Pesticide Action Network Europe

Brussels, 27th February 2022

Ms. Stella Kyriakides
Commissioner for Health and Food Safety
European Commission - Directorate-General for Health and Food Safety

Subject: Request to suspend the approval's discussions on the herbicide Asulam sodium until EFSA's assessment protocol is aligned with regulation and science

Dear Commissioner Kyriakides,

We would like to ask you to employ your political leadership to ensure the Commission does not give in to current pressure to see approved a pesticide's substance found harmful to human health (so-called "cut off substances"). As things stand, this approval would run against Regulation (EU) 1107/2009, Directive (EU) 2009/128, and the EU political commitments made in the context of the EU Green Deal.

The substance in question is an herbicide called Asulam sodium that is currently not approved in the EU. An application for approval was submitted in 2013 and led the European Food Safety Authority (EFSA) to identify the substance as an endocrine disruptor interfering with the thyroid function of humans[1]. Thyroid disruption may cause developmental defects, tumors, hypo or hyper functions of hormones[2]. The exposure of pregnant women is of particular concern due to a risk of neurological damages on unborn children[3]. In line with Article 4(1) and Point 3.6.5 of Annex II of Regulation (EC) 1107/2009, pesticide's substances having "*endocrine disrupting properties that may cause adverse effects in humans*" cannot be approved in the EU. Point 3.6.5 of Annex II indicates that any contact with humans must be prohibited to ensure the high level of protection of human health, including that of the most vulnerable groups, animal health and the environment required by Recital 8 and Article 1(3) of Regulation (EC) 1107/2009. Furthermore, in 2020, the Commission committed in better protecting EU

[1] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties.

[2] Murthy MB, Murthy BK. Thyroid disruptors and their possible clinical implications. Indian J Pharmacol. 2012 Jul-Aug;44(4):542-3. doi: 10.4103/0253-7613.99351. PMID: 23087529; PMCID: PMC3469971.

[3] Boas M, Feldt-Rasmussen U, Main KM. Thyroid effects of endocrine disrupting chemicals. *Mol Cell Endocrinol*. 2012;355(2):240-248. doi:10.1016/j.mce.2011.09.005

citizens and the environment from exposure to endocrine disrupting chemicals[4], and in halving the use of more hazardous pesticides[5] to provide the next generations with a toxic free environment.

Yet, we are concerned to hear that the Commission is now seriously considering proposing to Member States a 5-year approval of Asulam sodium, by way of derogation from the above-mentioned safety requirements. Although this possibility is foreseen by Article 4(7) of Regulation (EC) 1107/2009, we observe an abusive interpretation of the strict requirements of this provision in EFSA's assessment protocol[6] and in its specific conclusions on Asulam sodium[7] substantiating the approval proposal currently under consideration by your services. Article 4(7) is restricted to circumstances where 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*". As recently stated by the EU Court of Justice in its preliminary ruling on Article 53[8], articular provisions of Regulation (EC)1107/2009 must be read in the context of the primary purpose of Regulation (EC) 1107/2009 to ensure human, animal and environmental health protection and in combination with Article 14(1) of Directive (EU) 2009/128, which requires to Member States to *"take all necessary measures to promote low pesticide-input pest management, giving wherever possible priority to non-chemical methods, so that professional users of pesticides switch to practices and products with the lowest risk to human health and the environment among those available for the same pest problem.*". Against this background, the interpretation of Article 4(7) by the Commission must be strict and its use justified by a strong demonstration that the derogation criteria are met. **In the light of the protocol used by EFSA to conduct this assessment, we consider that the need to provide a derogation to Asulam sodium for some uses, and thus to expose citizens and the environment to a cut off substance, has been insufficiently demonstrated by EFSA. This is due to the assessment protocol it has used to assess whether the requirements of Article 4(7) were met**.

In its assessment of Asulam sodium, EFSA considered a derogation to be "*scientifically supported*" for 5 uses against the Mayweed and Groundseld. However, this conclusion was reached building on a protocol which does not meet the strict requirements of Article 4(7) of Regulation (EC) of 1107/2009 and lacks empirical backing. The main issue with this stepwise protocol lies in the approach taken by EFSA to assess the strategy of resistance management to pesticides/the ability to control pests. This approach relies on the "multiple chemical strategy" and consists in assuming that farmers can solely address this risk of cross-resistance of target organisms by using a large diversity of chemical pesticides operating differently (having a different mode of action), regardless of the availability, applicability and effectiveness of non-chemical alternatives. In the case of Asulam sodium, it leads EFSA to consider the number of chemical active substances approved in the EU for the uses under assessment not high enough to manage resistance risk to weeds. Following this rationale, the approval of Asulam sodium

[4] EU Chemical Strategy for Sustainability.

[5] EU Farm to Fork Strategy. Cut off substances are included in the definition's scope of more hazardous pesticides.

[6] EFSA, 2016, Protocol for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means.

[7] EFSA, 2021, Updated peer review of the pesticide risk assessment of the active substance asulam (variant evaluated asulam sodium). Against the weeds Mayweed MATSS and Groundsel SENVU on marigold (DK), fennel (BE), bleached celery (BE), leaf celery (BE), and in spinach (DK, NL, DE).

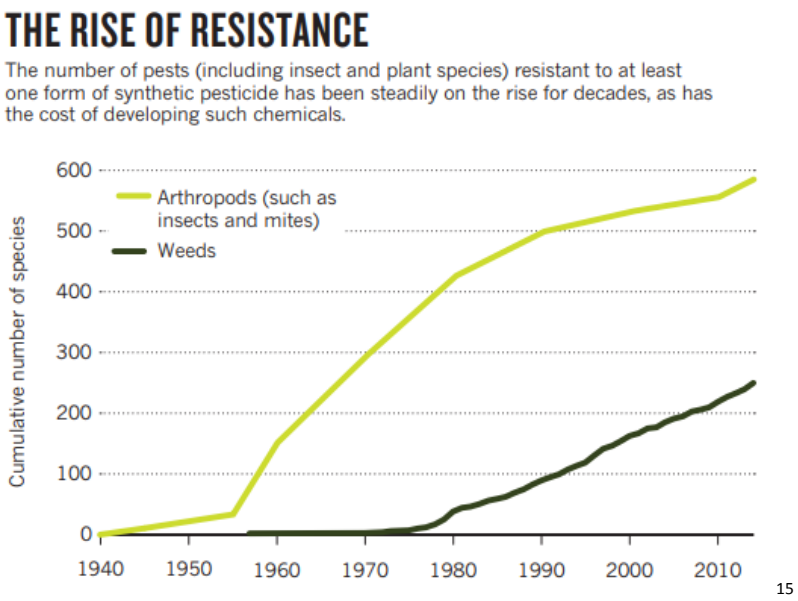
[8] Judgment of the Court, C-162/21, Pesticide Action Network Europe ASBL v. Etat belge.

would be critical to control these weeds, even if most EU farmers currently grow and protect their crops without this substance[9] and if multiple non-chemical preventive and curative methods[10] are considered as efficient to contain these weeds in most Member States. We would like to alert the Commission that this multiple chemical strategy endorsed in EFSA's protocol was created by the pesticide industry itself in the 1980s, is not in line with the EU legislative framework on pesticides and that its actual efficiency is empirically challenged.

Resistance to pesticides has been known for a long time. As early as in the 1970s, insects could no longer be controlled in tomatoes and cucumbers grown in greenhouses due to resistance. For a period of time, it even seemed like the greenhouse cultivation of these crops would have to stop. The introduction of biological control has saved greenhouse cultivation and is now used on almost all of tomato and cucumber crops by professional growers. This experience demonstrated that the only effective response to resistance was to use non-chemical methods. Obviously, this conclusion did not fit well with the profit-generating model of the pesticide industry. As early as 1984, an initiative (the Insecticide Resistance Action Committee, IRAC) was formed to provide a coordinated response by the pesticide industry to the problem of insecticide resistance which had become a serious threat to its profits. The solution was found in the multiple chemical strategy which claims that using many different pesticides (with different modes of action) enables to keep the resistance under control. This strategy was replicated for other families of pesticides (including herbicides and fungicides)[11]. This was a very clever strategy which invites the pesticide industry to continuously develop new (and expensive) pesticides to address ever growing resistance and averts the use of other plant protection methods.

As a result, the multiple chemical strategy has now been applied for more than 40 years by most farmers who rely on the guidance of advisors linked to the pesticide industry. The strategy was also uncritically endorsed by both the European and Mediterranean Plant Protection organisation (EPPO)[12] and EFSA[13] in their respective methodologies to assess alternatives. Yet, resistance to pesticides has kept increasing for virtually all organisms (insects, fungi, plants) during the same 40 years, on a scale that the industry itself admits: *"Resistance to conventional pesticides — among insects, weeds or microbial pathogens — is common on farms worldwide. CropLife International, an industry association based in Brussels, supports efforts that have counted 586 arthropod species, 235 fungi and 252 weeds with resistance to at least one synthetic pesticide*"[14] .

[9] We take note that a few Member States made use of Article 53 to temporarily put the substance on the market.
[10] Including primary tillage, false seed beds, cover crops, crop rotation and hand weeding as highlighted in Appendix C and D of EFSA's peer review.
[11] Herbicide Resistance Action Committee (HRAC), Fungicide Resistance Action Committee (FRAC).
[12] EPPO, PP 1/213 - Resistance Risk Analysis; PP1/271(3) Guidance on efficacy aspects of comparative assessment.
[13] See also Protocols on Articles 4(7) for fungicides and insecticides. Used by EFSA to assess the need for Member States to use Article 53(1) on emergency situations.
[14] With pesticide resistance rising, crop scientists look to CRISPR, bacteria for solutions - Genetic Literacy Project



[15]

Independent scientists challenge the relevance of the multiple chemical strategy and acknowledge that integrated use of agronomic, mechanical, physical and biological alternatives is the most effective strategy to manage pest resistance and control[16]. According to Hicks and al.[17], the system of applying more and more pesticides is counterproductive: "*Resistance was correlated with the frequency of historical herbicide applications suggesting that evolution of resistance is primarily driven by intensity of exposure to herbicides but was unrelated directly to other cultural techniques"*. Other resistance scientists including Gould and al[18] state that it is an illusion to consider that resistance can be tackled by synthetic pesticides: "*We mostly continue to use pesticides as if resistance is a temporary issue that will be addressed by commercialization of new pesticides with novel modes of action"*. Likewise, Hoy[19] stresses that *"resistance will remain an ongoing dilemma in pest management and we can only delay the onset of resistance to pesticides*". The solution *"involves employing effective agronomic practices to develop and maintain a healthy crop, monitoring pest densities, evaluating economic injury levels so that pesticides are applied only when necessary, deploying and conserving biological control agents, using host-plant resistance, cultural controls of the pest, biorational pest controls, and genetic control methods"*. Comont and al.[20] clearly question the effectiveness of the multiple chemical strategy: "*We*

[15] Borel, B. When the pesticides run out, Nature, Vol 543 (2017).

[16] Sowa G, Bednarska AJ, Ziółkowska E, Laskowski R. Homogeneity of agriculture landscape promotes insecticide resistance in the ground beetle Poecilus cupreus. PLoS One. 2022;17(4):e0266453. Published 2022 Apr 26. doi:10.1371/journal.pone.0266453.

[17] Hicks, HL. et al. The factors driving evolved herbicide resistance at a national scale, Nat Ecol Evol. 2018 Mar;2(3):529-536. doi: 10.1038/s41559-018-0470-1.

[18] Gould, F et al, Wicked evolution: Can we address the sociobiological dilemma of pesticide resistance?, Science 360 (6390), 728-732. Doi: 10.1126/science.aar3780.

[19] Hoy MA. Myths, models and mitigation of resistance to pesticides. *Philos Trans R Soc Lond B Biol Sci*. 1998;353(1376):1787-1795. doi:10.1098/rstb.1998.0331.

[20] Comont, D., Lowe, C., Hull, R. and al. Evolution of generalist resistance to herbicide mixtures reveals a trade-off in resistance management. Nat Commun 11, 3086 (2020). doi: https://doi.org/10.1038/s41467-020-16896-01.

contend that where specialist and generalist resistance mechanisms co-occur, similar trade-offs will be evident, calling into question the ubiquity of resistance management based on mixtures and combination therapies ”. Whelan and al.[21] clearly point out the pesticide's industry responsibility: “T*he agriculture industry recognized the problem of pesticide resistance and responded by developing and enforcing guidelines on resistance management and prevention. These guidelines, (...) do not encourage eradication of pests but instead strive to maintain pests, even with the presence of resistant strains, at a level that does not cause economic damage to the crops.*”.

In this context, it is highly questionable that EFSA uncritically endorsed this strategy in its assessment protocol used to provide the Commission and Member States with scientific insights for decision making. In the case of Asulam sodium, the questionable reliability of EFSA's protocol does not seem to have been compensated by clear empirical evidence of weed resistance or the 5 uses needed to demonstrate the existence of a “*serious threat*”. Likewise, EFSA's assessment lacks independent and empirical evidence that resistance management strategies will become more effective in combating resistance if Asulam sodium is approved (e.g. no evidence that Member States that use Article 53 to put temporarily the substance on the market have better control of weeds than those that do not). Further, the assessment of non-chemical alternatives seems to have been performed considering each individually while an integrated approach was needed to reflect Article 14(1) of Directive (EU) 2009/128. Last but not least we wonder whether EFSA relied on other sources of information than the ones provided by the applicant and Member States to carry out its evaluation.

In that context, we consider that the necessity to grant a derogation to Asulam sodium was insufficiently demonstrated with regard to the requirements of Article 4(7) and the hazards of the substance. It is therefore the legal and political responsibility of the Commission to suspend any approval's discussions of Asulam-sodium until EFSA fully reconsiders its approach of resistance in the context of Article 4(7).

From beforehand, thank you for your consideration and your support. We remain available to discuss further about the content of this letter.

Sincerely yours,

Martin Dermine, Executive Director of PAN (Pesticide Action Network) Europe

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[21] Whelan CJ, Cunningham JJ. Resistance is not the end: lessons from pest management. Cancer Control. 2020;27(1). doi:10.1177/1073274820922543