Council of the European Union
General Secretariat

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From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus VI (Chemicals) - Presentation from the Commission (11 July)

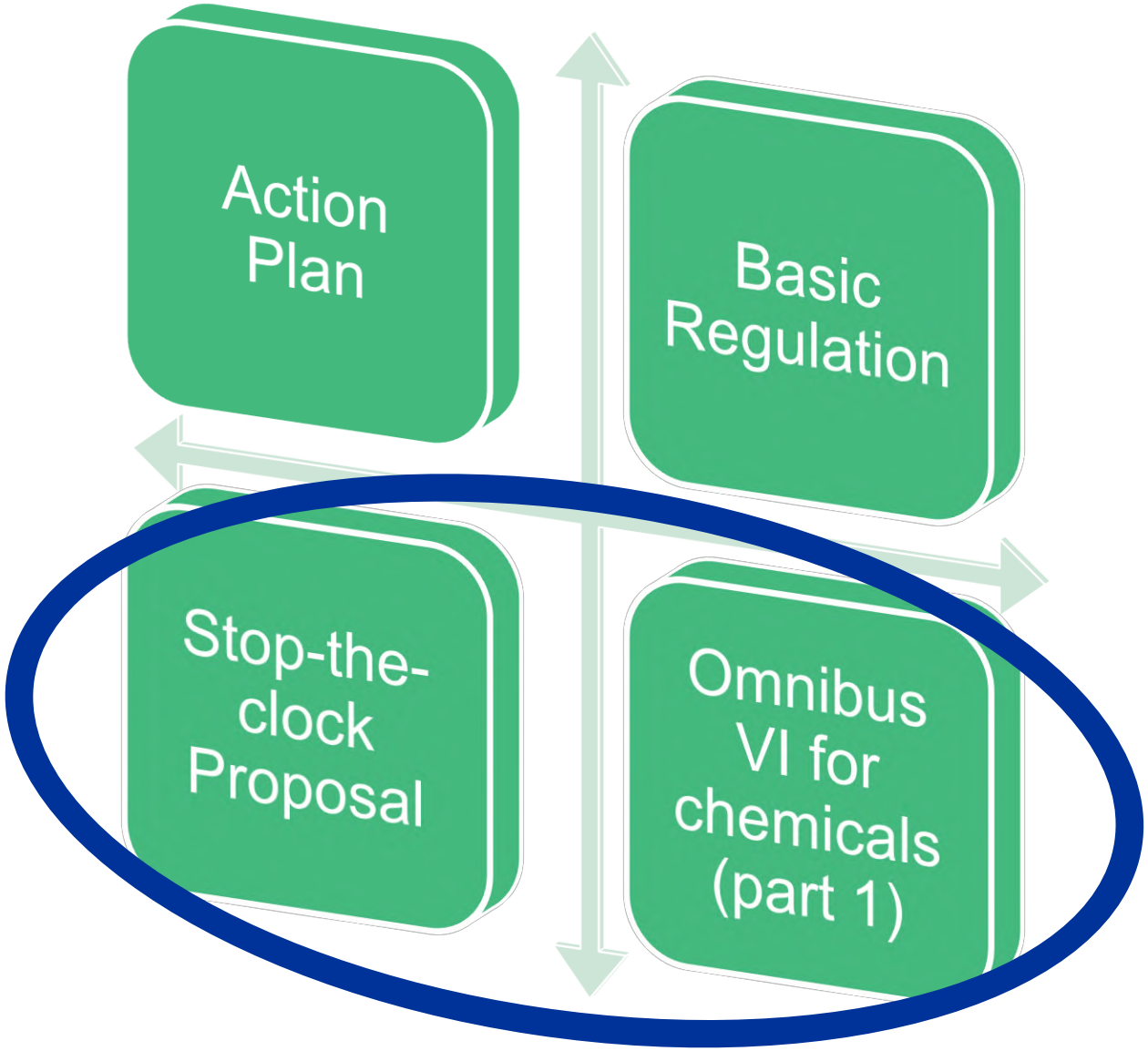
Delegations will find attached a presentation from the Commission on Omnibus VI (Chemicals) presented at the meeting of the Antici Group (Simplification) on 11 July 2025.

Proposal for an Omnibus on simplification for certain chemicals

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

European Commission

The Commission adopted a Chemicals package on 8 July 2025



Targeted amendments to:

- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (‘CLP Regulation’)
- Regulation (EC) No 1223/2009 on cosmetic products (‘the Cosmetic Products Regulation’, or ‘CPR’)
- Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products (‘Fertilising Products Regulation’)

Objective: Simplification and burden reduction for industry and authorities, while ensuring a high level of protection of human health and the environment.

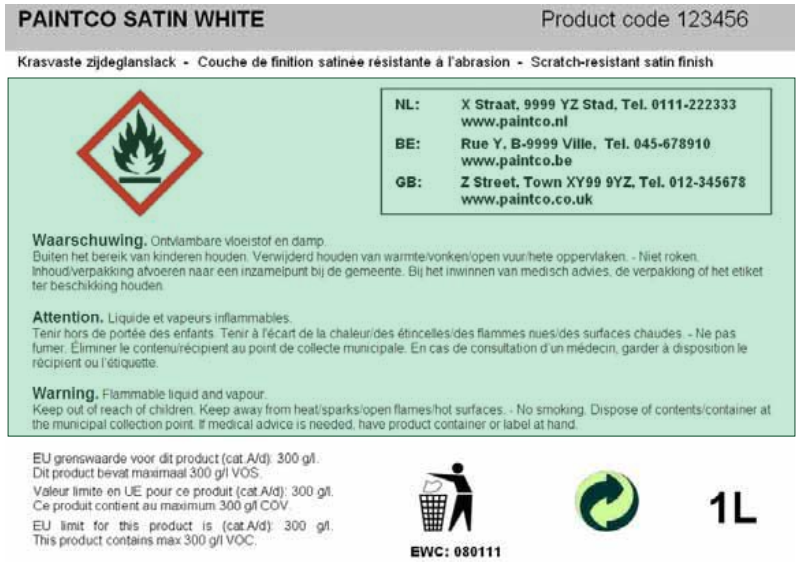
European Commission

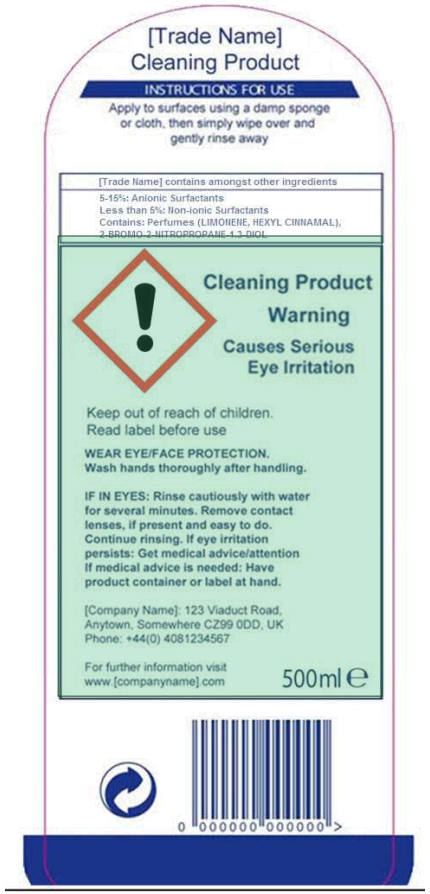
CLP Regulation

Proposed amendments to Regulation (EC) No 1272/2008

Reg. (EC) No 1272/2008 (CLP)

- Horizontal legislation applying to hazardous substances and mixtures. Some examples: detergents, cement, paints, glues, dishwasher tablet, fertilisers, essential oils, etc.
- Transposition of UN Globally Harmonised System for classification and labelling
- Classification, labelling and packaging of hazardous substances and mixtures
- Pre-requisite before products are placed on the market
- Each supplier is responsible for compliance (manufacturer, downstream user, distributor)
- **Recent revision by Regulation 2024/2865**





Overview of the changes

2 legislative proposals

- Postponement of application dates of some rules of Regulation (EU) 2024/2865 to allow comprehensive discussion between co-legislators (“Stop-the clock”) (COM(2025)526)

- Simplification Omnibus, introducing changes to provisions on formatting, advertisements and online sales, further simplifying labelling rules and adding more digitalisation (COM(2025)531)

Overview of the changes

- Bringing flexibility to companies to ensure legibility of labels (Article 31(3), Annex I)
- Simplification of advertisement and online sales rules (Articles 48 and 48a)
- Bringing flexibility to companies as regards timing to relabel after classification changes (Article 30)
- Further simplification of certain labelling rules (derogations for small packages, labels on fuelling stations)
- More digitalisation (alignment with Omnibus IV)

COM(2025) 526 final

Where we are (applicability dates)

10/12/2024

Entry in force Reg (EU) 2024/2865

Transition

01/07/2026

Application of rules (1st batch)

Online sales
Advertisement
Relabelling obligation
Fuelling stations labelling
Digital labelling
Other provisions

01/01/2027

Application of rules (2nd batch)

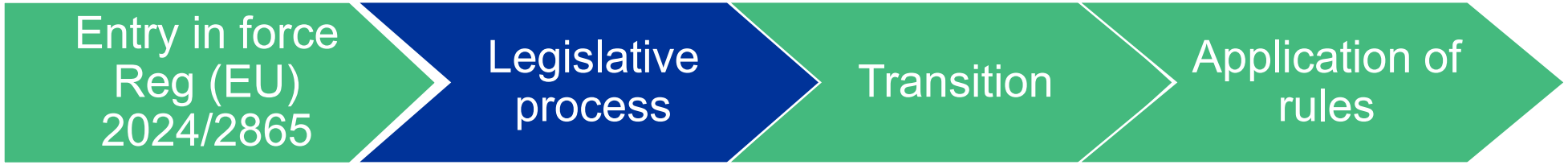
Formatting requirements: (font sizes, line spacing, background requirement

What we suggest to change
(applicability dates)

~~01/07/2026~~
~~01/01/2027~~

10/12/2024

01/01/2028



Formatting requirements
Online sales
Advertisement
Relabelling obligation
Fuelling stations labelling

What we suggest to change (labelling)

COM(2025) 531 final (CLP)

Current situation

- Ensuring legibility of labels via:
  - Mandatory formatting requirements (minimum font sizes, line spacing, background colour)
- Conditional labelling derogations
- Detailed labelling for fuel stations
- Some label elements moved to digital label

Omnibus

- Generic obligation of labels to be legible

  [Additional guidance and details in ECHA's guidelines]
- Simplified labelling derogations
- Simplified labelling for fuel stations
- Additional elements moved to the digital label (details of additional supplier), introduction of a digital contact

COM(2025) 531 final (CLP)

What we suggest to change (advertisements and online sales)

Current situation	Omnibus

• Obligation to add extensive CLP label elements in advertisements for hazardous chemicals:
  • Pictograms, signal words
  • (EU) Hazard statements
  • Invitation to read the label information
	- Generic statement referring customers to hazard information on the label

• Rules on advertisements and online sales applicable to consumers and professionals	- Rules on advertisements and online sales applicable to consumers (as professionals have access to SDS)

What we suggest to change (Relabelling)

COM(2025) 531 final (CLP)

Current situation	Omnibus
• Obligation to update labels without undue delay but no later than within 6 months when switching to a new or a more severe self-classification	- Obligation to update labels without undue delay when switching to a new or a more severe classification
• Obligation to update labels without undue delay but no later than within 18 months in all other cases	- No change

European Commission

Cosmetics Regulation

Proposed amendments to Regulation (EC) No 1223/2009

Regulation (EC) No 1223/2009 (Cosmetic Products Regulation, CPR)

- Product regulation (maximum harmonisation)
- Purpose:
  - Ensuring **high level of protection of human health**
  - Ensuring **functioning of the internal market**
- Principle of **free movement of cosmetic products** in the EU (Member States cannot, for reasons related to CPR requirements, refuse, prohibit or restrict making available on the market of products complying with the CPR.
- Numerous requirements ensuring the **safety of cosmetics** made available on the EU market:
  - Responsible person established in the EU
  - Notification in the Cosmetic Product Notification Portal (CPNP)
  - Appropriate label information
  - Safety assessment documented in the product information file (PIF)
  - List of prohibited substances (over 1700), restricted substances (over 370) and allowed colorants, preservatives and UV filters
  - Almost automatic prohibition of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) cat. 1 A, 1B and 2
  - The assessments of Scientific Committee on Consumer Safety of safety of substances used in cosmetics for human health.

Background and context

Ongoing discussions:

- with Member states and cosmetic industry in the Working Group on Cosmetic Products
- Numerous position papers from the cosmetic industry and associations
- Pilot Project on cosmetics (presented in joint session of the Industry and Better Regulation WP on 24/04/2025)
- ‘Reality Check’ (workshop) on cosmetics (16 May 2025; 226 participants)

We propose in the Simplification Omnibus **targeted** changes in the Simplification Omnibus

- **To address the most urgent problems**
- **To reduce unnecessary burden**

Ongoing comprehensive evaluation of the Cosmetics Regulation (Q1 2025 – Q2 2026) which may be followed by an impact assessment and the Commission proposal to revise the Cosmetics Regulation

Overview

- New procedure for adding colorants, preservatives and UV filters to Annexes IV – VI to the Cosmetics Regulation (New Article 14a)
- Simplification and clarification of timelines, transitional periods, derogation criteria, approach to natural Complex Substances (NCS) and focus on dermal exposure (Article 15)
- Removal of administrative burden:
  - pre-notification of cosmetic products containing nanomaterials (changes to Art.16/ Annex I)
  - reporting obligations by national authorities (changes to Art.22)
  - obligation to adopt the glossary of common ingredient names as Commission Decision (Article 33)

Art. 14a – new procedure for adding colorants, preservatives and UV filters

Current situation

- Art. 14 of the CPR: only those colorants, preservatives or UV filters can be used which are listed in Annexes IV – VI to the CPR
- Art. 31(2) – general empowerment on the Commission to amend CPR Annexes to adapt them to technical and scientific progress

Omnibus

Art. 14a added laying down a procedure according to which new substances can be added to Annexes IV – VI:

- Request with scientific evidence from the industry to the Commission
- SCCS opinion within 12 months
- Commission changes the Annexes

Art. 15: timelines and transitional periods

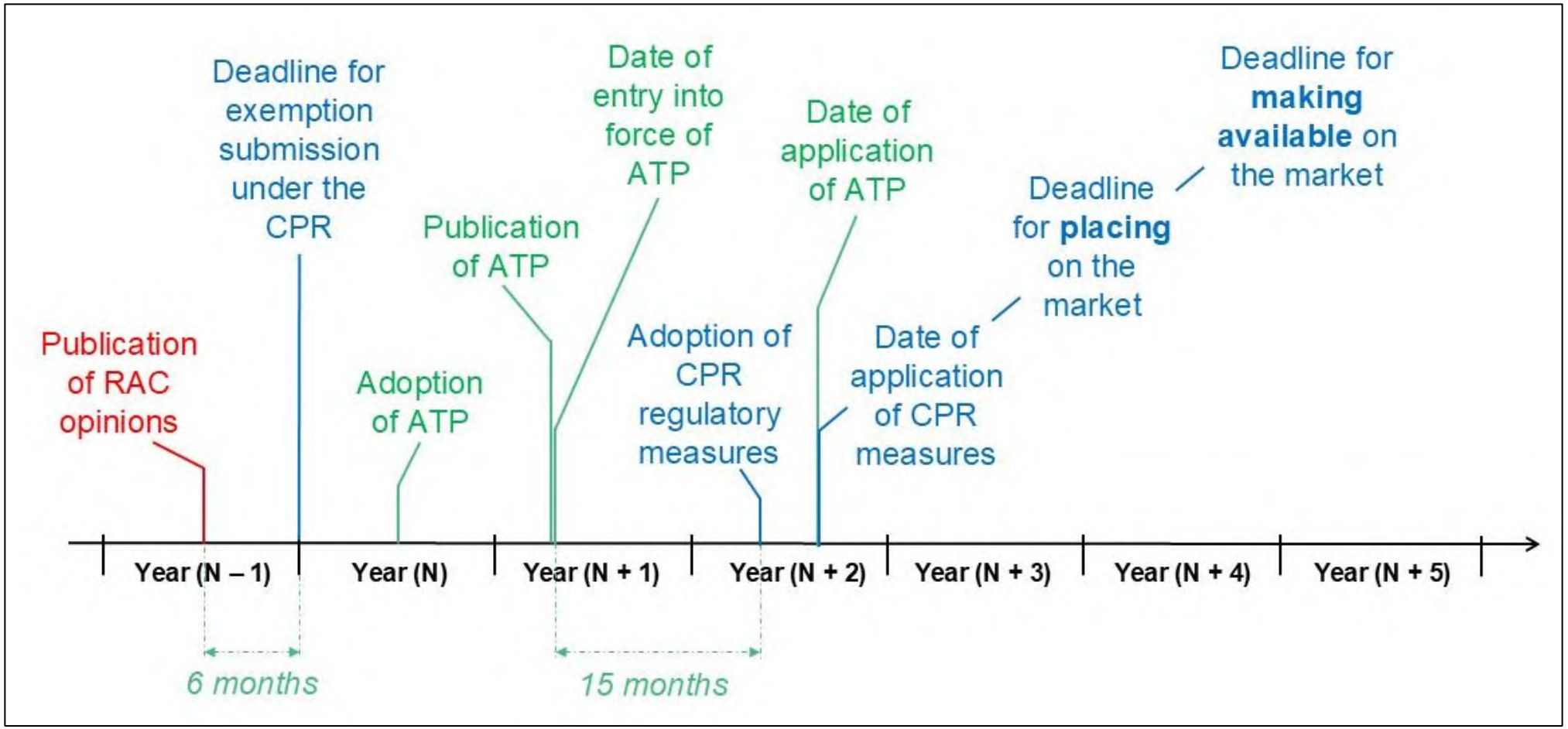
Current situation

- No deadline to submit a request for derogation from the prohibition from the use of a CMR substance cat. 1A or 1B in cosmetics, however, **in practice 6 months after the publication of the RAC opinion**
- Commission must adopt the ban/restriction **within 15 months of the inclusion** of substance into the CLP Regulation
- **In practice 2,5 – 4 months** for industry to adapt

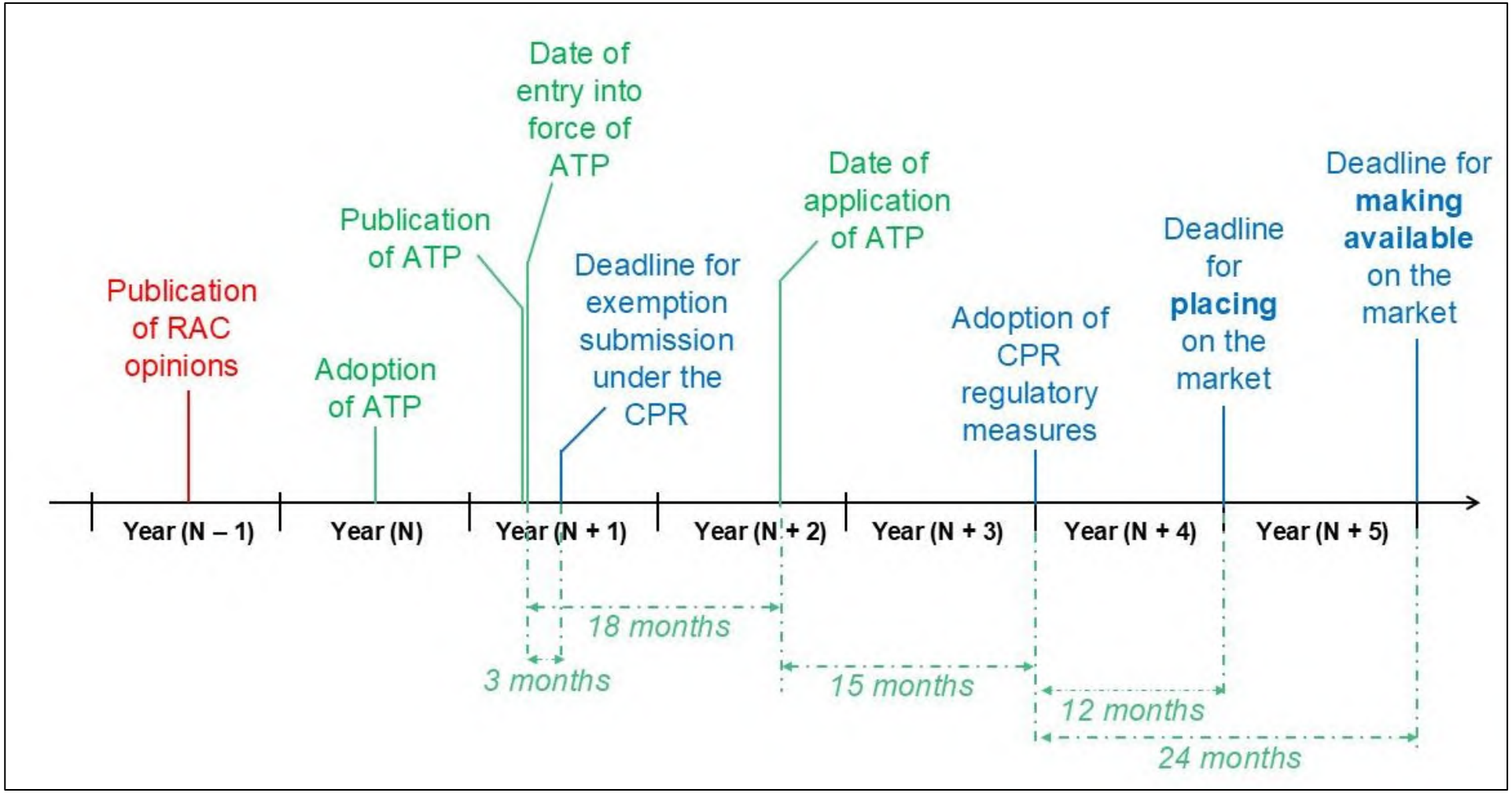
Omnibus

- A request for derogation must be submitted to the Commission **at the latest 3 months** after the entry into force of the amendments to the CLP Regulation
- **15 months from the entry into application** of changes to the CLP Regulation
- Transitional periods: **12 months** (for new products) and **24 months** for products already on the market

Art. 15: Timelines under the current Cosmetics Regulation



Art. 15: Timelines in the Omnibus Proposal



Art. 15(2): clarified and streamlined derogation criteria

Current situation

Substance classified as CMR cat. 1 A or 1B can be used in cosmetics if all the below criteria are met:

1. the substance complies with the food safety requirements
2. there are no suitable alternatives
3. application has been made for a particular use of the product category with a known exposure, and
4. the substance has been evaluated and found safe by the SCCS

Omnibus

The following changes to the derogation criteria are proposed:

- The 1st criterion - **compliance with food safety requirements - is deleted**
- The 3rd criterion (particular use) is part of the 4th criterion (SCCS assessment)
- **Conditions are added to guide a decision** whether a substance can be considered a **suitable alternative** to the classified substance

Art. 15: focus on dermal exposure and approach to natural complex substances

Dermal exposure

- New paragraph introduced relevant to route specific classification under the CLP.
- The prohibition under Art. 15 does not apply if the CMR classification is linked to oral or inhalation route of exposure.
- COM will be asking the opinion of the SCCS if human health concerns arise from the use of cosmetic products that may result in inhalation and oral exposure.

Natural Complex Substances

- New paragraph introduced.
- Clarification that the presence of a constituent that is classified as CMR of a plant extract does not *per se* lead to a ban under Art. 15 of that plant extract (i.e., an essential oil containing a CMR classified constituent will not be banned in cosmetics).
- However, COM will be asking the opinion of the SCCS if human health concerns arise from the use of such NCS in cosmetic products.

Removal of administrative burden

Article 16 / Annex I

- No more obligation to pre-notify cosmetic products containing nanomaterial 6 months before placing them on the market
- Information which was part of prenotification must be provided in cosmetic product safety report

Article 22

- No more obligation on competent authorities to assess and report to the COM and other MSs on their market surveillance activities
- The reporting is done through Information and Communication System on Market Surveillance (ICSMS)

Article 33

- No more obligation on the COM to adopt glossary of common ingredient names and publish in the Official Journal
- These names can be still consulted in CosIng (Cosmetic Ingredients Database)

European Commission

Fertilising Products Regulation

Proposed amendments to Regulation (EU) 2019/1009

Fertilising Products Regulation
Regulation (EU) 2019/1009

- **Scope:** 7 categories of fertilising products ('PFCs', e.g. fertilisers, soil improvers, plant biostimulants…), 15 different component material (= ingredient) categories ('CMCs', e.g. compost, micro-organisms, food industry by-products…)
- **Objectives:**
  - incentivise large scale fertilising products production in the EU from domestic organic or secondary raw materials;
  - easier access to the internal market;
  - address soil contamination.
- **Optional harmonisation:**
  - Compliance with the Fertilising Products Regulation → free movement
  - Compliance with national rules → adaptation, mutual recognition

Overview of proposed amendments

- Removal of the extended REACH registration requirement (Annex II, Part II, several Component Material Categories (CMCs))
- New empowerment to introduce general safety and agronomic efficiency criteria for the assessment of micro-organisms in CMC 7 (Article 42)
- Digitalisation in alignment with Omnibus IV ‘paper to digital’ (several provisions in main act and Annexes I and IV)
- Removal of the ‘unbundling clause’ (Article 43)

Removing the extended REACH registration requirement

Baseline:

Annex II, Part II, CMC 1, point 2, and several other Component Material Categories (CMCs)

The Fertilising Products Regulation **goes beyond horizontal REACH requirements**:

- **All substances** in EU fertilising products need to be registered, at least, with information normally required for substances manufactured or imported at 10-100 t/year:
  - Substances below <1 tonne need to be registered;
  - Substances between 1-10 tonnes need to be registered with more information;
  - No matter the concentration of the added ingredient in the final product.
- A **chemical safety report** with exposure scenario is always required, not only for hazardous substances at 10-100 t/year;
- **Only certain registration obligation exemptions** in REACH apply (Annex IV and points 6, 7, 8, 9 or 10 (only for magnesia of Annex V).

Removing the extended REACH registration requirement

Facts:

- Manufacturers of EU fertilising products have **little means to ensure compliant registration** at the required level.
- Registration is **costly, not affordable** for many SMEs.
- Some EU manufacturers market their products **under national rules or in third countries** instead.
- Others may **reformulate their products**, using different and sometimes less performing substances.

Reasoning for amendment:

- Horizontal REACH requirements (as also applicable to national fertilising products), other provisions in the Fertilising Products Regulation and EU food and feed legislation **ensure safety**.
- The requirement seems **disproportionate** and **reduces the added value** of placing products on the Single Market **under the Fertilising Products Regulation**.

Removing the extended REACH registration requirement

Proposal:

Deleting the requirement from the CMCs in the Fertilising Products Regulation

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

New empowerment for CMC 7

Baseline:

Annex II, Part II, CMC 7: MICRO-ORGANISMS

- Plant biostimulants may **only** contain strains from the **4 groups of micro-organisms** listed the positive list

Article 42(4)

- The Commission is **empowered to add additional micro-organisms or strains** of micro-organisms to the positive list **after an assessment** showing that the strains:
    - **Do not present a risk** to human, animal or plant health, to safety or to the environment
    - **Ensure agronomic efficiency**

New empowerment for CMC 7

Facts:

- **Microbial plant biostimulants**
  - increase plants‘ **nutrient use efficiency** → allow for reduced use of fertilisers → allow for reduction of nutrient run-off and pollution
  - increase plants’ **resistance to abiotic stress**
- **High interest by industry** in timely inclusion of additional strains to positive list
- **Ongoing technical study**: assessment of 34 strains for potential inclusion
- Uncertainty about any **future studies**
- Absence in the list means **no free movement** on the Single Market
- Products **developed in the EU**, with EU funding**, move to third countries**

New empowerment for CMC 7

Reasoning for amendment :

- **Current mechanism is too slow** compared to the **speed of innovation** in the plant biostimulants sector
- Need for **incentives** to develop new products for the single market
- Provide to **EU farmers access to innovative products** to reduce high fertilisation costs and cope with climate change

New empowerment for CMC 7

Proposal:

- **New empowerment** in Article 42 to set out **criteria and a methodology for the assessment of micro-organisms** to be used during conformity assessment

Assessment in technical study

(external contractor)

Assessment during conformity assessment

(manufacturers and notified bodies)

Digitalisation

Baseline:

Articles 2, 6-9, 15, 16 and 41, Annex I, Part II, Annex IV, Part II

- Economic operators are to indicate the product name, their trade name or trademark and their postal address on the packaging.
- Format (paper or digital) of EU declaration of conformity not specified, EU DoC does not need to accompany the products.
- Format of documents for authorities and in the context of conformity assessments not specified.

Reasoning for amendment:

- Fertilising Products Regulation currently **not 'fit for the digital age'**
- **Alignment** with other NLF legislation (Omnibus IV).

Digitalisation

Proposal:

- EU declaration of conformity shall be drawn up **in electronic form** and made accessible through an **internet address or data carrier** (ensuring coherence with other digital tools)
- Economic operators shall indicate a **‘digital contact’** on the products;
- **Reporting** to national authorities and **exchanges** with notified bodies in **‘electronic form’** only.

Removal of the ‘unbundling clause’ (Article 43)

Baseline:

Article 43

- When amending component material categories in Annex II, Commission **must adopt a separate delegated act in respect of each component material category.**

Reasoning for amendment:

- Component Material Categories (CMCs) provisions are constantly developed
- Similar amendments may be introduced across CMCs

  Examples:

  - The proposed amendment on the REACH registration requirement would have required 12 delegated acts.
  - Amending the limit values for PAHs would require 7 delegated acts.
- Duplication of procedures (drafting, stakeholder consultations, adoption…)

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