Arnold & Porter

ATTORNEY-CLIENT PRIVILEGED

Memorandum

From: Arnold & Porter LLP

Date: 25 February 2022

Re: EC Communication on a fast track procedure for microbial PPPs

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1. The present memo addresses the question whether the European Commission (**Commission**) can supplement the existing EU legislation governing the placing of plant protection products (**PPPs**) on the market by adopting a Communication concerning a fast track procedure for the approval of active substances contained in microbial PPPs and the market authorization of such PPPs, given their low risk to human and animal health (cf. Annex for a preliminary draft Communication).[1]

2. The short answer is that there is no limit on what the Commission can include in a Communication in terms of *advocacy* for microbial PPPs, it being understood that such advocacy could, in addition, also include preliminary ideas about how to better regulate the matter. In contrast, the Communication cannot serve as a self-executing instrument to actually *regulate* the matter in lieu of the EU legislator. If the Commission would use a Communication for that purpose, it would disregard the procedural requirements that Regulation n° 1107 of the European Parliament and the Council of Ministers of 21 October 2009 concerning the placing of plant protection products on the market (**Regulation n° 1107**) has set forth for the amendment of the existing legal framework governing PPPs.

3. We will start this memorandum with a brief overview of the provisions of the Treaty on the Functioning of the European Union (**TFEU**) which provide the legal basis for the adoption of EU measures concerning microbial PPPs (section 1). It should be recalled that Regulation

[1] We refer to 'microbial' PPPs or 'low risk microbial PPPs' when we specifically have in mind Commission actions that could facilitate market entry of these products. We use the broader term 'low-risk' PPPs or active substances whenever the existing EU legislation refers to such PPPs or active substances.

n° 1107 has a triple legal basis: Art. 43 (2) TFEU (agricultural policy), Art. 114 TFEU (approximation of laws) and Art. 168 (4) (b) TFEU (public health policy). We will however focus on Art. 168 because in the area of public health it explicitly provides the possibility for the Commission to take an initiative in close contact with the Member States to adopt forms of soft law, such as guidelines, or to promote best practices.

4. We will then review the provisions in Regulation n° 1107 which already ensure some degree of favourable treatment for low-risk PPPs or may serve as a basis for increasing the favourable treatment of these PPPs (section 2).

5. We will then clarify what we think can be the scope of a Commission Communication concerning a fast-track procedure for the authorization of biological PPPs, in particular microbials (section 3).

Section 1 The legal basis for EU public health measures in the TFEU

6. **Support competence.** Pursuant to Art. 6 (a) TFEU, the protection and improvement of human health is, in principle, a field for which the EU only has the competence to "carry out actions to support, coordinate or supplement the actions of the Member States". In other words, the Member States take, in principle, the lead while the EU can only act as a back-up authority by supporting, coordinating or supplementing these actions. In this regard, Art. 168 (2) TFEU provides that "the Commission may, in close contact with the Member States, take *any useful initiative* to promote such coordination, in particular initiatives aiming at the establishment of *guidelines and indicators*, the organisation of exchange of *best practice*, and the preparation of the necessary elements for periodic monitoring and evaluation" (our emphasis).

7. **Shared competence**. It is worth recalling that Regulation n° 1107 is based *inter alia* on Art. 168 (4) (b) TFEU. Pursuant to this provision, the EU's competence is not limited to the adoption of measures supporting or supplementing Member State actions in the field of public health. It grants the EU legislator (i.e. the Council and the European Parliament) a

shared competence (i.e. a competence shared with the Member States) to adopt "measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health". This is clear from the opening language in Art. 168 (4) TFEU. It stipulates that EU legislation adopted pursuant to this provision occurs "by way of derogation from Art. 2 (5) and Art. 6 (a) TFEU and in accordance with Art. 4 (2) (k) TFEU". As already explained, Art. 6 (a) TFEU refers to the (weaker) support competence. In contrast, Art. 4 (2) (k) TFEU refers to the (stronger) shared competence.

8. **Communication**. Given the broad language in Art. 168 (2) TFEU ("any useful initiative"), the Commission could usefully refer to this Treaty provision for the purpose of adopting a Communication that would advocate *practical action points* for Member States within the framework of the *existing* legislation or float *preliminary ideas* concerning *amendments* to the existing legislation with a view to accelerating or otherwise facilitating market entry for microbial PPPs.[2] In contrast, the Commission cannot use a Communication to adopt itself such amendments. Only the Council and the European Parliament can adopt amendments to Regulation n° 1107 under Art. 168 (4) (b) TFEU and the Commission can only amend any implementing Regulations by following the relevant advisory or regulatory committee procedures (for details, cf. section 2).

9. **Binding Communication?** The Court of Justice has observed at numerous occasions that the Commission is bound by its own Communications (including Guidelines, Notices), "where they do not depart from the rules of the TFEU and are accepted by the Member States" (cf. judgment of 10 March 2021 in case C-572/19P Ertico – ITS Europe v. Commission, point 85). In another recent case, Advocate General Hogan also stated that notices and guidelines "might impose a limit on the exercise of the Commission's discretion

[2] In principle, the Commission could also issue a Recommendation to achieve the same objectives. We make this comment because Art. 292 TFEU explicitly confers upon the Commission the power to adopt Recommendations. There are numerous provisions in the TFEU that refer to such Recommendations, e.g. in the areas of social policy, economic policy or monetary policy. In contrast, the TFEU does not contain any references to Commission Communications. However. Council or Commission Recommendations have "no binding force" (Art. 288 TFEU). This explains why the adoption (or the failure to adopt) these acts is not subject to judicial review (Art. 263 and Art. 265 TFEU). It follows that what we will explain below with regard to a Commission Communication would also apply to a Recommendation.

(…) to the extent that those texts do not depart from the proper application of the rules in the TFEU, as guidelines and notices emanating from the Commission can obviously not derogate from those Treaty provisions" (cf. opinion of 7 May 2020 in case C-594/18P, Republic of Austria v. Commission, para. 52).

10. In our view, a Commission Communication that would advocate practical action points for Member States within the framework of the existing legislation or float ideas concerning amendments to that legislation would not "depart from the proper application of the rules in the TFEU" and be binding upon the Commission.

11. Obviously, to the extent the Commission would merely advocate a series of practical action points for Member States to consider in order to facilitate market entry of microbial PPPs under the current legislation, this self-binding nature of the Communication would not mean all that much. At most, once the Commission would have issued the Communication, we could remind it of its advocacy efforts and, if necessary, request that it pushes the Member States to follow suit and take action.

12. The self-binding nature of the Communication would have more teeth if the Commission would come up with preliminary ideas for amendments to the existing EU legislation (either Regulation n° 1107 or the implementing regulations). After all, the Commission has the exclusive power to propose legislative changes and, to quote Advocate General Hogan's words, once the Commission has floated preliminary ideas in this regard, a Communication would impose "a limit on the exercise of its discretion" to walk away from these ideas when later using its power to propose legislative changes. Other formal Commission positions, e.g. answers to written or oral questions in the European Parliament, might also limit the Commission's discretion, but to our knowledge, there is no case law confirming this view.[3]

Section 2 Low-risk PPPs under Regulation n° 1107

[3] In our view, formal Commission positions should be distinguished from letters of individual Commissioners, their Heads of Staff or top Commission officials, *unless* these officials hold special powers to take decisions that produce legal effects vis-à-vis third parties (e.g. the Hearing Officer in competition cases).

13. Provisions already favouring low-risk PPPs. By way of reminder, it is worth recalling that the current text of Regulation n° 1107 contains four provisions that specifically offer favourable treatment to low-risk PPPs.

    a. First, Art. 22 (1) provides that low-risk active substances can be approved for a longer period, i.e. up to 15 years, instead of 10 years for other active substances (see Art. 5).[4]

    b. Second, Art. 47 (3) provides that Member States must, in principle, decide within 120 days (i.e. roughly 4 months) whether to approve an application for authorization of PPPs containing low-risk active substances. This is a shorter period than the 12 months for other PPPs (see Art. 37 (1)).

    c. Third, Art. 50, which concerns the "comparative assessment of PPPs containing candidates for substitution" enables Member States to focus on the authorisation of alternative PPPs, including low-risk ones, in particular if these PPPs are significantly safer for human or animal health or the environment (see criteria set out in Annex IV of Regulation n° 1107).

    d. Fourth, Art. 66 seeks to avoid misleading advertising about PPPs but shows some degree of leniency for low-risk PPPs. Art. 66 (2) provides that "only in the case of low-risk plant protection products shall the term 'authorised as low-risk plant protection product in accordance with Regulation (EC) No 1107/2009' be allowed in the advertisement" while adding that "it cannot be used as a claim on the label of the plant protection product".

[4] In this regard, Art. 22 (2) refers to point 5 in Annex II of Regulation n° 1107 which clarifies when an active substance cannot be considered as low-risk and to Art. 13 (4) of the same Regulation pursuant to which the Commission shall maintain an electronic list of approved active substances and keep that list available for the public.

14. Other provisions with potential to favour low-risk PPPs. A number of other provisions in Regulation n° 1107 could provide a basis for additional favourable treatment of low-risk PPPs. Before we review these provisions, it is important to emphasize that each of them can be linked to an introductory recital in Regulation n° 1107. From a legal point of view, it should further be emphasized that these introductory recitals do not have any legal force by themselves. It follows that the Commission cannot use these recitals in isolation as a legal basis for a Communication introducing amendments to the existing legislation.

15. Let us now turn to the specific recitals and provisions in Regulation n° 1107 that are of interest to us.

16. Recital n° 17 and Article 22 (3). In our view, recital n° 17 must be read as cross-referring to Art. 22 (3). The latter provision specifically concerns the substantive approval criteria for active substances in low-risk PPPs.

17. Recital n° 17 announces that "the evaluation of an active substance may reveal that it presents considerably less of a risk than other substances", that "in order to favour the inclusion of such a substance in plant protection products, it is appropriate to identify such substances and to *facilitate* the placing on the market of plant protection products containing them" and that "incentives should be given for the placing on the market of low-risk plant protection products" (our emphasis).

18. This recital clarifies the *rationale* for Art. 22 (3) of Regulation n° 1107 which gives the Commission the power to "review and, if necessary, specify new criteria for approving an active substance as low-risk active substance in accordance with Art. 78 (1) (a)" of the Regulation.
19. Art. 78 (1) (a) confers upon the Commission the power to supplement the Regulation with "amendments to the Annexes, taking into account current scientific and technical knowledge". However, it requires the Commission to follow the "regulatory procedure with scrutiny referred to in Art. 79 (4)" of the Regulation. This procedure provides *inter alia* that

the Commission shall be assisted by a Scrutiny Committee composed of Representatives of the Member States.[5]

20. In short, recital n° 17 merely clarifies the underlying thinking behind Art. 22 (3) pursuant to which the Commission can amend the approval criteria for the active substances in low-risk PPPs (and possibly thereby also accelerate their approval) via the regulatory procedure set forth in Art. 79 (4). Recital n° 17 cannot serve as a legal basis for a self-executing Commission Communication that would bypass this regulatory procedure in order to achieve the same result.

21. Recital n° 26 and Article 30. This recital must be read as cross-referring to Art. 30 which concerns the authorization of PPPs generally, i.e. it does not specifically mention low-risk PPPs.

22. According to recital n° 26, "where the decision on approval cannot be finalised within the period provided for due to reasons not falling under the responsibility of the applicant, Member States should be able to grant the provisional authorisations for a limited period in order to facilitate the transition to the approval procedure provided for under this Regulation".

23. This is reflected in Art. 30 (1) which provides that Member States may authorize the placing on the market of PPPs containing an active substance not yet approved within the time limits set in Regulation n° 1107 (i.e. 30 months + possible extensions) for a provisional period not exceeding 3 years. There is no doubt that low-risk PPPs could, in principle, benefit from a provisional authorization under Art. 30 (1).

24. However, Art. 30 (3) provides that this provisional authorization track was only available "until 14 June 2016" and that the Commission must follow the "regulatory procedure with

[5] This procedure is set forth in Art. 5 (a) of Council Decision n° 2006/512 of 17 July 2006 laying down the procedures for the exercise of implementing powers conferred on the Commission. The relevant Committee is SCoPAFF (Standing Committee on Pesticides, Animals, Food and Feed).

scrutiny referred to in Art. 79 (4)" of the Regulation in order to prolong this faster authorization track. Recital n° 26 briefly explains the rationale for this time limitation: "in the light of the experience gained from the approval of the active substances under this Regulation, the provisions on provisional authorisations should cease to apply or be extended after the period of five years, if necessary".

25. In any event, Art. 30 (3) is clear: the only way in which the Commission could revive Art. 30 (1) is by following the same regulatory procedure as the one it must follow to apply Art. 22 (3). A Commission Communication cannot do the trick on its own force.

26. Recital n° 53 and Articles 76 – 78. In our view, there is also a clear link between, recital n° 53 and these three provisions in the body of the Regulation. Like introductory recital n° 26 and Art. 30, recital n° 53 and Art. 76 - 78 do not specifically mention low-risk PPPs.

27. Recital n° 53 is helpful in so far as it provides that "the Commission should facilitate the application of this Regulation" and that "therefore, it is appropriate to provide for the necessary financial resources and the possibility of amending certain provisions of this Regulation in the light of experience or of developing technical notes for guidance".

28. Let us now take a look at the three provisions in the Regulation to which we think recital n° 53 refers: Art. 76 ("expenditure by the Commission"), Art. 77 ("guidance documents") and also Art. 78 which we already commented on. We will take each of these provisions in turn.

29. We need to discard Art. 76 from the outset. This provision essentially listed a number of activities that the Commission can budget for when performing its "risk management role" mentioned in introductory recital n° 12, e.g. by organising the "development of *guidance* to facilitate the *day-to-day* application of the Regulation" (Art. 76 (f), our emphasis). This provision would thus have enabled the Commission explore ways of improving the effectiveness (*effet utile*) of the Regulation n° 1107 in its current, unamended form, in particular for microbial PPPs. However, the EU legislator repealed Art. 76 in 2014 and

adopted instead a Regulation concerning the management of expenditure relating to food and food safety as well as feed and feed safety.[6]

30. Let us therefore turn to Art. 77. This provision enables the Commission to "adopt or amend technical and other *guidance* documents such as explanatory notes or *guidance* documents on the content of the application concerning micro-organisms, pheromones and biological products, for the implementation of this Regulation" (our emphasis). When the Commission wishes to provide such guidance, Art. 77 specifies that it must do so "in accordance with the advisory procedure referred to in Article 79 (2)".

31. This advisory procedure is set forth in Art. 3 of Council Decision n° 1999/468 of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.[7] Art. 3 provides *inter alia* that the Commission shall be assisted by an advisory committee composed of Representatives of the Member States. Art. 77 adds that the Commission may also "ask the Authority [i.e. the European Food and Safety Authority] to prepare or to contribute to such guidance documents".

32. It follows that the Commission cannot bypass the advisory procedure set forth in Art. 79 (2) if it wishes to provide the type of guidance mentioned in this provision for microbial active substances or PPPs containing these substances. It must consult the Member State representatives. However, given that the Commission and the Member States share the responsibility of implementing Regulation n° 1107, it would seem to make eminent sense for the Commission to discuss its suggestions with the Member States through this advisory procedure. In any event, its advocacy efforts would fall on a cold plate if there was no buy-in from the Member States. Let us also remember that Art. 168 (2) TFEU promotes a close and constant liaison between the Commission and Member States in the area of public health. Moreover, and from a practical point of view, Art. 3 (3) of Decision n° 1999/468 provides that the Commission chairs the advisory committee in question and that it can set

6 Cf. Regulation n° 652/2014 of 15 May 2014, O.J. L 189/1 of 27 June 2014, in particular Art. 53.

7 O.J. L 184/23 of 17 July 1999. The Council amended this Decision in 2006 (O.J. L 200/11 of 22 July 2006) but its Art. 3 remained unchanged

a deadline for its opinions "according to the urgency of the matter". Finally, although the Commission should take utmost account of the opinion of the committee, it can adopt the guidance without being blocked by the Member States. In other words, the advisory procedure should not cause undue delays in the discussions.

33. As for Art. 78, we already mentioned Art. 78 (1) (a) in connection with recital n° 17 and Art. 22 (3). Recital n° 53 provides the *rationale* for Art. 78 (1) (b) according to which the Commission can make "amendments to the Regulation on data requirements for active substances and for plant protection products (…) taking into account current scientific and technical knowledge" . However, as for Art. 22 (3), the Commission must follow the "regulatory procedure with scrutiny referred to in Art. 79 (4)" of the Regulation.

34. The Commission has in fact made use of this power under Art. 78 (1) (b) of Regulation n° 1107 by adopting Regulation n° 283/2013 concerning data requirements for the approval of active substances in chemical PPPs (part A) and biological PPPs (part B) and Regulation n° 284/2013 concerning data requirements for the authorization of chemical PPPs (part A) and biological PPPs (part B). As you know, the Commission has recently proposed amendments to both implementing Regulations.

Section 3 Scope of a Commission Communication

35. In Section 1, we explained that the Commission can usefully refer to Art. 168 (2) TFEU when adopting a Communication in order to either advocate practical action points for Member States within the framework of the existing legislation or to float preliminary ideas concerning amendments to the existing legislation – in both instances with a view to accelerating market entry of microbial PPPs.

36. Advocacy under the existing legislation. It would be entirely uncontroversial for the Commission to open a Communication with some high level advocacy language about the need to prioritize the use of low-risk microbial PPPs in order to achieve a 50% reduction in the use of chemical pesticides by 2030 (Farm to Fork Strategy). Reference could be made

to the Council's Implementation Plan of 28 June 2016 and to the European Parliament's Resolutions of 15 February 2017, 13 September 2018 and 20 October 2021. In this most recent resolution, the European Parliament stressed "the need to establish fast-track evaluation, authorisation and registration processes for non-chemical low-risk pesticides". Reference could also be made to the explanatory memorandum of the Commission's 2022 proposal for a Regulation on the sustainable use of plant protection products and repealing Directive 20009/128/EC according to which "as part of the Farm to Fork Action Plan, the Commission plans to launch, by the end of April 2022, simplified authorized procedures for alternatives to chemical pesticides".[8] While the Commission has not yet provided details in this regard, we assume that such simplified authorized procedures will accelerate market entry for these alternatives. In addition, the Commission has recognized in its "Questions and Answers: Farm to Fork: new rules for micro-organisms used in plant protection products" of 10 February 2022 that micro-organisms are "naturally occurring", that most of them are "harmless" and that biological PPPs containing micro-organisms are "inherently safer than chemicals".

37. Turning to more specific points, it would seem to us that the Commission could take inspiration from Art. 77 to discuss with Member States ways of enhancing the effectiveness (*effet utile*) of the *existing* legislation, i.e. without requiring the amendment of Regulation n° 1107 or its implementing regulations.

38. The Commission could start by acknowledging that Regulation n° 1107 focuses more on containing the health risks of chemical PPPs than on facilitating market entry for microbial PPPs but that, in the absence of a separate Regulation that would specifically deal with microbial PPPs, it can think of a number of ways to facilitate and speed up the procedure for the market authorization of these PPPs under the existing Regulation n° 1107. It could emphasize that these *procedural* suggestions supplement the recent draft amendments to four implementing Regulations (endorsed by Member States on 10 February 2022) which aim at making the *substantive* data requirements for microbial PPPs "more fit for purpose

[8] See section 1 'Context of the Proposal', at p. 4.

and flexible".[9] Below is a non-exhaustive list of ideas that the Commission could float in its Communication in order to either shorten the approval / authorization procedures for microbial PPPs or otherwise enhance their market position .

39. First, although point 5 in Annex II of Regulation n° 1107 concerning the procedure and criteria for the approval of active substances only specifies when an active substance is *not* low-risk, we read nothing in this Annex (or in the list of definitions in Art. 3 of Regulation n° 1107) that would prevent the Commission from clarifying in its Communication that an active substance contained in a microbial PPP meets the criteria for low-risk when it does not contribute to anti-microbial resistance, provided it is not a human pathogen. Moreover, in recital n° 9 of Regulation n° 2017/1432 of 7 August 2017, the Commission already observed that "a micro-organism may be considered to be of low-risk unless at strain level it has demonstrated multiple resistance to antimicrobials used in human or veterinary medicine".

40. Second, when producers of microbial PPPs submit their application dossier to the Rapporteur Member State (**RMS**) of their choice, the Commission could encourage the RMS to (i) prioritize the handling of these dossiers if the applicant indicates at the pre-submission meeting that the active substance meets the low-risk criteria (i.e. they would jump the queue of pending chemical PPP dossiers), (ii) indicate, when conducting the completeness check, that this active substance may qualify as low-risk, subject to further examination (iii) then confirm in its draft assessment report (**DAR**) that the active substance contained in these PPP is indeed low-risk. This should speed up matters under the *existing* legislation. For an additional benefit that would require an amendment of Art. 30 (3) of Regulation n° 1107, see point 48 below.

41. It would seem to us that such an examination at the stage of the DAR would be in line with Art. 11 of Regulation n° 1107 which instructs the RMS to submit its DAR to the Commission "assessing whether the active substance can be expected to meet the approval

[9] Add ref. to the four Implementing Regulations.

criteria provide for in Art. 4". Also, point 5 in Annex II mentions this examination and we read nothing in this Annex that would prevent Member States from conducting this check at the stage of the DAR.

42. Third, it is our understanding that, as a result of the focus of Regulation n° 1107 on chemical pesticides, the entire approval / market authorization process for biological pesticides has largely been in the hands of chemical experts at the relevant authorities, be it at the level of the RMS or at the EFSA. In our view, the Commission could use the Communication to advocate the putting into place of separate, dedicated review teams at these authorities, i.e. populated by chemical experts for the chemical PPPs and by biology/ecology experts for microbial PPPs. This would improve the review process and likely also speed up that process (e.g. better targeted questions). Point 1.3 in Annex II of Regulation n° 1107, according to which "the evaluation by the Authority and the rapporteur Member State must be based on scientific principles and be made with the benefit of expert advice", is sufficiently broadly worded to allow the Commission to make this proposal within the existing legal framework.

43. It is to be welcomed that the Commission has proposed more flexible data requirements for microbial PPPs. However, for the effective day-to-day application of Regulation n° 1107, it is of key importance that the risk assessments for these PPPs be performed separately by dedicated teams of well-educated and well-trained experts in microbiology in order to have a scientifically valuable evaluation. Chemical experts do not have the technical expertise to perform a risk assessment of microbial PPPs.

44. Fourth, the Commission could urge Member States to comply with Art. 47 (3) of Regulation n° 1107 which provides that they must decide within a deadline of 120 days (only to be prolonged by no more than six months in case additional information is needed) whether to approve an application for authorization of PPPs containing low-risk active substances.

45. Fifth, the Commission could encourage Member States to make better use of the possibility foreseen in Art. 50 of the Regulation which concerns the "comparative assessment of PPPs containing candidates for substitution" and enables Member States to focus on the

authorisation of alternative PPPs, including low-risk ones, if these PPPs are significantly safer for human or animal health or the environment. In its final REFIT Evaluation report, Ecorys noted that a total of 83 "candidates for substitution" had been identified over the years but that none of them had been replaced under Art. 50[10]. The Commission could also welcome the fact that certain Member States (e.g. Denmark, the Netherlands and France) have proactively removed certain candidates for substitution from the market in recent years and encourage other Member States to follow this best practice.

46. Sixth, the Commission could suggest that microbial PPPs be considered for temporary market authorizations under the procedure set forth in Art. 53 of Regulation n° 1107. This provision allows Member States to authorize PPPs "for limited and controlled use" during a period not exceeding 120 days in order to address a "danger that cannot be contained by any other reasonable means". In its REFIT Evaluation report, Ecorys noted that the number of these market authorisations increased considerably, e.g. from 58 in 2008 to 217 in 2011 and 714 in 2017.[11] However, it also noted that "emergency authorisations are granted without first considering other *non-chemical* approaches" and that "the increase in emergency authorisations emerges as a symptom of a system (…) in which new or *alternative* products and methods are still not fully promoted" (our emphasis).

47. Seventh, Art. 66 (2) of Regulation n° 1107 provides that the term 'authorised as low-risk plant protection product" can only be used in the advertisement, albeit not as a "claim on the label of the plant protection product". The Commission could clarify that the claim can therefore not be made in the mandatory text of the label but that a reference to the authorisation as low-risk PPP can be made in the free text of the label.
48. Preliminary ideas for amendments to the existing legislation. There are a series of other measures in favour of microbial PPPs that the Commission cannot itself enact through a

[10] Cf. Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) n° 1107/2009 and Regulation (EC) n° 396/2005 of 10 October 2018, in particular p. ___.

[11] Cit., in particular p.47.

Communication but that it could flag as measures for which it will consider proposing amendments to the existing legislation. The following examples come to mind.

49. First, the Commission could announce in a Communication that it will adduce evidence "in light of the experience gained from the approval of the active substances" (cf. recital 26) in support of using the regulatory procedure with scrutiny to revive Art. 30 (3) of Regulation n° 1107. It will be recalled that Art. 30 (3) enabled Member States until 14 June 2016 to grant provisional market authorizations for PPPs containing an active substance not yet approved within the time limits. However, Art. 30 (3) also provides that "if necessary, that time limit may be extended". Such an extension would benefit, in particular, low-risk PPPs.

50. Second, the Commission could announce in a Communication that it will conduct an impact assessment with a view to examining whether the EU legislator should remove the 15 years time limit set forth in Art. 22 (1) of Regulation n° 1107 for the approval of low-risk substances. It could instead provide for re-evaluation after 15 years, but only if evidence of harmful effects would have been reported . Obviously, only the EU legislator can amend Art. 22 (1) to actually achieve this.

51. Third, and infinitely more ambitiously, the Commission could announce that it will reflect on the need for the adoption of a separate Regulation that would specifically govern the approval of active substances in microbial PPPs and the market authorisation of PPPs containing these substances. If it were to do this, the Commission would, of course, have to set a time frame for its reflection, including the preparation of an impact assessment that would demonstrate the need for such a separate Regulation. If it did, we could then hold the Commission to its commitment, as the Communication would be binding upon it.