MICROBIAL PLANT PROTECTION PRODUCTS TASK FORCE

25/02/2022

Preliminary Draft Communication

- Facilitating market entry of microbial plant protection products in the EU -

1. Introduction

- The Treaty. Pursuant to Art. 168 (2) TFEU, the Commission may take "any useful initiative" to promote the coordination of Member States' actions in the area of public health, and would therefore be applicable to microbial PPPs To this effect, it may adopt "guidelines" or encourage Member States to adopt "best practice".

- Farm-to-Fork Strategy. Within the framework of the European Green Deal[1], the Commission issued a Communication concerning a Farm-to-Fork Strategy for a fair, healthy and environmentally-friendly food system in which it announced "additional action to reduce the overall use and risk of chemical pesticides by 50% and the use of more hazardous pesticides by 50% by 2030".[2] Such action, which will necessarily entail the withdrawal of a significant number of chemical pesticides, goes hand in hand with a policy to prioritize the placing on the market and use of low-risk microbial PPPs with a view to ensuring sustainable crop protection.

  The Agricultural and Fisheries Council of Ministries already embraced this prioritisation policy on 18 June 2016 when it took note of an "Implementation Plan on increasing low-risk plant protection product availability and accelerating integrated pest management implementation in Member States" prepared by the Expert Group on Sustainable Plant Protection. The European Parliament did so too in its Resolution of 15 February 2017 on low-risk pesticides of biological

1 Cf. Communication COM (2019) 614 final of 11 December 2019.

2 Cf. Communication COM (2020) 381 final of 20 May 2020.

origin and again in its Resolution of 13 September 2018 concerning implementation of the PPP Regulation.[3]

- Regulatory initiatives already underway. The Commission has recently adopted several proposals to amend the existing legislation regarding the placing on the market of PPPs in order to facilitate market entry for low-risk microbial plant protection products ("PPPs"). On the one hand, these concern amendments to four Commission Implementing Regulations relating to Regulation n° 1107 of the Council and the European Parliament which governs the *placing on the market* of PPPs ("Regulation n° 1107"). These Implementing Regulations are scheduled to enter into force in the 4th quarter of 2022. On the other hand, the Commission has launched a draft Regulation of the Council and the European Parliament concerning the sustainable *use* of PPPs ("SUR"). This Regulation will repeal the current Directive ("SUD"). In its Explanatory Memorandum, the Commission announces that it plans to launch, by the end of April 2022, simplified authorization procedures for alternatives to chemical pesticides.

- More should be done. Notwithstanding the above-mentioned regulatory initiatives that are already underway, the Commission takes the view that there is room for additional action aimed at further facilitating the market entry and use of microbial PPPs. It welcomes the fact that this view is shared by the Dutch authorities which were a driving force behind the 2016 Implementation Plan.[4]

  The present Communication serves the purpose of lining up a number of additional action points to promote the placing on the market and use of low-risk microbial PPPs.

- Within the existing regulatory framework. Leaving aside the broad wording of Art. 168 (2) TFEU mandating the Commission to take such an initiative, Art. 77 of Regulation n° 1107 specifically empowers it to "adopt or amend technical and other guidance documents such as explanatory notes or guidance documents on

[3] Cf. resp. documents 2016/2903 RSP and 2017/2128 INI.

[4] Cf. letter of Minister of Agriculture Henk Staghouwer of 25 January 2022 to the Dutch Parliament.

the content of the application concerning micro-organisms, pheromones and biological products, for the implementation of this Regulation".

The Commission reads this provision as enabling it to liaise with the Member States (via the advisory procedure) in order to discuss with them practical action points or clarifications that can contribute to quicker market entry and increased use of microbial PPPs within the framework of the current legislation. Section 2 will list these action points.

- Beyond the existing regulatory framework. Recital n° 53 of Regulation n° 1107 also mentions the "possibility of *amending* certain provisions of this Regulation in light of experience or of developing technical notes for guidance" (emphasis added). Furthermore, recital n° 17 of Regulation n° 1107 specifically states that it is appropriate to "facilitate" the placing on the market of PPPs that contain low-risk active substances. This recital primarily relates to Art. 22 (3) of Regulation n° 1107 which empowers the Commission to propose new criteria for approving an active substance as low-risk active substance via the regulatory procedure set forth in Art. 79 (4) of the Regulation. However, it also mentions, more generally, that "incentives should be given for the placing on the market of low-risk PPPs.

  In light of these recitals, the Commission also wishes to use the present Communication to float a number of preliminary ideas regarding amendments to Regulation n° 1107 which would enhance the position of microbial PPPs. Section 3 covers this.

2. Enhancing the effectiveness of the current legislation

- Defining low-risk active substances in PPPs. Regulation n° 1107 contains a number of provisions which specifically offer favourable treatment of low-risk PPP (i.e. Art. 22 (1) re: approval of low-risk active substance up to 15 years, Art. 47 (3) re: a 120 days timeline for the authorization of low-risk PPPs when certain conditions are met, Art. 50 re: candidates for substitution and Art. 66 re: advertising). However, the Regulation does not contain a clear definition of low-

risk active substances contained in PPPs. Point 5 in Annex II of the Regulation only specifies when an active substance is *not* low-risk. The Commission wishes to clarify that this point applies to chemical active substances. In principle, an active substance contained in a microbial PPP can be presumed to be low-risk because it is not going to present any of the features listed there. However, it would be useful to add features that are specifically tailored to the nature of non-chemical PPPs. In the Commission's view, one can confer low-risk status to the active substances contained in microbial PPPs even these are (a) not a human pathogen and (b) do not contribute to anti-microbial resistance.

- Confirming low-risk at the stage of the draft assessment report ("DAR"). Art. 11 of Regulation n° 1107 instructs the Rapporteur Member State ("RMS") to submit its DAR to the Commission "assessing whether the active substance can be expected to meet the approval criteria provide for in Art. 4". In the Commission's view, neither this provision, nor point 5 in Annex II of the Regulation which sets out the procedure and criteria for the approval of active substances prevents Member States from already checking the low-risk nature of a microbial PPP at the stage of the DAR.[5]

- Dedicated expert teams for chemical and microbial PPPs. The Commission acknowledges that the existing approval / market authorization process for 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, given that Regulation n° 1107 focuses more on containing the health risks of chemical PPPs than on facilitating market entry for microbial PPPs. However, in light of the EU's policy to step up its efforts to achieve a 50% reduction in the use of chemical pesticides by 2030 and of the fact that since a number of years, the majority of new active substances submitted in the EU are of a biological nature[6], this is an

[5] The 2016 Implementation Plan already contains a recommendation to "expedite where possible the approval or renewal process of substances identified as potentially low-risk". In a progress report, the Commission noted that "six Member States reported to have taken specific measures to expedite the evaluation of potentially low-risk substances within the existing legal constraints" and that "three Member States reported they are prioritising the evaluation of potentially low risk substances". See note General Secretariat of the Council n° 10238/19 of 27 June 2019, at p. 11.

[6] Cf. the list of pending active substances in the EU database for pesticides (A&P: is this reference precise enough?)

anomaly and requires an adjustment of the evaluation system that is currently in place. The Commission therefore urges Member States to invest in the mobilisation of biology expert teams for the purpose of assessing the microbial PPPs and the active substances contained therein. 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.

- Compliance with timelines set in Regulation n° 1107. The Commission expresses the hope that the above-mentioned action points (i.e. working with a clear definition of low-risk active substances, conducting the low-risk assessment at the stage of the DAR and having this assessment conducted by a dedicated team of biology experts), combined with more flexible data requirements (once these will have been adopted later this year) will assist Member States in doing a much better job at meeting or even beating the timelines set by the Regulation for the approval of active substances (cf. Art. 9 – 13) or the authorization for the placing on the market and use of the PPPs (cf. Art. 37).

  Similarly, the Commission urges Member States to comply better with the time-limit set forth in Art. 47 (3) pursuant to which they States should decide within 120 days whether to approve an application for authorization of a low-risk PPP that do "not contain a substance of concern" and are "sufficiently effective" within the meaning of Art. 47 (1)). The Commission is ready to assist Member States in this regard, e.g. by exchanging views on best practices with them and EFSA.

- Making better use of Art. 50. The Commission encourages 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. It refers in this regard to its Farm-

to-Fork Questions & Answers of 10 February 2022 where it observed that PPPs containing micro-organisms are "inherently safer than chemicals".

- Making more appropriate use of Art. 53. The derogatory procedure set forth in this provision for "emergency situations in plant protection" enables a Member State to authorize for a period of maximum 120 days PPPs "for limited and controlled use" in case of "danger which cannot be contained by any other reasonable means".

  Given the very short period for which the authorization can be granted, this procedure has its limitations for low-risk microbial PPPs. However, the Commission believes that Member States could make more appropriate use of it if they followed its recommendation to assess the low-risk nature of the active substances contained in microbial PPPs at the early stage of preparing the draft assessment report ("DAR").

- Approving low-risk active substances for all crops. Given that an active substance deemed to be a low-risk microbial active substance does not contribute to environmental or human health risks, there is no need to establish maximum residue levels ("Mrls") or monitor these for acceptable daily intake ("ADI"). As a consequence, there is no need to limit the approval to one or more crops. Approvals should cover all crops where applicable.

3. Thoughts about further amendments to the current legislation

- Revive Art. 30 (3) of Regulation n° 1107. It will be recalled that Art. 30 (1) enabled Member States until 14 June 2016 to grant for three years provisional market authorizations for PPPs containing an active substance not yet approved within the time limits set forth in Art. 9 – 13 of the Regulation. Art. 30 (3) added that "if necessary, that time limit may be extended". In its REFIT Final Report of 10 October 2018, Ecorys did not identify a particular reason why such an extension should not be considered.

Upon reflection, the Commission believes that it is worth revisiting this issue and it is therefore willing to collect evidence "in light of the experience gained from the approval of the active substances" (cf. recital 26) and then use the regulatory procedure with scrutiny to revive Art. 30 (3) of Regulation n° 1107.

- Amend Art. 22 (1) of Regulation n° 1107. The Commission 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.

- Separate Regulation for microbial PPPs. The Commission acknowledges that Regulation n° 1107 focuses more on containing the health risks of chemical PPPs than on facilitating market entry for microbial PPPs. It therefore considers that it might be better to have two separate regulations applying side-by-side to these two entirely different types of PPPs, with assessment criteria, expertise and procedures tailored to each type of these PPPs. It commits to conduct an impact assessment later this year (2022) with a view to demonstrating the need for such a separate Regulation.

With the advice and support of Arnold & Porter/PA International Foundation