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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Council Conclusions on the report from the Commission to the European Parliament and the Council evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides – Approval

1. On 20 May 2020, at the same time with its Farm to Fork Strategy, the Commission adopted a Report to the European Parliament and to the Council on the evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides (hereinafter *'the REFIT report'*).

2. The REFIT report has been submitted pursuant to Articles 82 and 62(5) of the PPP Regulation and of Article 47 of the MRL Regulation and is accompanied by a Commission Staff Working Document. It presents the results of an evaluation carried out by the Commission of the PPP and MRL Regulations covering the period of their respective entry into application until 2018, as part of the Commission's regulatory fitness and performance programme (REFIT).

3. The REFIT report was presented by the Commission to the Working Party on Agricultural Questions (Pesticides/Plant Protection Products) in an informal videoconference on 22 July 2020. On the basis of the interventions of the delegations and of their subsequent written contributions, the German Presidency proposed draft Council Conclusions which were examined and discussed in three more informal videoconferences of the members of the Working Party on Agricultural Questions[1].

4. On 30 November 2020, the third revised draft text of Council Conclusions was submitted to the delegations through a silence procedure which was not broken by any delegation. However, following informal comments from one delegation, the text of the Council Conclusions contains one additional modification in paragraph 39a. Compared to the previous version (WK 8635/20 REV 3), the word **'assessment'** (marked in **bold)** is replacing the word ~~'approval'~~ (marked with ~~strikethrough)~~.

5. In light of the above, the Permanent Representatives Committee is invited to confirm the agreement on the text of the draft Council Conclusions on the Commission's REFIT report set out in annex to this Note and to submit it to the Council for approval in one of its upcoming meetings.

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[1] 18 September, 30 October and 27 November 2020

ANNEX

Draft COUNCIL CONCLUSIONS on the

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides

THE COUNCIL OF THE EUROPEAN UNION,

RECALLING:

- The communication from the Commission of 11 December 2019 „The European Green Deal“[1];
- The communication from the Commission of 20 May 2020 to the European parliament, the Council, the European Economic and Social Committee and the Committee of the Regions “A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system“[2];
- The Council Conclusions on the Farm to Fork Strategy[3];
- The communication from the Commission of 20 May 2020 to the European parliament, the Council, the European Economic and Social Committee and the Committee of the Regions “EU Biodiversity Strategy for 2030, Bringing nature back to our lives”[4];
- The Council Conclusions on the EU Biodiversity Strategy[5];
- The Report from the Commission to the European Parliament and the Council on the experience gained on the implementation of national targets established in their National Action Plans and on progress in the implementation of Directive 2009/128/EC the sustainable use of pesticides;[6]

1 COM(2019) 640 final, doc 15051/19+ADD1
2 COM(2020) 381 final; doc 8280/20+ADD1
3 Doc 12099/20
4 COM(2020) 380 final; doc 8219/20+ADD 1
5 Doc 12210/20
6 Doc. 8238/20 + ADD 1

- The European Parliament's (January 2019) Report on the Union's authorisation procedure for pesticides (2018/2153(INI)) - Special Committee on the Union's authorisation procedure for pesticides[7];

- The European Parliament's (September 2018) Report on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009 (2017/2128(INI))[8];

- The European Commission's Reflection Paper "Towards a Sustainable Europe by 2030"[9];

- Council Conclusions "Towards a Sustainable Chemicals Policy Strategy of the Union"[10]

1. WELCOMES the effort that has been put by the Commission into the examination and evaluation of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market ("PPP Regulation") and of Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin ("MRL Regulation");

2. ACKNOWLEDGES that the PPP Regulation and the MRL Regulation contribute substantially to the provision of safe food for more than 440 million European citizens, while ensuring a science based high level of protection for the environment and human and animal health; RECOGNISING that the use of plant protection products may involve risks and hazards for humans, animals and the environment;

3. POINTS OUT the growing awareness in society regarding the necessity for not only safe and affordable but also sustainably and locally produced food and SUPPORTS the Commission in its intention to minimise the impact of plant protection products on human health and the environment through focussing on alternative methods as well as on low risk and non-chemical plant protection products;

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7 A8-0475/2018
8 A8-0268/2018
9 COM(2019)22 of 30 January 2019
10 Doc. 10713/19

4. WELCOMES in general the actions already planned by the Commission for increased transparency and for better implementation and alignment of the relevant legislations and SHARES many of the findings and considerations of the evaluation;

5. NOTES the high level of ambition of the measures considered in the report and CALLS UPON the Commission and the Member States to give priority to such areas for improvement which are crucial for the shift towards more sustainable plant protection products and alternative methods with a focus on the availability of low risk and non-chemical plant protection products;

Strengthened protection of human health and the environment

(Better implementation – addressing delays and increasing transparency)

6. RECOGNISES the problem of delays in evaluation and approval procedures and NOTES the responsibility of all parties involved to reach the targets and timelines of both regulations. In this respect, RECALLS that Member States shall make available the necessary resources or arrangements to the competent authorities to fulfil their tasks and ENCOURAGES the Commission to ensure that the draft Regulations on active substances and MRLs are put to the vote as soon as possible after EFSA's assessments are available;

7. NOTES that experience has shown that the timelines set out in the PPP Regulation have become challenging, inter alia regarding the requirements for decision-making, content and layout of assessment reports, and extended collaboration on the EU or zonal level;

8. HIGHLIGHTS that the Commission, EFSA, and the Member States jointly have to take all necessary means to further improve and optimise the implementation of the procedures supported by guidelines and evaluation criteria and put efforts in following the legal deadlines;

9. EMPHASISES the need for the Commission, Member States and EFSA to respond to new emerging risks and concerns, as for example cross-resistances and neurotoxicity;

(Improved implementation of the cut-off criteria)

10. AGREES with the Commission's recommendation that Member States make full use of Article 11(4) of Regulation (EU) No 844/2012 and only continue the full risk assessment if either the active substances do not meet the cut-off criteria or at least one of the derogation possibilities for their approval is invoked. Additionally, NOTES that the same principle applies in the context of Article 4(1) of Regulation (EC) No 1107/2009 and Article 11(4) of Regulation (EU) No 2020/1740. In this context, ENCOURAGES the Commission to finalise the guidance document on negligible exposure;

11. REMARKS that the determination of toxicological endpoints, the residue definitions and the analytical methods for substances meeting the cut-off criteria may become necessary, in particular for assessing import tolerances requests and enforcement purposes;

(Simplify the comparative assessment of candidates for substitution)

12. WELCOMES that the Commission will propose an amendment of Annex IV of the PPP Regulation to the Member States in order to improve the effectiveness of comparative assessments of products containing candidates for substitution at the end of 2021 and CALLS ON Member States to contribute to this process;

(Cumulative risk assessment)

13. RECOGNISES that monitoring results on pesticide residues showed a high compliance with established MRLs and therefore that the food available to consumers is considered well controlled and safe;

14. WELCOMES the intention of the Commission to develop an action plan by the end of 2020, setting out priorities for the ongoing work on the methodology and implementation of a cumulative risk assessment and UNDERLINES the need to step up the efforts in this area;

15. EMPHASISES the need for regularly reviewing the scientific progress and assessing it in view of a progressive implementation of cumulative risk assessment in risk management practice, taking into account the potential impact on regulatory timelines and the available resources;

(Environmental- and Biomonitoring)

16. WELCOMES the monitoring of environmental concentrations and effects, and ENCOURAGES the Commission to make use of monitoring programs that are already in place under the existing legal frameworks and to further develop monitoring plans;

16a. In this context, RECOMMENDS a coordination at EU level for monitoring the effects and impacts of active substances in order to assess information and bring it to the Commission's and Member States' attention, where necessary;

17. PROMOTES a better understanding of the actual impact of plant protection products on ecosystems in order to lead to sound decision making; and ENCOURAGES the Commission to develop guidance on how to incorporate the results of monitoring into risk assessment;

(Define Environmental Protection Goals and Update Guidance Documents)

18. ENCOURAGES the Commission to develop a methodology to define specific environmental protection goals, e.g. to further improve the consideration of biodiversity in the risk assessment process. ENCOURAGES the Commission and EFSA to update the guidance documents on risk assessment methodologies in the light of scientific progress, including in particular the guidance on the protection of bees and other pollinators, taking into account the Member States' feedback and the technical feasibility of the implementation;

Competitiveness and the internal market

(Improve the zonal system for authorisations of PPPs)

19. AGREES that strengthening the zonal cooperation will support the functioning of zonal authorisations and POINTS OUT Member States' own responsibilities to increase mutual trust in each other's risk assessment and decisions which should reflect input from the Member States which are members of the zone;

20. RECOGNIZING the need to allow for national requirements, for example concerning groundwater protection, in accordance with the rules of Regulation 1107/2009;

21. […]

(Solutions for minor uses)

22. WELCOMES the efforts of the Commission with regard to solutions for minor uses, e.g. the dynamic revision of the Extrapolation Guidelines for the broader use of results from residue trials while ENCOURAGING further initiatives and agreements on minor use crops;

22a. ENCOURAGES the Member States to ensure the work of the Minor Uses Coordination Facility and ASKS the Commission to further support the Member States' initiatives on improving the efficiency in the minor use authorisation procedures;

Emergency authorisations

(Increase oversight of emergency authorisations)

23. EMPHASISES that more detailed analysis on the emergency situation is needed to demonstrate the reasons for emergency authorisations, which are among others the lack of regular PPP authorisation applications;

24. SUPPORTS a faster and more responsive procedure for setting EU wide accepted, temporary MRLs in connection with emergency issues and RECOMMENDS that if swift action is already being taken by the Commission, the setting of national MRLs should be avoided as much as possible;

(Further reduce the need for vertebrate animal testing)

25. WELCOMES the efforts and achievements in the reduction of animal testing. However, CALLS FOR strengthening these efforts and therefore SUPPORTS the Commission in the further development of guidance and methods, in particular regarding the use of read across to limit the use of animal testing;

Sustainability of plant protection and low-risk products

(Promote sustainable plant protection, low-risk solutions and efficient risk mitigation)

26. ACKNOWLEDGES the achievements in promoting low-risk active substances including semiochemicals and basic substances as well as microorganisms and WELCOMES the ongoing reflections on principles and criteria for these substances taking into account their natural occurrence, where relevant;

27. HIGHLIGHTS that the availability of low risk plant protection products is crucial for achieving the goals of the European Green Deal and CALLS UPON the Commission to support initiatives of the Member States for developing guidance for the accelerated authorisation procedure within 120 days that is provided for low risk plant protection products, including MRL setting;

27a. REMINDS that basic substances and non-chemical methods may be useful for plant protection as complementary tools and that such alternatives should be promoted according to IPM principles enshrined in Directive 2009/128;

27b. SUPPORTS the training initiatives under Better Training for Safer Food (BTSF), for example for the assessment of non-chemical active substances or for the implementation of guidance documents on risk assessment, and CALLS ON the Commission to continue these training initiatives in relevant areas;
(former para 9)

Enforcement

(Better enforcement of the PPP and MRL Regulation)

28. WELCOMES the intention of the Commission to clarify by the end of 2021 the scope of the term "exceptional circumstances" for setting temporary MRLs in order to avoid misunderstandings and delays in this regard in the future and SUPPORTS the effort regarding the examination of possibilities for accepting specific MRLs set under a different legal framework;

28a. SUPPORTS the Commission to continue to mandate EFSA without delay to revise MRLs in case that toxicological endpoints have been lowered due to a current outcome of a risk assessment and when there are indications that this could constitute a potential risk for consumers;

29. TAKES NOTE of the Commissions statement, that no potential risk has been identified, which would result in the need to set specific MRLs for feed, fish and processed products and ENCOURAGES the Member States to monitor these commodities under their national programmes and report these findings to the Commission for further follow up;

30. REQUESTS the Commission to consider the development of some guidance on the application of current MRLs for processed feed to ensure more harmonized enforcement action taken by the Member States, before taking into consideration the setting of legally binding MRLs for commodities exclusively used for animal feed production;

31. ENDORSES the intention of the Commission to clarify the provisions of the MRL Regulation for processed products, including the use of processing factors, and to provide some guidance to the Member States and food business operators;

32. INVITES the Commission to assess the need and feasibility of establishing harmonized processing factors in the MRL Regulation, also taking into account the action proposed in the previous paragraph;

32a. ENCOURAGES Member States and the Commission to fight against the illegal trading of counterfeit or non-authorised plant protection products;

(former para 34a)

Faster responses in the context of the MRL Regulation to emerging issues and technical progress

33. APPRECIATES the initiative of the Commission to start exploring solutions regarding the integration of new non-chemical active substances into the Annex to the MRL Regulation and thus allowing more flexibility and a possible adaptation to technical progress;

International trade

(Using green diplomacy to promote our green agenda for pesticides)

34. AGREES that the EU should promote phasing out at global level the use of active substances no longer approved in the EU and promote low-risk substances and alternatives at international level in line with the Green Deal Communication, which will contribute to the EU objectives regarding human and environmental health;

34a. […] *(moved to 32a)*

35. WELCOMES the intention of the Commission to review import tolerances for pesticides and to take into account environmental effects, when assessing requests for import tolerances (for substances no longer approved in the EU) in accordance with WTO standards and obligations and UNDERLINES the necessity to explain and promote this approach in different international fora with a view to consensus and transparency;

35a. AGREES with the Commission's intention to consider, if found necessary, a revision of the MRL Regulation, regarding the inclusion of environmental aspects in the setting of import tolerances and the transfer of Codex Maximum Residue Limits (CXLs) into EU law;

36. WELCOMES the Commission's intention to contribute at international level to the development of risk assessment and risk management methodologies to facilitate the alignment of EU MRLs with CXLs;

Internal coherence and consistency with other EU legislation

(Increase internal coherence and consistency with EU legislation)

37. WELCOMES any efforts towards an increased internal coherence and consistency with relevant EU legislation;

38. SUPPORTS the harmonisation of the MRLs that cover dual / multiple use substances in the MRL Regulation with other sectoral legislation for the same substance;

39. REMARKS that the MRL Regulation seems to be an appropriate regulation for setting MRLs for biocides, as their residues result from intentional use and in this respect are more comparable to pesticide residues than to contaminants;

39a. RECOGNIZING that substances can be used for pest and disease control either as a plant protection product or as a biocide under similar circumstances and therefore CALLS UPON the Commission – in line with the principle of "one substance, one assessment" - to explore how the ~~approval~~ **assessment** of active substances under Regulation (EC) 528/2012 (the Biocide Regulation) can be mutually accepted in an efficient procedure under Regulation (EC) 1107/2009, which might eventually lead to the alignment of certain safety principles and data requirements.

40. RECOGNISES the inconsistency between on the one hand the hazard based cut-off criteria of the PPP Regulation and on the other hand, setting import tolerances based on a risk assessment according to the MRL Regulation and SUPPORTS the Commission's efforts to improve clarity on the impacts of the cut-off criteria on MRLs for the substances concerned;

41. CALLS UPON the Commission to ensure that, when appropriate, new active substances and basic substances are approved swiftly for organic farming by adapting Annex II of Regulation (EC) No. 889/2008.