was introduced in 2024 and will start applying in 2027.
- **Evaluation** of the digital labelling rules mandatory by October 2031.

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Feasibility and transitional period

- **Several consultations** carried out in preparation of Omnibus IV → **broad support from industry**
- **FPR Reality Check** on 7 May → **no general feasibility concerns**
- Transitional period aligned to Omnibus IV, corresponds to suggestions from industry in FPR Reality Check (1-3 years)

Update of labelling guidance

- The labelling guidance document **will be updated** before the new provisions (digital labelling and Omnibus VI) will start applying.



Deletion of ‘unbundling clause’

PUBLIC

Will the deletion of the unbudling clause delay timely adoption of amendments?

- Removal of the unbundling clause allows for **reduction of adminitrative burden**, while maintains flexibility
- If certain amendments need extended discussions: **COM may keep current approach** and address changes of one CMC in one separate legal act

Why now?

- **15 COM delegated regulations** adopted since 2019 (+2 more in preparation); several of them could be merged.
- FPR evaluation will not necessarily be followed by a revision

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