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Legal Opinion

on

The Lawfulness of the Planned Amendments through the „Food and Feed Safety Omnibus“

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Prepared on behalf of
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A. Background and questions presented

For about a year, European Union policy has been dominated by the drive towards simplification.

To that end, the Union has drawn up a total of ten 'Omnibus' packages, some of which have already been adopted. Each package amends an entire bundle of regulations and directives within a (at least loosely) related policy area.[1]

There is nothing fundamentally wrong with the goal of simplifying procedures and thereby easing the administrative burden on the Union and the Member States, as well as on businesses and consumers. However, experience with the Omnibus packages to date suggests that minor progress in reducing bureaucracy has come at the cost of abandoning key achievements in the areas of human rights, health, and environmental protection.

On December 16, the Commission proposed the tenth omnibus package – the so-called Food and Feed Safety Omnibus[2]. It consists of three proposed legislative acts and an accompanying document, namely:

- Proposal for a regulation amending Regulation (EU) No 528/2012 as regards the extension of certain data-protection periods[3]
- Proposal for a directive amending Council Directive 98/58/EC and Directive 2009/128/EC of the European Parliament and of the Council as regards simplifying and strengthening requirements on food and feed safety and repealing Council Directives 82/711/EEC and 85/572/EEC[4]
- Proposal for a regulation amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 396/2005, (EC) No 1099/2009, (EC) No 1107/2009, (EU) No 528/2012 and (EU)

[1] An overview is provided by the European Commission at https://commission.europa.eu/law/law-making-process/better-regulation/simplification-and-implementation/simplification_en, last accessed on 13 January 2026.
[2] European Commission, Food and Feed Safety Simplification Package – December 2025, available at https://food.ec.europa.eu/horizontal-topics/simplification-legislation_en, last accessed on 6 January 2026.
[3] COM(2025) 1020 final, available at https://food.ec.europa.eu/document/download/d8c35be0-ecc9-432b-a645-fd363681f5d3_en?filename=horiz_omnibus_reg_com-2025-1020-1-p1.pdf, last accessed on 6 January 2026.
[4] COM(2025) 1021 final, available at https://food.ec.europa.eu/document/download/f08402e6-de66-4082-bf8d-ec3aff7787bb_en?filename=horiz_omnibus_dir_com-2025-1021-1part1.pdf, last accessed on 6 January 2026

2017/625 as regards simplifying and strengthening requirements on food and feed safety[5] (hereinafter “draft amending regulation”), together with the related Commission Staff Working Document[6]

The third proposed legislative act contains proposals for far-reaching amendments to the EU Plant Protection Products Regulation (EC) No 1107/2009, which would lower the level of protection in this area.

This analysis is limited to this part of the Omnibus package.

The clients request an assessment of the effects of the proposed amendments to Regulation (EC) No 1107/2009 on the level of protection under plant protection products law and of their compatibility with higher-ranking law.

B. Executive summary

The amendments to Regulation (EC) No 1107/2009 proposed by the Commission would lower the level of protection for the environment and human health.

Especially the proposed shift from time-limited approvals of active substances to predominantly unlimited approval duration represents a major step backwards in terms of environmental and health protection. Already today, it is a problem that new scientific findings on risks to health and the environment are not swiftly translated into regulatory decisions. The implementation of the proposal would exacerbate the problem.

Active substances that do not meet the approval criteria would be allowed to be temporarily approved under simplified conditions pursuant to Article 4(7) of Regulation (EC) No 1107/2009. According to the proposal, the absence of “reasonable” alternatives should be sufficient for such a temporary approval of an active substance. This constitutes a problematic watering down of the existing requirement that alternatives are not available.

[5] COM(2025) 1030 final, available at https://food.ec.europa.eu/document/download/b0817113-6edc-4219-b638-8060fee037d5_en?filename=horiz_omnibus_reg-com-2025-1030_en.pdf and, in an editorially revised version, as COM(2025) 1030 final/3 at https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A52025PC1030%2802%29&qid=1767695026766, both last accessed on 6 January 2026.
[6] SWD(2025) 1030 final, available at https://food.ec.europa.eu/document/download/863722d6-85d9-4273-b1f6-475b1bcde200_en?filename=horiz_omnibus_2025-1030_swd_en.pdf, last accessed on 6 January 2026.

In addition, Member State authorities would no longer be permitted to consider new scientific findings concerning the active substance when granting national product authorisations. This would be equivalent to freezing the state of knowledge at the time of the last approval. This point in time can be far in the past, particularly in view of the planned abolition of the periodic review of active substance approvals.

The requirement for prior authorisation of treated seed is to be removed entirely, provided that the seed has been treated with a plant protection product authorised in another Member State. Considering the risks to the environment and health associated with the use of treated seed, this exemption would entail a critical lowering of the level of protection.

Moreover, various privileges are proposed for substances that the Commission expects to be less harmful (including biocontrol substances, low-risk active substances and basic substances). In some cases, these exemptions lead to the waiver of the authorisation requirement or to automatic authorisation upon expiry of the decision period. Since the actual harmlessness of these privileged substances is not ensured by restrictive criteria and definitions, this would create a problematic loophole for circumventing authorisation control.

Transitional periods for the placing on the market and use of plant protection products are to be extended – including for substances that are questionable from a safety perspective. This would prioritise economic interests over the protection of health and the environment.

The proposed amendments raise serious doubts as to their compatibility with the precautionary principle and with the high level of protection for health and the environment guaranteed by Article 191(2) of the Treaty on the Functioning of the European Union (TFEU) and the obligations and rights set out in the Charter of Fundamental Rights of the European Union (CFR).

The Commission’s approach in preparing the proposal is also not consistent with higher-ranking law.

Contrary to the Interinstitutional agreements and the Better Regulation Guidelines, the Commission refrained from carrying out an impact assessment and the associated public stakeholder consultation. Instead, it merely quantified the expected cost savings and sought feedback on an abstract description of its project in a targeted consultation.

The Commission had at its disposal numerous indications of the risks to the environment and human health associated with a lowering of the level of protection. Nevertheless, it proceeded on the assumption - without further substantiation - that the planned changes would not pose any risk to health and environmental protection. It is not apparent that the Commission sought information on the expected effects as an alternative to the impact assessment that was not carried out.

This approach violates the principle of proportionality, as the information required to assess proportionality was not available, even though significant environmental and health impacts were to be expected. Furthermore, serious doubts arise as to whether this approach is compatible with the principles of equal treatment and the protection of legitimate expectations. Finally, the omission of a health impact assessment and the lack of a health-specific statement of reasons for the initiative would suggest a breach of Article 168(1) TFEU (in conjunction with Article 296(2) TFEU), if the legislative act were adopted.

C. The Commission initiative and its legality

I. Classification of the key proposed amendments

The draft amending regulation proposed by the Commission provides for a series of amendments to Regulation (EC) No 1107/2009 that would significantly lower the level of protection in the fields of health and environmental protection.

1. Removal of time limits on approvals of active substances

a. Abolition of the current periodic review

At present, first approvals of active substances are limited to a period of no more than ten years.[7] On application, the approval of an active substance shall be renewed if it is

[7] Article 5 of Regulation (EC) No 1107/2009.

established that the approval criteria set out in Article 4 are satisfied.[8] For that purpose, companies must submit a comprehensive and up-to-date dataset containing toxicological, ecotoxicological and environmental information.[9]

The Commission proposal provides for a fundamental shift towards approvals of active substances that are, as a rule, unlimited. Only for candidates for substitution, active substances within the meaning of Article 4(7) of Regulation (EC) No 1107/2009, and those for which, pursuant to Article 6(j) of Regulation (EC) No 1107/2009, a limited approval period has been set due to relevant uncertainties, approval duration would remain limited.[10] All other active substances are to be approved without a time limit. Under the transitional rule proposed by the Commission, this would in principle apply to all active substances that are approved at the time the amendments enter into force.[11] For active substances that are already in a renewal procedure when the amendments enter into force, that procedure is to be completed. The renewal of the active substance approval would be, subject to the above exceptions, unlimited.[12]

This substantially lowers the level of protection.

The reason why approval duration is limited is to ensure that developments in science and technology are taken into account.[13] In practice, it is quite common that, in the course of the periodic review of an active substance approval, new scientific evidence on harm to the environment and human health leads to the finding that the conditions for approval are not met.[14]

[8] Article 14(1) of Regulation (EC) No 1107/2009.
[9] Article 6 Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012.
[10] Article 5 of Regulation (EC) No 1107/2009 (Draft). These rules are also to apply to active substances that are approved at the time the draft amending regulation enters into force, see Article 27a of Regulation (EC) No 1107/2009 (Draft).
[11] Cf. Article 27a(1) of Regulation (EC) No 1107/2009 (Draft) and the exceptions provided for there.
[12] Cf. Article 2(1) of the draft amending regulation; recital 26 of the draft amending regulation.
[13] Recital 15 of Regulation (EC) No 1107/2009.
[14] Cf. for example, Commission Implementing Regulation (EU) 2024/20 of 12 December 2023 concerning the non-renewal of the approval of the active substance S-metolachlor; Commission Implementing Regulation (EU) 2025/910 of 20 May 2025 concerning the non-renewal of the approval of the active substance flufenacet.

Without an obligation on companies to submit updated toxicity data at regular intervals, significantly fewer new scientific data would be generated.[15] The state of knowledge could then evolve only through independent scientific literature, without the industry being obliged to contribute to it.

The exceptions, inter alia, for candidates for substitution or active substances pursuant to Article 4(7) of Regulation (EC) No 1107/2009, are insufficient to ensure an acceptable level of protection. They would concern only a small proportion of active substances. According to PAN Europe 90% of active substances would receive an unlimited approval under this proposal – including highly problematic substances such as acetamiprid and PFAS active substances.[16]

The proposal of unlimited approval duration is officially justified with the intention to reduce the administrative workload and to facilitate the transition to more sustainable active substances and plant protection products.[17] It is questionable whether the proposed move to open-ended approvals will contribute to the latter or, rather, will lead to problematic active substances remaining on the market for a longer time.

b. No compensation through Articles 18, 18a and 21 of Regulation (EC) No 1107/2009

Although the proposal provides for mechanisms by which open-ended active substance approvals can also be reviewed, these do not ensure that new scientific findings are promptly translated into regulatory decisions.

aa. Periodical identification of active substances that must be reviewed

According to the Commission's proposal, Article 18 of Regulation (EC) No 1107/2009[18] should stipulate that the Commission shall “periodically” after consulting EFSA, adopt implementing acts identifying active substances or groups of active substances with unlimited approval periods for which a renewal procedure shall be conducted.[19]

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[15] PAN Europe, Briefing ‘Food and feed safety omnibus’ threatens pesticide rules, available at https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/briefings/Briefing_Omnibus%20threatens%20pesticide%20rules%20.pdf, last accessed on 16 January 2026.16
[16] PAN Europe, fn. 15, p. 2.
[17] Recital 14 of the draft amending regulation.
[18] This provision currently governs the Commission’s power to establish a work programme setting priorities for the mandatory review of active substances.
[19] Article 18(1) of Regulation (EC) No 1107/2009 (Draft).

This identification of the active substances concerned “shall take into account”, among others, indications of safety concerns for human or animal health or the environment, new scientific or technical knowledge and available monitoring data and “may” take into account requests from Member States.[20] Where relevant approval criteria set out in Annex II, data requirements or relevant guidance documents become applicable, the Commission shall adopt an implementing act identifying all relevant active substances at the latest within three years.

The implementing acts shall, among others set deadlines for the submission of applications for renewal of the approval of the active substances concerned that “allow sufficient time for the generation of the necessary data and the submission of the said applications” and set expiry dates for the approvals of the active substances concerned that “allow sufficient time for the submission and evaluation of the applications and for the adoption of decisions on the renewal” of the approval of the active substances concerned.

This mechanism set out in Article 18 of the Commission’s proposal cannot replace the currently foreseen mandatory periodic review.

The proposed obligation on the Commission to decide “periodically” is too vague in terms of time, because it leaves open the question of how often a decision on the need for renewal procedure must be taken (annually, every five, ten or 20 years?). The timetable for identifying the active substances to be reviewed is thus left to the Commission’s discretion. Only in the case of amended approval criteria, data requirements or guidance documents there is a specific (but very long) three-year deadline set for the identification of the active substances to be reviewed.

Furthermore, the Commission is granted overly broad discretion in identifying the active substances to be reviewed. The proposed Article 18 does not stipulate clearly enough that a review must be initiated where there are indications of safety gaps, new scientific findings and monitoring data. Nor is there a sufficiently clear obligation to respond to review requests from Member States. It is therefore to be feared that the Commission will claim broad discretion in assessing the available state of knowledge and the resulting

[20]Article 18(1), second subparagraph, of Regulation (EC) No 1107/2009 (Draft).

need for review. In addition, less data on health and environmental risks will be available if companies are no longer obliged to generate them.

In addition, the implementing acts identifying the active substances that need to undergo a renewal procedure are adopted with the participation of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), which is composed of representatives of national ministries. This creates the risk of political influence.[21]

Furthermore, the duration of the review procedure is not clearly circumscribed: Already today, review procedures often take far too long.[22] The same problem is likely to happen for substances chosen under Article 18 of the draft, because this provision leaves open by when the renewal procedure must be completed. It provides only vague requirements that the implementing regulation is to set deadlines for the submission of applications for renewal of the approval of the active substances concerned, which allow "sufficient time" for the generation of the necessary data and the submission of the said applications". Similarly, expiry dates for the active substance approvals are to be set which leave "sufficient time" for the submission and evaluation of the applications and for the adoption of decisions on the renewal of the active substances concerned.[23] These vague formulations, as well as the reference to Article 17 (technical prolongation), give rise to concerns that problematic active substances could remain on the market for a very long period without being reviewed.

bb. Targeted reassessment under Article 18a

Whereas the proposed Article 18 of Regulation (EC) No 1107/2009 (Draft) foresees a full review of the approval of an active substance, a new Article 18a is intended to regulate a selective reassessment of active substances approved for an indefinite or limited period with regard to individual approval criteria.

The proposed provision stipulates that the Commission "may" at any time, based on the criteria laid down in Article 18(1) initiate a targeted reassessment of the approval of active substances to verify whether certain approval criteria, or specific aspects thereof, are still

[21] PAN Europe, fn. 15, p. 2.16
[22] Cf. in this context, the recent judgments of the General Court, judgments of 19 November 2025, Cases T-412/22, T-94/23 and T-565/23, concerning the need for a restrictive application of so-called technical extensions pursuant to Article 17 of Regulation (EC) No 1107/2009.
[23] Article 18(2) of Regulation (EC) No 1107/2009 (Draft).

met in light of current scientific and technical knowledge. To that end, after consulting the Authority, the Commission “may” adopt implementing acts under the committee procedure identifying the active substances to be reassessed, the scope of the targeted reassessment, data requirements, the guidance documents to be used, and deadlines for the submission of required data. If the data are not submitted within the prescribed deadline, or if the review concludes that the approval criteria are not met, the approval shall be withdrawn.

This provision in Article 18a also does not ensure that active substance approvals are swiftly adapted to the latest state of science and to monitoring data. It is designed as a purely discretionary provision, empowering the Commission to initiate a partial review but not obliging it to do so. In view of the way in which the existing review option under Article 21 of Regulation (EC) No 1107/2009 (see below) has been handled to date, there is reason to fear that the Commission will rarely exercise this discretion to initiate a targeted review. Furthermore, the added value compared to the existing possibility of ad hoc review under Article 21 of Regulation (EC) No 1107/2009 appears to be low. Finally, the criticism raised above regarding Article 18 of the proposal, namely that the criteria for identifying the active substances to be reviewed are not regulated clearly enough, also applies here.

c. Ad hoc review under Article 21 of Regulation (EC) No 1107/2009

According to the Commission's proposal, the existing possibility of ad hoc review under Article 21 of Regulation (EC) No 1107/2009 should remain in place.[24]

According to this provision, the Commission may review the approval of an active substance at any time. This includes both a targeted review and a full review. It “shall take into account” a request of a Member State to review, in the light of new scientific and technical knowledge and monitoring data, the approval of an active substance. Where, in the light of new scientific and technical knowledge it considers that there are indications that the substance no longer satisfies the approval criteria provided for in Article 4, or where requested data has not been provided, it review is initiated. Where the Commission concludes that the approval criteria are not met or where requested information has not been provided, a Regulation to withdraw or amend the approval shall be adopted.

[24] Recital 14 of the draft amending regulation.

Article 21 of Regulation (EG) No 1107/2009 is an expression of the precautionary principle.[25] Unfortunately,
it is currently being applied very restrictively by the Commission. There are only a few cases documented in the case law in which the provision has been invoked by the Commission to review an active substance approval.[26] In response to calls by environmental NGOs to apply this provision, the Commission invokes a very broad discretion to initiate a review.[27] Also Member State requests to apply Article 21 were not always followed by the Commission.[28]

Given the Commission's restrictive approach to the ad hoc review under Article 21 of Regulation (EC) No 1107/2009, also this provision cannot compensate for the removal of the current system of limited approval duration.

d. Adjustment of the duration of national product authorisations

As a consequence of the unlimited duration of active substance approvals, the time-limitation of product authorisations is also to be redesigned.

Currently, the duration of an authorisation is linked to the duration of the active substance approvals.[29] Under the Commission proposal, the duration of authorisations for plant protection products containing open-ended approved active substances may in future be up to 15 years; otherwise, the maximum authorisation duration (as before) is a maximum of one year after expiry of the active substance approval.[30]

In future, where the contained active substances are approved without a time limit, the application for renewal of the authorisation is to be submitted at the latest nine months before expiry of the authorisation. Otherwise, the existing rule is to remain, namely that

[25] CJEU, judgment of 1 October 2019, C-616/17, paras. 99 et seq.
[26] General Court, judgment of 17 May 2018, T-584/13, paras. 157 et seq.; CJEU, judgment of 6 May 2021, C-499/18 P, paras. 81 et seq., 121.
[27] Cf. for example, the Commission's replies to the requests for internal review IR/2025/931238 and IR/2025/378391, available at https://environment.ec.europa.eu/law-and-governance/aarhus/requests-internal-review_en, last accessed on 16 January 2026.
[28] For example, the Commission has so far not acted on Member State requests to initiate an ad hoc review of several active substances regarding the formation of trifluoroacetate (TFA), see Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Legislation, 1–2 October 2025, p. 12, available at https://food.ec.europa.eu/document/download/884895c3-94e2-45ad-8861-ba67b4615401_en?filename=sc_phyto_20251001_ppl_sum.pdf, last accessed on 16 January 2026.
[29] Approval period + 1 year, cf. Article 32(1) of Regulation (EC) No 1107/2009.
[30] Article 32(1) of Regulation (EC) No 1107/2009 (Draft).

the application must be submitted within three months after renewal of the active substance approval.[31] However, the processing time limit is to be 12 months after submission of the application for renewal of the product authorisation, rather than – as previously – 12 months after renewal of the active substance approval.[32]

The possibility for Member States to review product authorisations ad hoc under Article 44 of Regulation (EC) No 1107/2009 and, where appropriate, to withdraw them is to remain – just like the parallel rule in Article 21 at active substance level. The provision is also to be supplemented by an obligation to adapt authorisations following a targeted review pursuant to Article 18a.[33] For the reasons set out above, this cannot replace a full review of the authorisation on the basis of the latest state of science and technology.

2. Simplification of temporary approvals of active substances

Under Article 4(7) of Regulation (EC) No 1107/2009, an active substance may, by way of derogation, be approved on a temporary basis for a maximum of five years even though it does not meet the approval criteria. To date, this requires "documented evidence included in the application" demonstrating that the active substance is necessary to control a "serious danger to plant health which cannot be contained by other available means including non-chemical methods". Given the strict requirements, this provision has not yet been used.[34]

According to the Commission proposal, these requirements are to be watered down.

The proposal provides that the derogation is also to apply in the event of a serious danger to "plant production" (no longer only "plant health").[35] The term "plant production" is neither used nor defined anywhere in Regulation (EC) No 1107/2009. Its inclusion tends to extend the scope to problems that do not primarily concern the health of plants but rather the quantity of production. .

In addition, the proposal shifts the focus to the lack of "reasonable" alternatives rather than on the lack of objectively "available" other means. This softer standard threatens to

[31] Article 43(2) of Regulation (EC) No 1107/2009 (Draft).
[32] Article 43(5) of Regulation (EC) No 1107/2009 (Draft).
[33] Article 44(1a) of Regulation (EC) No 1107/2009 (Draft).
[34] PAN Europe, fn. 15, p. 3.16
[35] Article 4(7) of Regulation (EC) No 1107/2009 (Draft).

be used to dismiss existing alternatives as "unreasonable" on the grounds that they require greater effort or entail higher costs. At least, this was the aim of demands made by the agricultural industry.[36] Making the assessment depend on the reasonableness of alternatives would therefore be a gateway for an extensive interpretation of Article 4(7) of Regulation (EC) No 1107/2009 and thus a weakening of the level of protection.

According to the proposal, it would be sufficient for temporary approval that the compelling necessity of the active substance for plant health or plant production becomes apparent during the authorisation procedure. It would no longer no longer be mandatory to document and prove this in the application. The application of Article 4(7) of Regulation (EC) No 1107/2009 could thus also be based on facts that only become known at a later stage. This, too, broadens the scope of this derogation.

Mutagenic substances[37], carcinogenic substances (Cat. 1A/B) [38], substances toxic to reproduction[39] (only Cat. 1A) and substances classified as POP[40], PBT[41] or vPvB[42] are not to fall within the derogation in Article 4(7). However, endocrine-disrupting substances (Annex II, 3.6.5) or reproductive toxic substances of category 1B (Annex II, 3.6.4), as well as substances that do not meet the ecotoxicological criteria set out in Annex II, No. 3.8, and the groundwater-protection criterion in Annex II, No. 3.10 could potentially be temporarily approved under the extended exemption.

Finally, the proposal suggests deleting the seventh subparagraph of Article 4(7) of Regulation (EC) No 1107/2009. This provision requires Member States, when authorizing a plant protection products containing an active substance temporarily approved under Article 4(7), to simultaneously draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods and submit it to the Commission. The removal of this provision is detrimental from an environmental and health protection perspective.

[36] IVA, Simplification of food and feed safety legislation - The opinion of the Industrieverband Agrar e.V., October 2025, p. 6.
[37] Cf. Annex II, point 3.6.2 of Regulation (EC) No 1107/2009.
[38] Cf. Annex II, point 3.6.3 of Regulation (EC) No 1107/2009.
[39] Cf. Annex II, point 3.6.4 of Regulation (EC) No 1107/2009.
[40] Cf. Annex II, point 3.7.1 of Regulation (EC) No 1107/2009.
[41] Cf. Annex II, point 3.7.2 of Regulation (EC) No 1107/2009.
[42] Cf. Annex II, point 3.7.3 of Regulation (EC) No 1107/2009.

3. Extended privileges and exemptions for certain substances

The central objective of the proposal is to improve access to and availability of "sustainable plant protection products".[43] The Commission proposal therefore contains several provisions intended to facilitate market access for allegedly more sustainable substances. These proposed significant facilitations in the approval and authorisation procedure seem partly problematic, because there is a risk that also harmful substances could benefit from them.

a. Biocontrol substances

The proposal would introduce far-reaching privileges in favor of biocontrol substances.

aa. Definition

Under the proposed legal definition, "biocontrol substances" encompass microorganisms, “inorganic substances as occurring in nature, with the exception of heavy metals and their salts” and “substances of biological origin or produced synthetically that are functionally identical and structurally similar to them".[44]

This definition is too broad. The fact that it covers not only naturally occurring substances used directly for plant protection, but also substances merely of biological origin and synthetically produced substances, raise concerns that problematic substances could be included in some cases.

The active substance Spinosad for example is obtained from a bacterium and is therefore of natural origin,.[45] but at the same time is a highly effective broad-spectrum insecticide that is not unproblematic from an ecological perspective.[46]

Another problem is that the suggested definition covers synthetically produced substances that are functionally identical and structurally similar to naturally produced substances. There is a concern that even synthetic pyrethroids (insecticides), which are

[43] Recital 4 of the draft amending regulation.
[44] Article 3(35) of Regulation (EC) No 1107/2009 (Draft).
[45] https://de.wikipedia.org/wiki/Spinosad.
[46] The approval of the active substance Spinosad was granted subject to the condition that Member States pay particular attention to the protection of aquatic organisms and earthworms and, where appropriate, lay down risk mitigation measures; cf. the Annex to Commission Implementing Regulation (EU) No 540/2011.

based on the main active ingredients of the natural insecticide pyrethrum,[47] could qualify as a biocontrol substance. These substances cannot be assumed to be a low risk to the environment and health. Some pyrethroids (e.g. cypermethrin) are even classified as candidates for substitution due to their hazardousness.

The definition of biocontrol substances would therefore urgently need to be drafted more narrowly and more concretely, so that only harmless substances are covered.[48]

bb. Privileges for biocontrol substances

The proposal allows for several regulatory privileges for biocontrol substances:

(1) Acceleration of the active substance approval procedure

Because some Member States currently do not have sufficient expertise to assess biocontrol substances, the Commission suggests that applications for the approval of these substances may be submitted directly to EFSA.[49] .

In addition, the approval process is to be accelerated by requiring the rapporteur Member State to give priority to applications for the approval of biocontrol substances.[50]

Even if facilitating market access for less harmful products appears sensible in principle, this must not lead to delays in the necessary review of approved synthetic active substances.

(2) Acceleration of product authorisation and mutual recognition

As regards the national authorisation of plant protection products that contain exclusively biocontrol substances, the EU is to be treated as a single zone.[51] In the zonal authorisation procedure, one Member State proposed by the applicant shall evaluate the application taking into account all zones, [52] so that separate assessments for the three different zones are no longer required. Similarly, mutual recognition under Article 40 should not

[47] https://de.wikipedia.org/wiki/Pyrethroide.
[48] See also PAN Europe, fn. 15, p. 5, with a concrete proposal for a narrower definition.16
[49] Article 7(1) of Regulation (EC) No 1107/2009 (Draft), recital 8 of the draft amending regulation.
[50] Article 11(1a) of Regulation (EC) No 1107/2009 (Draft).
[51] Article 3(17) of Regulation (EC) No 1107/2009 (Draft).
[52] Article 33(2) (b) of Regulation (EC) No 1107/2009 (Draft).

be limited to recognition within a zone but should be permitted regardless of which zone the reference Member State belongs to.[53]

These privileges assume that plant protection products containing exclusively biocontrol substances do not pose different risks in the individual Member States.[54] However, given the very broad definition, it cannot be assumed that only environmentally compatible substances fall within the concept of biocontrol substances. Accordingly, it cannot be assumed that these products are harmless throughout the European Union.

In order to speed up the authorisation process, plant protection products containing exclusively biocontrol substances as active substances are suggested to have priority in the authorisation procedure.[55]

Partly, the authorisation can even be assumed: according to the Commission proposal, where a plant protection product contains only biocontrol substances as active substances and the Member States concerned have not adopted a decision after 120 days,authorisation shall be deemed as having been granted by the Member States.[56] Similarly, mutual recognition is to be deemed to have taken place if no decision on the recognition has been taken within 120 days.[57] A "decision" within the meaning of these proposals is likely to require not just any reaction by the authority, but a final authorisation or refusal. In light of the staff shortages in Member State authorities,[58] this amount to a problematic partial waiver of the authorisation requirement.

This is highly concerning, because even natural substances, such as microbial organisms, can entail risks,[59] and the proposed definition of biocontrol substances encompasses too many problematic substances. It is therefore of great importance that these substances are subject to a thorough risk assessment and can be subject to national risk management.

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[53] Article 40(1) (c) of Regulation (EC) No 1107/2009 (Draft).
[54] Recital 10 ofthe draft amending regulation.
[55] Article 37(6) of Regulation (EC) No 1107/2009 (Draft), EEC 7 Draft amending regulation.
[56] Article 37(5) of Regulation (EC) No 1107/2009 (Draft).
[57] Article 42(3) of Regulation (EC) No 1107/2009 (Draft).
[58] Which are highlighted by the Commission itself COM (2025) 1030 final, Explanatory Memorandum, pp. 1, 20.
[59] In this regard, PAN Europe notes that microorganisms have the potential to survive, multiply, move and colonize new environments, with possible unintended impacts on biodiversity; see PAN Europe, fn. 15, pp. 5-6.16

(3) Provisional authorisations

For the same reasons, the proposal to enable provisional authorizations for plant protection products containing one or more biocontrol active substances that have not yet been approved[60] can be seen critically.

These provisional authorizations would only be possible if the draft assessment report of the rapporteur Member State concludes that the substance can be approved. However, given that the rapporteur Member State is proposed by the applicant itself,[61] the peer review procedure the EFSA[62] is an important step that should not be waived.

In addition, the envisaged validity period of a provisional authorisation of up to five years appears too long and unjustified, since it can be assumed that the peer-review procedure can be completed within a shorter time frame.

(4) Exemption from the recording obligation

To reduce the administrative burden for farmers, it is suggested that biocontrol substances are to be exempted from the obligation imposed on professional users to keep records for three years of the plant protection products used. As a result, farmers will no longer be required to record the name of the plant protection product, the date of use, the quantity used, the area treated and the crop for which the plant protection product was used.[63]

From an environmental protection perspective, this exemption is problematic. As explained above, it cannot be assumed that all biocontrol substances that would fall under the suggested definition are entirely harmless. In addition, without an obligation to record all applications of plant protection products, it would not be possible to effectively verify compliance with the mandatory principles of integrated pest management.[64] Moreover, where environmental damage occurs, it will become significantly more difficult to trace which products were used and thereby caused the damage.

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[60] Article 30 of Regulation (EC) No 1107/2009 (Draft).
[61] Article 7(1), third subparagraph, of Regulation (EC) No 1107/2009.
[62] Cf. Article 12 of Regulation (EC) No 1107/2009.
[63] Article 67 of Regulation (EC) No 1107/2009 (Draft).
[64] Cf. Article 55 of Regulation (EC) No 1107/2009 in conjunction with Article 14 and Annex III to Directive 2009/128/EC.

b. Privileges for low-risk active substances

Further facilitations are envisaged for plant protection products containing low-risk active substances. For these products, the obligation to accelerate the authorisation procedure and the concept of tacit authorisation set out in Articles 37 and 42 of Regulation (EC) No 1107/2009 (Draft) would apply as well.

At present, classification as a low-risk active substance requires that the active substance meets the criteria in Article 4 and Annex II, point 5, of Regulation (EC) No 1107/2009, which sets out certain hazard-based cut-off criteria. These requirements are to be maintained.

However, the additional requirement currently applicable under Article 22(1) of Regulation (EC) No 1107/2009, according to which also the plant protection products containing the substance of low-risk must be of low risk to human and animal health and the environment, is to be deleted. This suggested removal is justified with the argument that, at the time of approval or renewal of approval, it is not known whether the criteria for low-risk products under Article 47 of Regulation (EC) No 1107/2009 are met or not.[65] The proposal therefore suggests to focus only on the intrinsic properties of the active substance.[66]

This removal of the product-related element is highly problematic, particularly in the light of the fact that national authorisation controls for products containing low-risk active substances are to be relaxed and authorisation can be simulated.

In addition, the Commission suggests introducing the possibility of applying retrospectively for low-risk status.[67]

c. Privileges for basic substances

Another category of privileged substances are so-called basic substances. These are substances that are not primarily used for plant protection but are nevertheless useful

[65] Recital 12 of the draft amending regulation.
[66] Ibid.
[67] Recital 12 of the draft amending regulation, Article 7 Regulation (EC) 1107/2009 (draft).

for plant protection. In the past, this category included, for example, baking powder, sugar, fructose or vinegar.[68]

Already under the current regulatory framework, basic substances benefit from certain privileges, in particular a simplified approval procedure and unlimited approval duration.[69] Qualification as a basic substance currently requires, inter alia, that the substances are not substances of concern[70], that they cannot cause endocrine-disrupting, neurotoxic or immunotoxic effects, and that they are not marketed as plant protection products.[71]

The Commission wants to amend these rules, claiming that the previous rules on basic substances were unclear and made basic substances less available to farmers.[72] A definition of the term "basic substances" is proposed that would encompass active substances that are not predominantly used for plant protection purposes, including foodstuffs and substances assessed under other Union legislation, but are still useful in plant protection.[73] Suggested is a specification, which uses are covered by qualification as a basic substance (as distinct from an active substance for plant protection products). In addition to direct use of the basic substance, also formulations that contain, as a simple diluent, another basic substance or "substances necessary to stabilize the product". Here, again, it must be doubted whether this wording ensures that no problematic substances are used in the formulation.

According to the Commission proposal, basic substances are to be further privileged by exempting not only their use but also the placing on the market of basic substances from the requirement of national authorisation; this exemption is also to apply to products within the meaning of Article 23(1) of Regulation (EC) No 1107/2009 (Draft).[74]

From an environmental and public health perspective, the planned removal of the national authorisation requirement for the placing on the market of products containing

[68] BVL, Genehmigung von Grundstoffen, available at https://www.bvl.bund.de/DE/Arbeitsbereiche/04_Pflanzenschutzmittel/03_Antragsteller/09_GenehmigungGrundstoffe/psm_GenehmGrundstoffe_node.html, last accessed on 13 January 2026.
[69] Article 23(1) of Regulation (EC) No 1107/2009.
[70] Under Article 3(4) of Regulation (EC) No 1107/2009, a "substance of concern" means any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a plant protection product in sufficient concentration to present risks of such an effect.
[71] Article 23(1), second sentence, of Regulation (EC) No 1107/2009.
[72] Cf. Recital 13 of the draft amending regulation.
[73] Article 3 No 36 of draft amending regulation.
[74] Article 28(2) (a) of Regulation (EC) No 1107/2009 (Draft).

basic substances entails risks. The approval of the individual basic substance does not make a specific risk assessment for the product unnecessary, because the formulation can be more harmful than the basic substance considered in isolation. Moreover, even for basic substances, it must be noted that the dose makes the poison. It therefore cannot be assumed that products containing basic substances are harmless in every conceivable application and thus not require risk management.

The Commission proposal includes product-related assessments partly at the basic substance approval- The suggested criteria for approval as a basic substance are the following: first, the basic substance must not be a substance of concern, or the product must not fall under hazard classification pursuant to Regulation (EC) No 1272/2008. Second, the basic substance, or the product containing it, must not have endocrine-disrupting, neurotoxic or immunotoxic effects. Third, it must not be an active substance approved for use in plant protection products, and no such approval procedure may be pending. Fourth, the basic substance, or the product in which it is used, must not have immediate or delayed harmful effects on human and animal health or unacceptable effects on the environment. [75] Moreover, under the Commission proposal an application for classification as a basic substance must also contain information on intended uses and proposed conditions of use.[76]

However, this product reference is then devalued again by the proposal, that approval of a basic substance is to cover all approved uses and products and is not limited by the uses applied for. [77] This would mean that only some uses and formulations are actually subject to a risk assessment, while for the rest compliance with the substantive approval criteria in Article 23 of Regulation (EC) No 1107/2009 would be presumed.

d. Privileges for plant protection products required to prevent the establishment or spread of certain quarantine pests

The Commission proposal provides for simplifications for substances required to prevent the introduction and spread of certain pests pursuant to Regulation (EU) 2016/2031. For these substances, the European Union is to be treated as a single zone; authorisation is

[75] Article 23(2) of Regulation (EC) No 1107/2009 (Draft).
[76] Article 23a(1) of Regulation (EC) No 1107/2009 (Draft).
[77] Article 23a(4) of Regulation (EC) No 1107/2009 (Draft).

to be carried out by one Member State for the entire zone. [78] In addition, an accelerated procedure is also to apply here, under which the assessing Member State must endeavor to take a decision as quickly as possible and, in any event, within six months.[79]

Here too, a restrictive formulation of the uses covered is necessary to ensure that the derogation is not used to circumvent certain requirements of Regulation (EC) No 1107/2009.

4. Possibility for the RMS to seek EFSA support

To accelerate the initial approval procedure, the Commission proposal provides that the rapporteur Member State may request EFSA to provide technical or scientific support in assessing the application for approval.[80] This provision is intended to support Member States that do not have sufficient technical or scientific expertise.[81]

This proposal seems reasonable, provided that the independence of the experts is ensured and any conflicts of interest of the experts involved in the assessment are excluded.

5. Extension of grace periods

The proposal also provides for an extension of grace periods.

a. Rules on transitional periods at active substance level

At present, where the approval of an active substance is not renewed, the non-renewal Regulation may provide for a grace period of up to 18 months (6 months for distribution and sale, plus 12 months for disposal and use of existing stocks). However, according to the clear wording of the legislation, this option exists only 'where the reasons for not renewing the approval do not concern the protection of health and environment'.[82] Conversely, where renewal is refused for reasons relating to environmental and health

[78] Article 3(17), Article 33(2) (b); for mutual recognition, cf. Article 40(1) (c) of Regulation (EC) No 1107/2009 (Draft).
[79] Article 37(7) of Regulation (EC) No 1107/2009 (Draft).
[80] Article 11(2), fourth subparagraph, Regulation (EC) No 1107/2009 (Draft).
[81] Recital 17 of the draft amending regulation.
[82] Article 20(2), first subparagraph, Regulation (EC) No 1107/2009.

protection, no such transitional period may be set. This is currently disregarded by the Commission.

Under the proposed amendment, the 18-month grace period would apply irrespective of the reason for non-renewal or restriction, and thus also where there are concerns regarding environmental and health safety. The Commission's current practice (which is not compliant with the Regulation) would therefore be legalised.[83] In addition, transitional periods of a total of three years would be permissible where no other available, 'reasonable' alternatives to plant protection products containing the active substance concerned exist. Given the vagueness and breadth of the concept of 'reasonable' alternatives, there is a risk that the total transitional period of three years will become the rule rather than the exception. Plant protection products could be used for a substantial period even though their harmfulness to health and the environment has been proven. Compared to the status quo, this would constitute a worrying extension of transitional periods.

Article 20(2), second subparagraph, of Regulation (EC) No 1107/2009 requires the immediate cessation of placing plant protection products on the market (and use) where there is an 'immediate concerns for human health or animal health'. The Commission proposal would further restrict this possibility by requiring that the concern for health and the environment must also be 'serious'. This further raises the legal threshold to the detriment of health and environmental protection.

b. Rules on transitional periods at national level

Article 46 of Regulation (EC) No 1107/2009 concerns the setting of transitional periods by Member States in the event of the withdrawal or restriction of product authorisations.

To date, the first sentence of Article 46 of Regulation (EC) No 1107/2009 provides, in very general terms, that Member States 'may' set transitional periods. This discretion is limited by the rule in sentence 2, according to which the transitional period shall not exceed 6 months for sale and distribution and, in addition, no more than 1 year for disposal, storage and use of existing stocks of the plant protection product concerned, 'where the reasons for withdrawal, amendment or non-renewal of the authorisation are not related to the protection of human and animal health or the environment'. This means that, conversely, where an authorisation is terminated for reasons of environmental or health

[83] See also PAN Europe, fn. 15, p. 4.16

protection, transitional periods are not permissible. This provision, too, is incorrectly applied in the national enforcement practice.[84]

Under the Commission proposal, in cases where a Member State withdraws or amends an authorisation or does not renew it, as a result of a non-renewal or withdrawal of the active substance approval, Member States shall set a grace period within the limits of the maximum grace period set by the Commission. Where an authorisation is terminated for other reasons, Member States 'may' provide for a grace period of in total one year. The current limitation of this option to reasons not relating to environmental and health protection would thus be removed. As a result, transitional periods of up to 18 months would also be permissible where health and environmental protection are affected. This lowers the level of protection.

Member States would still be able to set shorter transitional periods or none at all. However, given the existing practice in implementing Article 46 of Regulation (EC) No 1107/2009, there is no guarantee that Member States will make use of this option.

6. Freezing the state of scientific knowledge

The proposal foresees a far-reaching adjustment of the legal standard against which applications for product authorisation are to be assessed.

A new sentence in Article 36(1) dirst subparagraph of Regulation (EC) No 1107/2009 is to provide that, for the active substances contained in the plant protection product, Member States “shall rely on the last assessment conducted at EU level”.

This means that the state of knowledge to be taken into account is frozen at the time of the last approval of the active substance. However, this point in time may lie far in the past, particularly if the proposed abolition of the periodic renewal of active substance approvals is implemented. National authorisation authorities would have to ignore scientific findings known to them on harmful effects on health and the environment in the authorisation procedure if these relate to the active substance.

[84] Cf. Higher Administrative Court of Lower Saxony (OVG Lüneburg), order of 3 November 2025, 10 ME 124/25, not published: The court clarifies that the national authorities must exercise their discretion when setting sell-out and use-up periods.

The implementation of this proposal would result in a significant reduction in the level of protection and would contradict the findings of the ECJ that the authorities of the Member States are obliged to take into account the latest scientific and technical findings when authorising plant protection products.[85]

Furthermore, it is unclear how findings on the active substance can be clearly distinguished from findings on individual products. Many of the effects of the active substance on the environment and health can only be determined by considering formulations, which is why representative formulations are also included in the assessment at the level of active substance approval.

The proposed provision would also lead to a problematic divergence in the state of knowledge to be taken into account: although the data requirements for active substances[86] and for plant protection products[87] are largely identical, an outdated state of knowledge would have to be applied regarding the data for active substances, whereas the latest state of knowledge would be relevant for plant protection products. This would lead to inconsistencies in risk assessment.

While the proposal provides that updates of the state of knowledge may also be taken into account with regard to active substances ('unless it considers an update is necessary in the light of current scientific and technical knowledge'), in such a case the Member State may only request the Commission to act under Articles 18, 18a or 21 of Regulation (EC) No 1107/2009.[88] The recitals explain that this adjustment is intended to ensure that findings can be assessed in a 'harmonised manner'.[89]

This 'detour' via the review of the active substance approval would mean that new scientific evidence on active substances could only be taken into account with a considerable time delay. For instance, if new scientific evidence on the endocrine-disrupting properties of an active substance approved for an unlimited period becomes available, the Member State would first have to persuade the Commission to adopt an implementing

[85] CJEU, judgment of 25 April 2024, Joined Cases C-309/22 and C-310/22, paras 81, 83 and 100.
[86] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.
[87] Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.
[88] Article 36(1), first subparagraph, second sentence, Regulation (EC) No 1107/2009 (Draft).
[89] Recital 18 of the draft amending regulation.

Regulation under Articles 18 and 18a of Regulation (EC) No 1107/2009, for which no specific deadlines are provided, or to initiate a review under Article 21 of Regulation (EC) No 1107/2009. The review would then still have to be carried out, which can take several years. The incorporation of new scientific findings would be significantly delayed.

Irrespective of this delay, it must be feared that the Commission claims a very wide discretion with regard to the application of Articles 18 and 18a of Regulation (EC) No 1107/2009 (Draft) and Article 21 of Regulation (EC) No 1107/2009.

7. Adjustments to the procedure for mutual recognition

To be welcomed is the proposal that mutual recognition of an authorisation is made subject to the additional condition that the authorised product is actually placed on the market in the reference Member State.[90] This is intended to prevent abuse of the mutual recognition system in view of the differing fees that Member States set for granting authorisations for plant protection products.[91]

A further extension of the scope of mutual recognition would result from the proposal that official or scientific bodies engaged in agricultural activities, or agricultural professional organisations should in future be able to apply for the mutual recognition of an authorisation even without the company's consent[92] and that the existing requirement to demonstrate a public interest in the use is deleted.[93]

Particularly problematic is the deletion of the current requirement to attach to the application a complete dossier or a summary dossier, as well as the assessment report of the reference Member State and its authorisation decision.[94] These documents are essential for an assessment within the meaning of Article 41(1) of Regulation (EC) No 1107/2009, which, inter alia, requires account to be taken of the conditions in the territory of the Member State granting recognition. The explanatory memorandum to the proposal notes that the authorities of the Member State granting recognition can obtain these documents directly from the reference Member State.[95] However, this increases the administrative burden (which is supposed to be reduced) and is contrary to the principle that the

[90] Article 40(1)(a) and (b), Regulation (EC) No 1107/2009 (Draft).
[91] Recital 20 of the draft amending regulation.
[92] Recital 21 of the draft amending regulation.
[93] Article 40(2), Regulation (EC) No 1107/2009 (Draft).
[94] Article 42(1), second sentence, Regulation (EC) No 1107/2009 (Draft).
[95] Recital 21 of the draft amending regulation.

applicant must submit the necessary documents. In addition, this additional procedural step, whereby the authority must first obtain the necessary documents, further shortens the already tight recognition period of 120 days.[96]

There are also particular concerns regarding the planned legal fiction of authorisation for plant protection products containing biological control agents and low-risk active substances (see above under C.I.3.a.bb.(2)).

8. Treatment of treated seed and plant reproductive material

The proposal suggests amending the provisions governing the treatment of treated seeds.

At present, the placing on the market and use of plant protection products used for seed treatment require a national authorisation decision under Article 28(1) of Regulation (EC) No 1107/2009. Under the Commission proposal, the placing on the market and use of treated seed and plant reproductive material would be exempted from this authorisation requirement, provided that the treatment was carried out with plant protection products authorised for that use in at least one Member State.[97] This would potentially allowto treat seed domestically with products that do not have a national authorisation but are merely authorised in another Member State. In view of the considerable risks that may arise from the use of treated seed,[98] this cannot be justified. Plant protection products used for seed treatment urgently require thorough national risk assessment and national risk management.

Another problematic aspect is the proposal to further raise the requirements for on internal market trade under Article 49 of Regulation (EC) No 1107/2009 with respect to seed treated abroad. At present, where there are serious concerns that seed treated abroad is likely to present a serious risk to health or the environment, 'measures to restrict or prohibit the use and/or sale of such treated seeds shall be taken immediately'.[99] Under the amending proposal, the adoption of such measures would be left to the Commission's

[96] See Article 42(2), Regulation (EC) No 1107/2009 (Draft).
[97] Article 28(2) (f), Regulation (EC) No 1107/2009 (Draft). It is not specified in the proposal whether this must be a Member State within the same zone; it must therefore be assumed that authorisations from Member States in other zones would also have to be taken into account.
[98] By way of reminder, reference may be made, for example, to the toxicity to bees of seed treated with neonicotinoids.
[99] Article 49(2), Regulation (EC) No 1107/2009.

discretion.[100] Here, too, it is clear that the proposal would reduce the importance of protection concerns.

Furthermore, it is proposed that machines for sowing treated seed would not constitute pesticide application equipment within the meaning of Article 8 of Directive 2009/128/EC.[101] This would mean that the inspection obligations laid down there would not apply. No technical reasons are given for this privilege; according to the recitals, it is intended solely to reduce the administrative burden for farmers.[102]

9. Easier market access for minor uses

The authorisation of minor uses under Article 51 of Regulation (EC) 1107/2009 is also to be facilitated.

The proposal suggests, inter alia, deleting the current requirement that extending the scope of an authorisation to minor uses must be of public interest.[103]

In addition, Member States are to be obliged to take measures to simplify or promote the submission of applications to extend the scope of an authorisation of plant protection products already authorised to minor uses.[104]

Furthermore, the possibility of mutual recognition of a minor use should no longer be subject to the requirement that the use is minor in the reference Member State.[105]

Such relaxations must be viewed critically, because authorisations of minor uses are exempt from some authorisation criteria, such as sufficient efficacy, and therefore do not rely on a comprehensive assessment.

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[100] See Article 49(4), Regulation (EC) No 1107/2009 (Draft).
[101] Article 49(7), Regulation (EC) No 1107/2009 (Draft).
[102] Recital 22 of the draft amending regulation.
[103] Article 51(2), Regulation (EC) No 1107/2009 (Draft).
[104] Art. 51(3) Regulation (EC) No 1107/2009 (Draft).
[105] Article 51(7), Regulation (EC) No 1107/2009 (Draft).

II. Compatibility with higher-ranking law

In shaping EU plant protection product law, the requirements of Article 191(2) in conjunction with Articles 114, 11 and 168 TFEU and Articles 35, second sentence, and 37 CFR, as well as state duties of protection derived from fundamental rights, must be observed.

The proposed amendments give rise to serious doubts as to their compatibility with the precautionary principle based on these provisions and the high level of protection for health and the environment that must be ensured.

1. Article 191 TFEU

The principles laid down in Article 191 are to be regarded as legally binding, fundamental and formative principles of European environmental policy and European environmental law.[106] They must be taken into account not only when interpreting secondary law[107] but also have a binding effect on the Union legislator.[108]

When exercising its powers in the environmental field pursuant to Articles 191 and 192 TFEU, the EU legislature enjoys a broad discretion.[109] Judicial review is limited to determining whether the EU legislature committed a manifest error of assessment.[110]

Article 191(2), first sentence, TFEU imposes on the Union an obligation, in its environmental policy, to aim at a high level of protection. The objective of protecting human and animal health and the environment takes precedence when granting an authorisation for a plant protection product, over the objective of improving plant production.[111] The high level of protection to be ensured in plant protection product law also takes precedence

[106] See, on Article 174 EC: CJEU, judgment of 14 July 1998, C-284/95, para. 36; judgment of 15 June 2002, C-9/00, para. 23.
[107] See in the context of plant protection product law, for example, CJEU, judgment of 6 May 2021, C-499/18 P.
[108] CJEU, judgment of 13 November 1990, C-331/88; judgment of 5 May 1998, C-157/96; judgment of 1 October 2019, C-616/17; General Court, judgment of 11 September 2002, Case T-13/99; judgment of 11 September 2002, Case T-70/99.
[109] Kahl, in: Streinz, EUV/AEUV, 3rd ed. 2018, Article 191 TFEU, para. 74; General Court, judgment of 2 March 2010, T-16/04, para. 143; judgment of 31 January 2024, T-745/20, para. 114.
[110] CJEU, judgment of 1 October 2019, C-616/17, para. 50; judgment of 21 December 2016, C-444/15, para. 46.
[111] CJEU, judgment of 19 January 2023, C-162/21, para. 48; judgment of 25 April 2024, joined Cases C-309/22 and C-310/22, para. 90.

over economic considerations and may therefore justify substantial adverse economic consequences for certain traders.[112]

Pursuant to Article 191(2), second sentence, TFEU, environmental policy is also based on the precautionary and preventive principle. These requirements also give rise to duties of protection on the part of the Union in the field of environmental protection and public health.[113]

According to the case-law of the European Court of Justice concerning Regulation (EC) No 1107/2009, the precautionary principle entails that, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves impossible to determine with certainty the existence or extent of the alleged risk because the results of the studies carried out are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures.[114]

A correct application of the precautionary principle in the field covered by Regulation (EC) No 1107/2009 requires, first, identification of the potentially negative effects of the use of active substances and plant protection products falling within its scope on health and, second, a comprehensive assessment of the health risk on the basis of the most reliable scientific data available and the most recent results of international research.[115]

The EU legislature is required to establish a normative framework enabling the competent authorities, when deciding on authorisations and approvals, to have sufficient information to assess, in a satisfactory manner, the hazards to health arising from the use of those active substances and those plant protection products, in accordance with the precautionary principle and on the basis of the most reliable scientific data available and the most recent results of international research.[116]

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[112] General Court, judgment of 17 May 2018, T-429/13 and T-451/13, paras 323, 106, 289; judgment of 9 September 2011, T-475/07, para. 143; judgment of 6 September 2013, T-483/11, not published, para. 85; judgment of 12 December 2014, T-269/11, not published, para. 138.
[113] CJEU, judgment of 26 June 2019, C-723/17, para. 33.
[114] CJEU, judgment of 1 October 2019, C-616/17, para. 43; cf. to that effect, CJEU, judgment of 22 December 2010, C-77/09, paras 73, 76; judgment of 17 December 2015, C-157/14, para. 81 et seq.; judgment of 22 November 2018, C-151/17, para. 38.
[115] CJEU, judgment of 1 October 2019, C-616/17, para. 46; judgment of 8 July 2010, C-343/09, para. 60; judgment of 22 December 2010, C-77/09, para. 75.
[116] CJEU, judgment of 1 October 2019, C-616/17, para. 47.

The precautionary and preventive principles also imply that environmental pollution must be addressed as a matter of priority through preventive measures, so that environmental damage is prevented rather than merely remedied - including in situations of scientific uncertainty.[117]

2. Article 114 TFEU and Article 11 TFEU

The requirement, under Regulation (EC) No 1107/2009, to maintain a high level of environmental protection is also implemented pursuant to Article 11 TFEU, under which environmental protection requirements must be integrated into the definition and implementation of Union policies and activities, in particular with a view to promoting sustainable development.

Article 114(3) TFEU also provides that, in its proposals for the approximation of laws which have as their object the establishment and functioning of the internal market, the Commission shall take as a base a high level of protection, inter alia in the field of environmental protection, taking account, in particular, of any new development based on scientific facts, and that the Parliament and the Council shall also seek to achieve that objective within the scope of their respective powers.

That protection takes precedence over economic considerations, so that it may even justify substantial adverse economic effects for certain economic operators.[118]

3. Article 37 CFR, Article 168 TFEU and Article 35, second sentence, CFR

Pursuant to Article 37 CFR, a high level of environmental protection and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development. The quality of the environment must therefore not only be preserved but improved.[119]

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[117] Epiney, in: Landmann/Rohmer UmweltR, 108th update (August 2025), TFEU Article 191 para. 23.
[118] General Court, judgment of 19 November 2025, T-94/23, juris para. 76 et seq., with further references.
[119] Jarass, Charta der Grundrechte der EU, 4th ed. 2021, Article 37 para. 6.

Environmental protection and the protection of human health are closely linked in the field of environmental policy.[120] In this context, the European Court of Justice refers to a right to live in an environment that is adequate for an individual's health and well-being.[121]

Regulation (EC) No 1107/2009 also aims to protect human health from plant protection products and is based, inter alia, on the public health legal basis in Article 168(4)(b) TFEU. Accordingly, Article 168(1) TFEU and the identically worded Article 35, second sentence, CFR must also be taken into account, pursuant to which a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

That principle is aimed primarily at the preventive safeguarding of the state of health.[122] In view of the potential health effects of the use of plant protection products, the precautionary principle must therefore also be observed. According to the case law of the European Court of Justice, it must also be applied in public health policy, and likewise where - as here - Union institutions, on the basis of the common agricultural policy or internal market policy, adopt measures to protect human health.[123]

When applying the precautionary principle, it must be borne in mind that health protection has particular weight. The wording of the cross-cutting clause in Article 168(1) ('shall be ensured') goes further than the wording of other cross-cutting clauses, for example in Articles 9, 11 or 12 TFEU, which merely provide for the integration or consideration of the relevant interest.[124] Article 168(1) TFEU and Article 35, second sentence, CFR must therefore be understood as an optimisation requirement. The greatest possible level of health protection must be realised; health protection interests are to prevail as far as possible.[125]

Accordingly, the case law of the Court of Justice shows that the protection of health must be given priority over economic considerations.[126]

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[120] CJEU, judgment of 25 June 2024, C-626/22, para. 68.
[121] CJEU, judgment of 25 June 2024, C-626/22, para. 72.
[122] Jarass, Charta der Grundrechte der EU, 4th ed. 2021, Article 35 para. 9.
[123] CJEU, judgment of 1 October 2019, C-616/17, para. 41, with further references.
[124] Schmidt am Busch, in: Grabitz/Hilf/Nettesheim, EUV/AEUV, 85th update (May 2025), Article 168 TFEU para. 95.
[125] Cf. Schmidt am Busch, in: Grabitz/Hilf/Nettesheim, EUV/AEUV, 85th update (May 2025), Article 168 TFEU para. 95, with further references.
[126] CJEU, judgment of 17 July 1997, C-183/75, para. 43, with further references.

Furthermore, the obligation, provided for in Article 168(1) TFEU and Article 35, second sentence, CFR, to ensure a high level of health protection means that the institutions of the European Union must ensure that their decisions are taken with full account taken of the best available scientific data and are based on the most recent results of international research.[127]

These principles arising from Article 37 CFR, Article 168(1) TFEU and Article 35, second sentence, CFR must be taken into account when applying Article 191 TFEU. Article 52(2) CFR provides that rights recognised by the Charter which are based on the Treaties shall be exercised under the conditions and within the limits defined by those Treaties.[128]

Article 168(1) TFEU and Article 35, second sentence, CFR must also be taken into account when reviewing compliance with the principle of proportionality laid down in Article 5 (4) TEU.

According to settled case law, the principle of proportionality, which forms part of the general principles of EU law, requires that acts of the institutions must not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the measure in question. Where there is a choice between several appropriate measures, the least onerous must be used, and the disadvantages caused must not be disproportionate to the aims pursued.[129]

If, in that balancing exercise, interests of health protection are not taken into account at all or are given incorrect weight, this constitutes a breach of the cross-cutting clause in Article 168(1), first subparagraph, TFEU and/or the principle in Article 35, second sentence, CFR, which goes hand in hand with a breach of the principle of proportionality.[130] In this context, due account must be taken of the principle that the protection of public health takes precedence over economic interests.[131]

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[127] General Court, judgment of 11 September 2002, T-13/99, para. 158.
[128] Cf. CJEU, judgment of 13 March 2019, C-128/17, para. 130 et seq., with further references.
[129] Cf. CJEU, judgment of 8 July 2010, C-343/09, para. 45, with further references.
[130] Cf. the discussion of Article 168(1), first subparagraph, TFEU in Schmidt am Busch, in: Grabitz/Hilf/Nettesheim, EUV/AEUV, 85th update (May 2025), Article 168 para. 103, and of Article 35, second sentence, CFR in Jarass, Charta der Grundrechte der EU, 4th ed. 2021, para. 13; CJEU, judgment of 4 May 2016, C-547/14, para. 156 et seq.
[131] Cf. CJEU, judgment of 19 April 2012, C-221/10 P, para. 99.

4. Duty to protect under Articles 2(1), 3(1) and 7 CFR

In addition, the fundamental rights enshrined in the EU Charter of Fundamental Rights give rise to obligations on the part of the Union to protect life and health, inter alia, from the hazards arising from the use of plant protection products.

For the interpretation of fundamental rights under the Charter, recourse must be had to the case law of the European Court of Human Rights (ECtHR). This is because, for Charter rights, Article 52(3) first sentence CFR provides that they shall have the 'same meaning and scope' as the corresponding rights under the European Convention on Human Rights (ECHR).[132] The ECHR therefore has particular significance where Charter rights overlap with the guarantees of the Convention.[133] The provisions of the ECHR constitute a minimum standard of protection. The protection guaranteed by the Charter may never be less than that afforded by the ECHR.[134]

Pursuant to Article 2(1) CFR, everyone has the right to life. Article 2(1) CFR - like the corresponding Article 2 ECHR - requires those bound by fundamental rights to protect life through active measures.[135] Article 2 ECHR must also be relied upon for the shaping of that fundamental right as a duty of protection in environmental law.[136]

Under Article 3(1) CFR, everyone has the right to respect for his or her physical and mental integrity. Article 7 CFR guarantees everyone the right to respect for his or her private and family life, home and communications. By reference to the corresponding Article 8 ECHR, Articles 3(1) and 7 CFR are understood as imposing an obligation to provide protective support for the legal interest of physical integrity and to promote that legal interest - particularly with regard to environmental burdens.[137]

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[132] Jarass, Charta der Grundrechte der EU, 4th ed. 2021, Article 52 para. 56.
[133] CJEU, judgment of 25 March 2004, C-71/02, para. 48; judgment of 3 September 2009, C-402/05, para. 283.
[134] Jarass, Charta der Grundrechte der EU, 4th ed. 2021, Article 52 para. 63, with further references.
[135] Borowsky, in: Meyer/Hölscheidt, Kommentar zur Charta der Grundrechte der Europäischen Union, 5th ed. 2019, Article 2 para. 37; Jarass, Charta der Grundrechte der EU, 4th ed. 2021, Article 2 para. 8.
[136] Borowsky, in: Meyer/Hölscheidt, Kommentar zur Charta der Grundrechte der Europäischen Union, 5th ed. 2019, Before Title I para. 9, Article 2 para. 38; Jarass, Charta der Grundrechte der EU, 4th ed. 2021, Article 2 para. 8.
[137] Jarass, Charta der Grundrechte der EU, 4th ed. 2021, Article 3 para. 10; Callies, in: Callies/Ruffert, 6th ed. 2022, EU-GrCH, Article 3 para. 11, Article 7 para. 32; Borowsky, in: Meyer/Hölscheidt, Kommentar zur Charta der Grundrechte der Europäischen Union, 5th ed. 2019, Article 3 para. 39.

For the purposes of specifying these duties of protection, recourse must be had to the ECtHR's case-law on the positive obligations arising from Articles 2 and 8 ECHR.

According to the case law of the ECtHR, Article 2 ECHR entails a positive obligation to take appropriate steps to safeguard life - both in respect of acts of public authorities and of private actors.[138]

According to the ECtHR, Article 8 ECHR gives rise to a duty to protect against environmental pollution, which applies well below the threshold of a risk to life. The ECtHR justifies this on the basis that severe environmental pollution may affect individuals' well-being and may lead to such a serious impairment of the enjoyment of their homes that it affects their private and family life, without necessarily endangering their health.[139] That duty applies both in cases where pollution is directly caused by the State and in cases where its responsibility is the result of a failure to regulate private activities of third parties adequately.[140]

With regard to climate change, the ECtHR has only recently held that Article 8 ECHR encompasses an individual right to effective protection by the public authorities against serious adverse effects of climate change on his or her life, health, well-being and quality of life.[141] The same applies in relation to environmental protection.

While the scope of the duties of protection depends on the circumstances of the individual case,[142] the measures to protect life and health and private and family life must nevertheless be effective.[143]

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[138] ECtHR, Öneryıldız, judgment of 30 November 2004, no. 48939/99, paras 71, 89 et seq.; Budayeva and Others, judgment of 20 March 2008, nos. 15339/02 et al., para. 128 et seq.; Nicolae Virgiliu Tanase, judgment of 25 June 2019, no. 41720/13, paras 140 et seq.
[139] Cf. ECtHR, Fadeyeva, judgment of 9 June 2005, no. 55723/00, para. 87; López Ostra, judgment of 9 December 1994, no. 16798/90, para. 51; Jugheli and Others, judgment of 13 July 2007, no. 38342/05, para. 71.
[140] ECtHR, Frankowski and Others, decision of 20 September 2011, no. 25002/09.
[141] ECtHR, Climate Seniors and Others, no. 53600/20, para. 519.
[142] Settled case-law, ECtHR, Kolyadenko and Others, judgment of 28 February 2012, nos. 17423/05 et al., paras 160 et seq.; Budayeva and Others, judgment of 20 March 2008, no. 15339/02, paras 136-137; Vilnes and Others, judgment of 5 December 2013, nos. 52806/09 and 22703/10, para. 220.
[143] See, on Article 2 ECHR: ECtHR, Brincat and Others, judgment of 24 July 2014, no. 60908/11, para. 79; likewise ECtHR, L.C.B., judgment of 9 June 1998, no. 14/1997/798/1001, para. 36. See, on Article 8 ECHR: ECtHR, Oluić, judgment of 20 May 2010, no. 61260/08, paras 48 et seq., 64 et seq.; Moreno Gómez, judgment of 16 November 2004, no. 4143/02, para. 55.

The establishment of an effective legal and administrative framework is of particular importance. The ECtHR derives from the positive obligations under Articles 2 and 8 ECHR a duty on the State to put in place a legislative and administrative framework ensuring effective prevention of harm to the environment and to human health and life.[144] Only under certain specific circumstances may it be assumed that positive obligations are met in practice even in the absence of relevant statutory provisions.[145]

Where environmental protection standards have been enacted, there is a violation of the Convention if they fail to strike a fair balance between the competing interests.[146]

The European Union's action or failure to act must also be assessed against that standard.

5. Application to the proposed amendments

Applying those principles to the amendments proposed by the Commission, there are serious doubts as to their compatibility with higher ranking law.

In the Blaise case, the European Court of Justice already had to rule on the compatibility with primary law of Regulation (EC) No 1107/2009. The Court emphasised that, when adopting rules on the placing on the market of plant protection products, the EU legislature must comply with the precautionary principle and ensure a high level of health protection:

> "There is therefore an obligation on the EU legislature, when it adopts rules governing the placing on the market of plant protection products, such as those laid down in Regulation No 1107/2009, to comply with the precautionary principle, in order to ensure, in particular, in accordance with Article 35 of the Charter of Fundamental Rights of the European Union and Article 9 and Article 168(1) TFEU, a high level of -protection of human health (see, by analogy, judgment of 4 May 2016, Pillbox 38, C-477/14, EU:C:2016:324, paragraph 116)."
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> CJEU, judgment of 1 October 2019, C-616/17, para. 42; see also General Court, judgment of 19 November 2025, T-412/22, juris, para. 46

[144] ECtHR, Brincat and Others, judgment of 24 July 2014, no. 60908/11, para. 112; Cordella and Others, judgment of 24 January 2019, no. 54414/13, para. 159; Moreno Gómez, judgment of 16 November 2004, no. 4143/02, para. 55; judgment of 9 April 2024, Climate Seniors and Others, no. 53600/20, para. 545; on Article 2: Öneryıldız, judgment of 30 November 2004, no. 48939/99, para. 89.
[145] ECtHR, Brincat and Others, judgment of 24 July 2014, no. 60908/11, para. 112.
[146] ECtHR, Fadeyeva, judgment of 9 June 2005, no. 55723/00, para. 132 et seq.

In that judgment, the Court interpreted the safeguards laid down in Regulation (EC) No 1107/2009 in a protection-oriented manner and in accordance with the precautionary principle, and, based on that restrictive interpretation, upheld the Regulation as compatible with primary law.

The Commission proposal provides for a significant lowering of the level of protection achieved by Regulation (EC) No 1107/2009. It is therefore questionable whether, if this proposal were to be implemented, the Court would still conclude that the Regulation complies with the principles of precaution and a high level of protection.

a. Indefinite approval of active substances

Significant legal concerns are raised by the proposal to grant approvals for plant protection product active substances with an unlimited duration.

In its current form, that proposal would mean that, the regular reevaluation of risks to the environment and human health would be removed for the vast majority of active substances.

However, as the European Court of Justice has emphasized in the Blaise-ruling, the precautionary principle requires that potential adverse effects on health be identified and subjected to a comprehensive assessment based on the most reliable scientific data available and the most recent results of international research.[147]

Those requirements are not met if an active substance approval is assessed only once and is then no longer updated in line with scientific and technical progress.

The high level of protection required under primary law pursuant to Articles 114(3), 168(1) and 191(2) TFEU is also unlikely to be maintained if such a far-reaching waiver of adaptation to scientific progress is granted. These principles require measures ensuring that existing approvals are reviewed regularly in the light of current scientific data.

No such safeguards are foreseen in the proposal. The provisions in Articles 18 and 18a of Regulation (EC) No 1107/2009 (Draft) cannot ensure that new scientific findings on

[147] CJEU, judgment of 1 October 2019, C-616/17, para. 46 et seq.; judgment of 8 July 2010, C-343/09, para. 60; judgment of 22 December 2010, C-77/09, para. 75.

health and environmental hazards are taken into account in a timely manner. A mere possibility of review provided for in discretionary provisions is insufficient in situations where scientifically proven risks to health and the environment arise. Article 21 of Regulation (EC) No 1107/2009 as well cannot fully compensate for the loss of a regular, systematic full review. That would apply even if the Commission were to abandon its hitherto restrictive approach to applying Article 21, because the possibility (and obligation) of ad hoc review does not render regular comprehensive review, including the generation of new data, dispensable.

The proposal for indefinite approvals also runs counter to the Court's findings that, in the field of plant protection products, the principle of legal certainty must be balanced against the precautionary principle. The Court held that those placing plant protection products on the market must at all times expect that circumstances may come to light showing that an active substance or a plant protection product has harmful effects on the health of humans or animals or unacceptable effects on the environment. The Commission and/or the Member States are required to take such findings into account and, where appropriate, to withdraw the active substance approval or the product authorisation.[148]

b. Freezing the state of scientific knowledge

Serious concerns under primary law are also raised by the proposal to prohibit Member States from taking account of the latest state of science in relation to active-substance data.

As explained above, the proposed rule in Article 36(1) of Regulation (EC) 1107/2009 (Draft) would mean that the national authorities would have to ignore new scientific findings or would only be able to take them into account many years later.

This is incompatible with the precautionary principle and the required high level of protection within the meaning of Article 191(2) TFEU, Article 168(1) TFEU, Article 35 and 37 CFR. The precautionary principle specifically enables and requires action in situations where there are indications of risks to human health and the environment, but the risk cannot yet be established with certainty. The proposal runs diametrically counter to this principle, as it not only fails to provide that action is mandatory, but even prohibits action

[148] CJEU, judgment of 25 April 2024, C-308/22, paras 107–109.

and directs national authorities only to initiate a multi-year review mechanism fraught with uncertainty.

Moreover, the proposal contradicts the findings of the European Court of Justice in its judgments of 25 April 2024 that, when examining authorisation applications, Member States are not confined to particular categories of scientific evidence or to specific points in time when that evidence became available, and that they must assess applications in the light of current scientific knowledge.[149] These findings are not a mere interpretation of secondary law, because the Court also relied on the objective, enshrined in primary law, of ensuring a high level of protection and on the precautionary principle.[150]

In addition, in the Blaise-ruling the Court of Justice explained that the obligation to take account of the latest state of science follows from the precautionary principle anchored in primary law. It therefore cannot be curtailed by an amendment to the Regulation.

c. Waiving prior authorisation and approval for certain substances

The insufficiently defined exemptions that provide for a complete waiver of an authorisation or approval decision are also questionable under primary law. These include, in particular, new exemptions from the authorisation requirement for treated seed and the automated authorisation/recognition for products containing biocontrol substances where the 120-day decision period is exceeded.

The precautionary principle and the principle of ensuring a high level of health protection are aimed at preventive safeguarding of health.[151] Against that background, the requirements in Regulation (EC) No 1107/2009 for prior approval of active substances and prior authorisation of plant protection products give expression to the precautionary principle.[152] Purely ex post control does not satisfy the requirements of the precautionary and preventive principles.

[149] CJEU, judgment of 25 April 2024, C-309/22 and C-310/22, para. 77; C-308/22, para. 91.
[150] CJEU, judgment of 25 April 2024, C-308/22, paras 102 et seq.
[151] Jarass, Charta der Grundrechte der EU, 4th ed. 2021, Article 35, para. 9.
[152] General Court, judgment of 19 November 2025, T-94/23, para. 45, juris; judgment of 17 -March 2021, T-719/17, paras 60 and 61, and the case-law cited-; CJEU, judgment of 22 December 2010, C-77/09, para. 74.

According to the European Court of Justice the harmlessness of plant protection products must not be presumed.[153] That is also reflected in the fact that the applicant must prove that the approval criteria are met.[154]

A waiver of the authorisation requirement, or an automated authorisation upon expiry of the time limit, is not compatible with these findings an the principles of precaution and a high level of protection.

The waiver of the authorisation requirement cannot be justified by the Commission's assertion that the substances are harmless. It cannot generally be assumed that, for example, products containing biological control substances have no harmful effects whatsoever on health and the environment, or that any doubts in that regard are purely hypothetical.

The waiver of the authorisation requirement triggered by the legal fiction in case of exceedance of the 120-day deadline also raises doubts as to the proportionality of the proposal. It is not even suitable for achieving the objectives of the amending regulation. The objective of promoting the accessibility and availability of sustainable plant protection products is not achieved, since the chosen definition does not ensure that only safe plant protection products benefit from the intended privilege. The objective of reducing the burden on national authorities and companies would likewise be promoted by the legal fiction only if, given the short deadline, the national authorities simply "capitulated" and did not even attempt an assessment. If, by contrast, the authorities attempt to process applications within 120 days which must be expected in a state governed by the rule of law - the pressure created by the proposed provision of tacit authorisation would mean that the authorities would have to build up and maintain human resources in order to issue legally secure approval or rejection decisions within the short time available. A streamlining of the authorities is then not to be expected. Even if relieving effects were to be expected and the proposal succeeded in paving the way for more sustainable plant protection products to enter the market, these marginal positive developments would be disproportionate to the significant risks to the environment and human health described above.

[153] CJEU, judgment of 1 October 2019, C--616/17, para. 80.
[154] CJEU, judgment of 1 October 2019, C--616/17, para. 80; judgment of 9 December 2021, C-374/20 P, para. 128; judgment of 22 Jun-e 2023, C-259/22 P, para. 73.

d. Temporary approval of active substances

Similar concerns regarding compatibility with the precautionary principle and the high level of protection are raised by the proposed relaxation of the requirements for temporary approval of active substances in accordance with Article 4(7) of Regulation (EC) No 1107/2009.

As outlined above, the planned focus on the absence of “reasonable” alternatives and on “plant production” creates the risk that this provision could be relied upon even where less harmful alternatives exist but entail greater effort or higher costs.

As a result, even substances that are extremely harmful to health (e.g. endocrine disruptors) could, despite the availability of alternatives, obtain an approval (albeit temporary) on economic grounds.

This is difficult to reconcile with the requirements of primary law under Article 191(2) TFEU, Article 168(1) TFEU, Article 35and 37 CFR. According to the case law of the EU Courts, environmental and health protection must take precedence over economic considerations and the improvement of plant production.[155]

e. Extension of grace periods for disposal/use

It is also questionable whether the provision of sales and use-up periods of up to 18 or even 36 months in cases where the authorisation or approval has been terminated for reasons of environmental and health protection is compatible with primary law.

These transitional periods, which tolerate continued exposure to substances harmful to health and the environment, appear disproportionately long and are incompatible with the high level of protection required by primary law. Furthermore, they are diametrically opposed to the precautionary principle. As explained above, the precautionary principle requires that active substances and plant protection products be withdrawn from the market as soon as there are serious indications of harmful effects on health. This is all the more true when a decision has already been taken not to renew authorisations and approvals for reasons of environmental and health protection.

[155] See CJEU, judgment of 19 April 2012, C-221/10 P, para. 99; judgment of 25 April 2024, C-309/22, para. 90.

The transition periods also violate the principle of proportionality. It is not clear how they contribute to reducing administrative burdens for authorities and companies. The withdrawal of a plant protection product authorisation is a simple administrative act. Its necessity in practice becomes apparent many months in advance. It is therefore not clear why administration would need several months to implement the withdrawal decision. Ultimately, the proposal seems to serve solely economic interests and the objective of improving plant production. That interest must be weighed against the interest in remedying identified risks to human health or the environment. The latter takes precedence.

In light of the foregoing, there are serious doubts as to the conformity of several of the Commission's proposals with primary law.

D. The Commission’s procedural approach and its lawfulness

Despite the expected significant environmental impacts and contrary to the Interinstitutional Agreement and the Better Regulation Guidelines, the Commission did not conduct an impact assessment. This constitutes an infringement of the principles of proportionality, equal treatment and the protection of legitimate expectations (see I. below). That infringement is exacerbated by the decision not to conduct a public consultation (see II. below).

I. Dispensing with an impact assessment

1. The Commission’s approach

The Commission did not conduct an impact assessment of its initiative. By way of justification, it states that a full impact assessment would add no value because the proposed simplification measures are highly technical in nature, there are no viable alternatives to achieve the objectives, and the proposed measures would not alter core policy objectives. In any event, significant cost savings for industry and the authorities are to be expected.[156]

Potential impacts on health and the environment are not mentioned in the section on the impact assessment. In the subsequent remarks on regulatory fitness and

[156] See COM(2025) 1030 final, fn. 5, p. 18.

fundamental-rights relevance, it is merely stated that the proposal would not undermine the protection of human and animal health and the environment.

Under the heading “Ex-post evaluations/fitness checks of existing legislation”, the Commission refers to the accompanying Commission Staff Working Document, which allegedly provides a detailed overview of the positive impacts of the proposed amendments. That overview is said to be based on available data and on information obtained from the “Call for Evidence” conducted from mid-September to mid-October, as well as previous analyses.[157]

The Commission Staff Working Document referred to contains an extensive analysis of the expected cost savings for businesses and the administration. As further positive effects, it mentions a reduced workload for businesses, faster and simpler decision-making by the competent authorities, and greater legal certainty. As regards possible impacts on health and the environment, it merely states that the protection of human and animal health would be maintained or even strengthened. There is no indication that the Commission expected any impacts on those legal interests.

2. Infringement of the Interinstitutional Agreement and the Better Regulation Guidelines

In accordance with point 13 of the Interinstitutional Agreement on Better Law-Making,[158] the Commission will carry out impact assessments of its legislative initiatives that are expected to have significant economic, environmental or social impacts. In doing so, it will consult as widely as possible.

The Commission has set out these Better Regulation principles for its work in the Better Regulation Guidelines[159] (hereinafter: “Guidelines”) and the accompanying Toolbox.[160]

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[157] See COM(2025) 1030 final, fn. 5, p. 17.
[158] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016, OJ L 123, p. 1, available at https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32016Q0512%2801%29, last accessed on 8 January 2026.
[159] European Commission, Better Regulation Guidelines, SWD(2021) 305 final, available at https://commission.europa.eu/document/download/d0bbd77f-bee5-4ee5-b5c4-6110c7605476_en?filename=swd2021_305_en.pdf, last accessed on 8 January 2026.
[160] European Commission, Better Regulation Toolbox, July 2023, available at https://commission.europa.eu/document/download/9c8d2189-8abd-4f29-84e9-abc843cc68e0_en?filename=BR%20toolbox%20-%20Jul%202023%20-%20FINAL.pdf, last accessed on 6 January 2026.

In Chapter 4 of the Guidelines, the Commission notes that an impact assessment is required for Commission initiatives that are likely to have significant economic, environmental or social impacts, or entail significant expenditure, and where the Commission has a choice of different policy options.[161]

In exceptional cases, the Commission may depart from the Guidelines and therefore also dispense with an impact assessment. The exceptions mentioned include political urgency, emergencies, deadlines in the legislative procedure, as well as the need to protect security-related or confidential information.[162] Where such a derogation is granted, an analytical document in the form of a Staff Working Document is to be prepared within three months of the initiative's adoption, presenting the evidence behind the proposal and the cost estimates.[163]

In the present case, the Commission did not carry out an impact assessment and justified this by stating that such an assessment would add no value due to the technical nature of the proposed measures, that there were no viable alternatives for achieving the objective, and that the measures would not alter core policy objectives.

It remains unclear whether the Commission considered that an impact assessment was not required in the first place because no significant economic, environmental or social impacts, or significant expenditure, were expected, or whether it claimed a derogation for itself. The former seems more likely, since in the past the Commission has expressly mentioned reliance on derogations on grounds of urgency.[164] Furthermore, in the present case the Commission indicated in several places that no negative impacts were to be expected.

In any event, its approach is not consistent with the Guidelines.

[161] See European Commission, Better Regulation Guidelines, fn. 159, p. 30.
[162] See European Commission, Better Regulation Toolbox, fn. 160, p. 10; Better Regulation Guidelines, fn. 159, p. 4.
[163] See European Commission, Better Regulation Guidelines, fn. 159, p. 30.
[164] See, for example, COM(2023) 754 final, p. 10; COM(2024) 139 final, p. 6; COM(2025) 80 final, p. 10; COM(2025) 81 final, p. 14.

The proposed amendments are expected to have significant environmental impacts (see above). Both under the Interinstitutional Agreement and under the Guidelines, an impact assessment should therefore in principle have been carried out.

Moreover, the reasons relied upon do not constitute a valid justification for dispensing with an impact assessment by way of derogation. The technical nature of measures may be relevant to the format of consultation, but not to the need for an impact assessment. The consequences of measures do not depend on their technical character. The assertion that there were no alternatives for achieving the objective is simply incorrect. The objective of reducing administrative burdens for businesses and the administration could have been pursued through a range of measures that ought to have been compared precisely in terms of their potential social, economic and environmental effects. Finally, whether the measures alter the core policy objectives could only be assessed after an impact assessment.

Lastly, the Commission also failed to address the expected impacts on the environment and health in its accompanying Staff Working Document, although this would have been required had it relied on a derogation.

3. Legal consequences

a. Violation of the principle of proportionality

Although the rules on impact assessment presumably do not confer any individual rights,[165] the absence of an impact assessment may nevertheless render a legal act unlawful by reason of an infringement of the principle of proportionality.[166]

According to settled case-law, the principle of proportionality forms part of the general principles of EU law and requires that the means employed by EU law provisions be appropriate for attaining the legitimate objectives pursued by the legislation at and must not go beyond what is necessary to achieve them.[167]

[165] General Court, judgment of 31 January 2024, T-745/20, para. 97.
[166] See the legal opinion by Baldon Acovats, Potential legal challenges under EU law to the proposed omnibus directive amending the CRSD and CSDD, 23 June 2025, p. 8 et seq.
[167] CJEU, judgment of 3 December 2019, C-482/17, para. 76.

Despite the broad margin of discretion, the EU legislature is required to base its decision on objective criteria and to examine whether the objectives pursued by the measure chosen can justify the adverse consequences resulting from it.[168] This dictum, formulated with reference to Article 5 of the Protocol (No 2) on the application of the principles of subsidiarity and proportionality in order to justify negative economic consequences, must also apply to adverse consequences for health and environment protection, given that these are enshrined in Art. 11 TFEU and Article 191 TFEU.

In the context of judicial review of the act by the Court of Justice, the EU legislature must be able to show that it has actually exercised its discretion, which presupposes that all relevant factors and circumstances of the situation intended to be regulated by that act have been taken into account.[169] This, in turn, requires a sufficient degree of information to be available in order to assess the proportionality of the measure.[170] If the EU legislature did not have that information, this results in an infringement of the principle of proportionality.[171]

This is where the impact assessments becomes relevant: the Court of Justice has expressly held, with reference to points 12 to 15 of the Interinstitutional Agreement, that the preparation of impact assessments is a step in the legislative process which must be carried out as soon as a legislative initiative is liable to have significant economic, environmental or social impacts.[172] The absence of an impact assessment cannot be classified as an infringement of the principle of proportionality where the EU legislature is in a specific situation requiring it to dispense with such an assessment and has a sufficient degree of information enabling it to assess the proportionality of the measure adopted.[173]

A violation of the principle of proportionality therefore exists, at the very least, where the EU legislature dispenses with an impact assessment despite expected economic, environmental or social consequences and has also not obtained, by other means, the

[168] CJEU, judgment of 3 December 2019, C-482/17, para. 79; judgment of 4 October 2024, C-541/20 to C-555/20, paras 243 and 721.
[169] CJEU, judgment of 3 December 2019, C-482/17, para. 81; judgment of 4 October 2024, C-541/20 to C-555/20, paras 244 and 722.
[170] CJEU, judgment of 4 October 2024, C-541/20 to C-555/20, paras 244 and 722.
[171] CJEU, judgment of 4 October 2024, C-541/20 to C-555/20, paras 244 and 722.
[172] CJEU, judgment of 3 December 2019, C-482/17, para. 82 et seq.; General Court, judgment of 27 November 2024, para. 270.
[173] CJEU, judgment of 3 December 2019, C-482/17, para. 85.

information required to review proportionality.[174] Accordingly, the Court of Justice declared an EU act void in an action for annulment brought by several Member States, because the EU legislature had taken into account the information necessary to assess the factual situation neither in the impact assessment nor by other means.[175]

In the present case, the Commission dispensed with an impact assessment and instead referred to the accompanying Staff Working Document, which was said to set out the positive effects of the Commission proposal. That document contains no indications of possible adverse impacts on the environment and human health.

Nor is it apparent that the Commission identified such impacts outside of an impact assessment to take them into account in the exercise of its discretion. The repeated assertion that the high standards for the protection of human and animal health and the environment is not substantiated at any point in the Commission's proposal.

If the Council and the Parliament also refrain from conducting an impact assessment or otherwise investigating possible environmental and health impacts, it would have to be assumed that these impacts were simply not examined and therefore could not be taken into account in the proportionality assessment. Correspondingly, the proportionality assessment in the statement of reasons of the Commission proposal is very brief and is limited to a single sentence.[176]

In view of the serious adverse effects on the environment and human health which are to be expected, their non-consideration constitutes a misuse of discretion and is incompatible with the principle of proportionality.

b. Violations of the principles of equal treatment and the protection of legitimate expectations

Dispensing with an impact assessment contrary to the Guidelines also gives rise to serious doubts as to compliance with the principle of equal treatment.

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[174] See, on the possibility of relying on other information, among others CJEU, judgement of 13 march 2019, C-128/17, paras 31 et seq., 42; judgment of 3 December 2019, C-482/17, para. 86 et seq.
[175] See CJEU, judgment of 4 October 2024, C-541/20 to C-555/20, para. 738.
[176] "The initiative does not go beyond what is necessary to achieve the objectives of simplification and burden reduction without lowering the protection of human health and environment.", COM(2025) 1030 final, fn. 5, p. 17.

According to the case-law of the Court of Justice, internal measures may form rules of practice from which the administration may not depart in an individual case without giving reasons that are compatible with the principles of equal treatment or the protection of legitimate expectations. Such measures therefore constitute a general and the officials and other staff concerned may invoke their illegality in support of an action against individual measures adopted on their basis.[177]

That case-law can likewise be applied to the Better Regulation Guidelines.[178] As the European Ombudsman correctly points out, stakeholders rely on the Commission's Better Regulation rules and plan their activities in accordance with them. They expect to have access to the Commission's impact assessments and to be able to submit their views on those assessments as early as possible.[179]

Accordingly, with regard to the general legal principles of equal treatment and the protection of legitimate expectations, the failure to carry out an impact assessment, contrary to the guidelines, calls into question the lawfulness of the Commission's approach.

c. Infringement of Article 168(1) TFEU

By virtue of the horizontal clause in Article 168(1) TFEU, all measures must be subjected to a health impact assessment which must take into account the above-mentioned standard of achieving a high level of health protection, for which all developments based on scientific findings must be taken into account.[180] A health impact assessment requires that all measures and projects be evaluated with regard to their potential effects on the health of the individual and/or of the population.[181]

It is not apparent that the Commission identified the effects of its proposal on human health. Apart from the repeated assertion that the proposal would not lower the level of

[177] CJEU, judgment of 28 June 2005, C-189/02 et al., para. 209 et seq.
[178] See also European Ombudsman, Recommendation on the European Commission's compliance with 'Better Regulation' rules and other procedural requirements in preparing legislative proposals that it considered to be urgent (983/2025/MAS – the "Omnibus" case, 2031/2024/VB - the "migration" case, and 1379/2024/MIK - the "CAP" case, recommendation of 25 November 2025, point 38.
[179] European Ombudsman, fn. 178, cited above.
[180] Schmidt am Busch, in: Grabitz/Hilf/Nettesheim, EUV/AEUV, 85th update (May 2025), Article 168 TFEU, para. 93.
[181] Schmidt am Busch, in: Grabitz/Hilf/Nettesheim, EUV/AEUV, 85th update (May 2025), Article 168 TFEU, para. 94.

protection of human or animal health or the environment, there are no comments on this subject.

The failure to carry out an impact assessment despite the expected significant impacts on human health, and thus contrary to the Guidelines, is therefore also contrary to EU law because of the obligation arising from Article 168(1) TFEU.

II. Insufficient stakeholder consultation

1. Approach of the Commission

The Commission did not conduct a public consultation, arguing that that the initiative did not aim to alter the objectives of the legislation and addresses technical adjustments aimed at efficiency gains within the existing framework.[182]

Instead, the Commission stated that it had carried out a proportionate, targeted stakeholder consultation. To that end, it relied on ongoing exchange formats with Member States and stakeholders as well as recent evaluations. In addition, in July 2025 it conducted a targeted Implementation Dialogue on biocides. Furthermore, a "Call for Evidence" was carried out, which generated a total of around 6,500 responses, including 319 position papers with detailed technical input. All of this was said to have been incorporated into the problem definition, the prioritisation of options and the safeguards.[183]

The Commission sets out the positions of the various stakeholder groups, clustered by topic, in the Commission proposal itself on approximately one page, concluding that stakeholders advocate a risk-based simplification which maintains a high level of health, environmental and consumer protection and is underpinned by transparency, independent science and strong enforcement.

The Staff Working Document contains a more detailed presentation of the stakeholders' positions, noting at several points that citizens and NGOs expressed the concern that the level of protection could be reduced.[184]

[182] See SWD(2025) 1030 final, fn. 6, p. 56.
[183] See COM(2025) 1030 final, fn. 5, p. 17; SWD(2025) 1030 final, fn. 6, p. 56.
[184] See SWD(2025) 1030 final, fn. 6, p. 56 et seq.

It is not comprehensible whether and how that concern was taken into account and addressed in the drafting of the Commission's proposal.

2. Infringement of procedural requirements as well as the Interinstitutional Agreement and the Better Regulation Guidelines

Pursuant to Article 11 (3) TEU, the Commission is required to conduct borad consultations with the parties concerned.

Article 2 of Protocol (No 2) on the application of the principles of subsidiarity and proportionality provides that the Commission consult widely before proposing a legislative act. In cases of exceptional urgency, it shall not conduct such consultations and give reasons for its decision in its proposal.

Similarly, point 19 of the Interinstitutional Agreement provides that, before adopting a proposal, the Commission shall carry out public consultations in an open and transparent way and ensure that the modalities and time limits of those public consultations allow for the widest possible participation.

Under the Guidelines, a public consultation of at least 12 weeks is required where an initiative is prepared which is accompanied by an impact assessment. For initiatives that are not accompanied by a public consultation, a Call for Evidence is planned to give stakeholders four weeks to provide their feedback.[185]

The Commission merely launched the Call for Evidence and otherwise asserted that it has taken into account existing findings from its exchanges with interest groups.

The findings already available from the past cannot replace the consultations, as they cannot relate to the Commission's project due to the passage of time.

The Commission limited itself to obtaining feedback in the Call for Evidence. That is consistent with the approach not to conduct an impact assessment. However, it illustrates the effects of the failure to conduct an impact assessment for stakeholder participation: instead of being able to comment on the initiative over a 12-week period and on the basis of extensive material, stakeholders were confined to commenting within four weeks on

[185] See European Commission, Better Regulation Guidelines, fn. 159, pp. 15-16.

the overall five-page Call for Evidence document. [186] That document contained only a brief overview of the planned measures and of the thematic areas to be addressed. The Call for Evidence did not provide any information on key measures such as the removal of the time limit on the approval of active substances.

This made it impossible to submit a targeted statement on the planned project.

3. Legal consequence: violation of the principles of proportionality, equal treatment and the protection of legitimate expectations

The General Court extends the case-law on the relevance of impact assessments to the conduct of wide consultations which are provided for in Protocol (No 2) on the application of the principles of subsidiarity and proportionality and in the Interinstitutional Agreement.[187]

The above-mentioned violation of the principles of proportionality, equal treatment and the protection of legitimate expectations by refraining from conducting an impact assessment is therefore exacerbated by the subsequent failure to conduct a public consultation which is actually provided for in the Guidelines prior to an initiative such as the present one.

Furthermore, it cannot be ruled out that the absence of the consultations provided for in the Guidelines can be challenged as an infringement of essential procedural requirements within the meaning of Article 263(2) TFEU.[188]

However, such an infringement is only to be assumed where the failure to conduct the consultations and hearings results in the Commission not having the necessary information at its disposal.[189] The infringement therefore merges into the violation of the

[186] Available at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14824-Food-and-feed-safety-simplification-omnibus_en, last accessed on 9 January 2026.
[187] General Court, judgment of 27 November 2024, T-526/19, paras 287–288 and 322.
[188] See the Court's assessment in General Court, judgment of 27 November 2024...; see also the legal opinion by Baldon Acovats, Potential l...us directive amending the CRSD and CSDD, 23 June 2025, p. 20 et seq.
[189] See the Court's assessment in General Court, judgment of 27 November 2024, T-526/19, para. 280.

principles of proportionality, equal treatment and the protection of legitimate expectations already described above.[190]

III. Statement of reasons of the proposal

Article 168(1) TFEU gives rise to an obligation to reflect the health-policy considerations to be undertaken, pursuant to Article 296(2) TFEU, in the statement of reasons. This requires that the statement of reasons disclose the key considerations, so that it can be reviewed whether the health-protection requirements were observed and correctly weighed.[191]

This did not occur, since the identification of the possible consequences for health was already omitted. The approach therefore also contravenes Article 296(2) TFEU in conjunction with Article 168(1) TFEU.

E. Conclusion and outlook

The amendments provided for in the Commission proposal significantly weaken the protection of human health and the environment under the EU Legislation on Plant Protection Products.

In addition to the extensive removal of time limits on active substance approvals, the freezing of the state of scientific knowledge at the time of approval of the active substance and the envisaged privileging of certain substances and substance groups, it is in particular the extension of grace periods which leads to a lowering of the level of protection.

The Commission proposal violates higher-ranking EU law in several respects, both in terms of its content and the procedure followed in its preparation. It is compatible neither with the precautionary principle laid down in Article 191(2) TFEU, nor does the Union fulfil its positive obligations guaranteed in the Charter of Fundamental Rights with the amended Regulation (EC) No 1107/2009. From a procedural point of view, the failure to carry out an impact assessment and the insufficient statement of reasons due to the lack

[190] See CJEU, judgment of 3 December 2019, C-482/17, para. 79; judgment of 4 October 2024, C-541/20 to C-555/20, para. 689.
[191] Schmidt am Busch, in: Grabitz/Hilf/Nettesheim, EUV/AEUV, 85th update (May 2025), Article 168 TFEU, para. 98.

of considerations on the effects on health lead to a violation of the principle of proportionality as well as of Article 168(1) TFEU and Article 296(2) TFEU.

Considering past experience with the so-called Omnibus packages, it is to be expected that the ordinary legislative procedure under Article 294 TFEU will be further accelerated by a whole series of measures, so that there can scarcely be any expectation of substantive debate in plenary of the European Parliament.