Pesticide Action Network Europe

Major flaw in EFSA's pesticide risk assesment policy.

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To: Food Authority EFSA
Mr. Url.

Concerning: Negative effects on biodiversity not taken into account.

Dear Mr. Url, with this letter we like to make you aware of new research[1] that demonstrates that pesticides are widely present in feed for dairy cows and that a number of these pesticides are transferred to manure. The pesticides in manure have a negative effect on the number of Coleoptera and as a consequence may also affect ecosystem services such as the disappearance of manure pats and the presence of insects in manure pats as feed for farm birds or bats. A total of 70 pesticides were detected in the different types of feed of eight farms studied, while also biocide use (fly treatment) contributed to contamination. The concentration of pesticides in the manure was on average 423 µg/kg DM (range of 112–1980 µg/kg DM). Those indirect effects of pesticides are currently disregarded in EFSA's risk assessment policy, which is not in line with regulation (EU) 1107/2009 that aims at ensuring a high level of protection for the environment.

On July 31, 2019 we already wrote a letter to you pointing at the results of a preliminary study[2] that indicated harm to the environment via the same route of animal feed to manure to wildlife in pastures[3]. And we asked you to change MRLs in animal feed to protect biodiversity as required by Art. 4.3.e.iii of the Pesticide Regulation (EU) 1107/2009. In your reply dated January 10, 2020 you took the position that setting MRLs for feed is "*likely not the best solution*", without making clear what the legal grounds are for such an argumentation. At the same time you promoted the view that a "*comprehensive and holistic risk assessment for predicting the environmental impact of the agricultural use of manure*" is a "*more suitable option*". But you apparently will only do this on the condition "*when changes occur of the current legal regulatory framework*".

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[1] Martine Bruinenberg, Maaike van Agtmaal, Nyncke Hoekstra, Nick van Eekeren, Residues of pesticides in dairy cow rations and fly treatments reduce the number of Coleoptera in dung, Agriculture, Ecosystems and Environment 344 (2023) 108307.

[2] Buijs. J. & M. Mantingh. 2019, Een onderzoek naar mogelijke relaties tussen de afname van weidevogels en de aanwezigheid van bestrijdingsmiddelen op veehouderijbedrijven, Commissioned by Province of Gelderland.

[3] An indicative calculation based on application of 20 Tons of manure/ha on the fields, resulted in an exceedance of the insecticides Cypermethrin and Chlorpyrifos of the LR-50 (lethal rate) for arthropods

We don't think that the current legal framework prevents you from taking indirect effects on biodiversity into account. The text in Art.4.3.e.iii "*its impact on biodiversity and the ecosystem*" does not limit assessing effects of pesticides to only direct exposure of humans and (to be protected) environmental organisms. We hold that all indirect effects, for the example of manure as discussed above, but also all indirect effects such as accumulation of pesticide residues in wildlife food chain (food web support) and food deprivation (insect to birds/bats for instance), should be discussed and assessed in risk assessment. At the minimum, based on art. 8.5 of the Regulation, all available data, including those on indirect effects, should be collected in risk assessment and EFSA's peer review of pesticides. And here we present data. Data showing harm. And thus we think that EFSA should take its responsibility and not hide behind alleged lacking data requirements or questionable claims like "*not the best solution*", while at the end of the day you fail to act.
Data requirements even oblige the applicants to consider indirect effects: *"(d) permit an assessment of the impact on non-target species (flora and fauna), including the impact on their behaviour, which are likely to be exposed to the active substance, its metabolites, breakdown and reaction products, where they are of toxicological or environmental significance. Impact can result from single, prolonged or repeated exposure and can be direct or indirect, reversible or irreversible*" (Regulation 283/2013, art. 1.11.d), and "*The potential impact of the active substance on biodiversity and the ecosystem, including potential indirect effects via alteration of the food web, shall be considered*" (Reg. 283/2013/EC art.8.5). EFSA therefore should conclude to a "critical area of concern" for any pesticide where testing outcome and data on indirect effects are lacking.

The poor state of biodiversity and current industrial agricultural of food production and pesticide use being its main driver [4],[5],[6],[7] should urge you to act and not wait while the disaster of biodiversity decline further unfolds. This is the more the case now a long range of studies [8], [9], [10], [11], [12], [13],[14],[15],[16],[17] point at a failing EFSA risk assessment policy to

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[4] Francisco Sánchez-Bayo, Kris A.G. Wyckhuys, Worldwide decline of the entomofauna: A review of its drivers, Biological Conservation 232 (2019) 8–27
[5] Geiger, F., Bengtsson, J., Berendse, F., Weisser, W., Emmerson, M. (2010): Persistent negative effects of pesticides on biodiversity and biological control potential on European farmland. Basic and Applied Ecology, Volume 11, Issue 2, Pages 97-105.
[6] IPBES (2016): The assessment report of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services on pollinators, pollination and food production. S.G. Potts, V. L. Imperatriz-Fonseca, and H. T. Ngo (eds). Secretariat of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services, Bonn, Germany. 552 pages. doi: 10.5281/zenodo.3402856
[7] Storkey, J., Meyer, S., Still, K.S., Leuschner, C. (2012): The impact of agricultural intensification and land-use change on the European arable flora. Proc Biol Sci. 2012 Apr 7;279(1732):1421-9. doi: 10.1098/rspb.2011.1686.
[8] Caspar A. Hallmann, Martin Sorg, Eelke Jongejans, Henk Siepel, Nick Hofland, Heinz Schwan, Werner Stenmans, Andreas MuÈ ller, Hubert Sumser Thomas HoÈ rren, Dave Goulson, Hans de Kroon, More than 75 percent decline over 27 years in total flying insect biomass in protected areas, PLOS ONE | https://doi.org/10.1371/journal.pone.0185809 October 18, 2017
[9] Matthias Liess et al., Pesticides are the dominant stressors for vulnerable insects in lowland streams, Water Research, Volume 201, 1 August 2021, 117262.
[10] Carsten A. Brühl and Johann G. Zaller, Biodiversity Decline as a Consequence of an Inappropriate Environmental Risk Assessment of Pesticides, Frontiers in Environmental Science | www.frontiersin.org 1 October 2019 | Volume 7 | Article 177.
[11] Carsten A. Bru¨hl, Thomas Schmidt, Silvia Pieper & Annika Alscher, Terrestrial pesticide exposure of amphibians: An underestimated cause of global decline?, Nature SCIENTIFIC REPORTS | 3 : 1135 | DOI: 10.1038/srep01135, 2013.

consider negative effects on biodiversity. Just like on the neonicotinoids that were responsible for major bee and insect decline, in the presence of overwhelming independent data, we again see an EFSA that doesn't take responsibility, hides behind formal arguments and looks the other way.

Indirect effects have been reported frequently in literature and it is concerning that EFSA does not take these research outcomes into account in its risk assessment as it should, based on Art. 8.5. We mention as an example the indirect effects of Glyphosate on microbial communities (Van Bruggen, 2021[18]), a study on birds (Boatman, 2004[19]) and one on vertebrate wildlife (Gibbons, 2015[20]). In a review of Sanchez-Bayo on insects and other arthropods[21], the authors discuss a range of these indirect effects: "*Application of insecticides to agriculture often results in subsequent pest outbreaks due to the elimination of natural enemies. The loss of floristic diversity and food resources that result from herbicide applications can reduce populations of pollinators and natural enemies of crop pests. In aquatic ecosystems, insecticides and fungicides often induce algae blooms as the chemicals reduce grazing by zooplankton and benthic herbivores. Increases in periphyton biomass typically result in the replacement of arthropods with more tolerant species such as snails, worms and tadpoles. Fungicides and systemic insecticides also reduce nutrient recycling by impairing the ability of detritivorous arthropods. Residues of herbicides can reduce the biomass of macrophytes in ponds and wetlands, indirectly affecting the protection and breeding of predatory insects in that environment*". While you mention a holistic approach of the impact of pesticides on manure, we consider that these scientific findings should be part of the holistic approach EFSA should already take in its current risk assessment, taking them into account in its peer reviews, to complement the imperfections of the current risk assessment. Instead, we observe that the already available information on the impact of pesticides on ecosystems and biodiversity is systematically disregarded and that non-industry data keeps being dismissed.

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[12] Anja Kna¨bel, Sebastian Stehle, Ralf B. Scha¨fer, and Ralf Schulz, Regulatory FOCUS Surface Water Models Fail to Predict Insecticide Concentrations in the Field, Environ. Sci. Technol. 2012, 46, 8397−8404.

[13] F. Samu, É. Szita, E. Botos, J. Simon, N. Gallé‑Szpisjak & R. Gallé, Agricultural spider decline: long‑term trends under constant management conditions, Nature Scientific Reports | (2023) 13:2305

[14] Sebastian Stehle & Ralf Schulz, Pesticide authorization in the EU—environment unprotected?, Environ Sci Pollut Res (2015) 22:19632–19647

[15] Sebastian Stehle and Ralf Schulz, Agricultural insecticides threaten surface waters at the global scale, www.pnas.org/cgi/doi/10.1073/pnas.1500232112, 2015.

[16] Sebastian Seibold at al., Arthropod decline in grasslands and forests is associated with landscape-level drivers, Nature | Vol 574 | 31 October 2019 | 671

[17] J. C. Biesmeijer at al., Parallel Declines in Pollinators and Insect-Pollinated Plants in Britain and the Netherlands, SCIENCE VOL 313 21 JULY 2006

[18] A. H. C. van Bruggen, M. R. Finckh, M. He, C. J. Ritsema, P. Harkes, D. Knuth and V. Geissen, Indirect Effects of the Herbicide Glyphosate on Plant, Animal and Human Health Through its Effects on Microbial Communities, Front. Environ. Sci. 9:763917, 2021. doi: 10.3389/fenvs.2021.763917

[19] NIGEL D. BOATMAN, NICHOLAS W. BRICKLE, JUSTIN D. HART, TIM P. MILSOM, ANTONY J. MORRIS, ALISTAIR W. A. MURRAY, KATHRYN A. MURRAY, & PETER A. ROBERTSON, Evidence for the indirect effects of pesticides on farmland birds, *Ibis* (2004), 146 (Suppl. 2), 131–143

[20] David Gibbons & Christy Morrissey & Pierre Mineau, A review of the direct and indirect effects of neonicotinoids and fipronil on vertebrate wildlife, Environ Sci Pollut Res (2015) 22:103–118.

[21] Francisco Sánchez-Bayo, Indirect Effect of Pesticides on Insects and Other Arthropods, Toxics 2021, 9, 177.

A disturbing new study is the pollution of birds of prey, the top of a food chain via diverse indirect ways, with pesticide residues (Badry, 2022[22]). Eighty-five different chemicals even are analysed. On top of disregarding indirect effects on these top predators, this reminds also the lack of consideration of cocktails in these predators (from agriculture like spiroxamine, pymetrozin, myclobutanil, bromoxynil, metalaxyl, etc. combined with medical products and with fluorinated chemicals). Even though wildlife species are exposed to multiple chemicals, chemical mixtures, so far this is not adequately assessed in the European risk assessment (Drakvik, 2020[23]). Once more, these findings point at the failure of EFSA to produce, since its creation, risk assessment tools that take into account multiple exposure, as well as indirect effects. We observe that these topics have been discussed in conferences as well as in research projects but that no progress has been made so far, questioning your capacity, as a scientific agency, to make use of available scientific knowledge to propose a protective methodology to risk assessors.

The problem on failing to include indirect effects becomes also clear if we consider the current risk assessment of herbicides such as Glyphosate, that is mainly focussing on direct toxicological effects of the respective pesticides. Such effects however insufficiently pose the main driver of the overall risk of a total herbicide like glyphosate to terrestrial organisms. The current risk assessment does not consider indirect effects on terrestrial organisms mediated via direct effects on the plants as fundamental prerequisite for an appropriate habitat e.g. loss of plant biomass for herbivores and floral resources for pollen/nectar feeders of simply loss of habitat, thereby jeopardizing the overall protection goal to avoid any long-term repercussions on the abundance and diversity of terrestrial populations in agricultural landscapes. For the in-field risk, the "recovery of abundance of these species within one year" is currently considered as protection goal. However, the definition of Specific Protection Goals (SPGs) for in-field have also to address the different functional roles of in-field terrestrial organisms in the ecosystem e. g. for the food web or the natural pest regulation. Whereas for certain functions in the ecosystem, a recovery within one year might be considered as appropriate this is not the case for the function of the organism in the food web as many other arable species such as amphibians or farmland birds depend on these organisms as food. Therefore, a sustained suppression not only of pest species but also of terrestrial organisms due to the above-mentioned indirect effects of total herbicides is the actual problem to address.

In the recent Glyphosate renewal of 2017, there was a slight opening for considering indirect effects. Member States were obliged to consider "*the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions" and "include risk mitigation measures….*". Indirect effects were considered as an important risk assessment issue. This is also the case for the current four Member States

[22] Alexander Badry, Gabriele Treu, Georgios Gkotsis, Maria-Christina Nika, Nikiforos Alygizakis, Nikolaos S. Thomaidis, Christian C. Voigt, Oliver Krone, Ecological and spatial variations of legacy and emerging contaminants in white-tailed sea eagles from Germany: Implications for prioritisation and future risk management, Environment International 158 (2022) 106934

[23] Drakvik, E., Altenburger, R., Aoki, Y., Backhaus, T., Bahadori, T., Barouki, R., Brack, W., Cronin, M.T.D., Demeneix, B., Hougaard Bennekou, S., van Klaveren, J., Kneuer, C., Kolossa-Gehring, M., Lebret, E., Posthuma, L., Reiber, L., Rider, C., Rüegg, J., Testa, G., van der Burg, B., van der Voet, H., Warhurst, A.M., van de Water, B., Yamazaki, K., ¨Oberg, M., Bergman, Å., 2020. Statement on advancing the assessment of chemical mixtures and their risks for human health and the environment. Environ. Int. 134, 105267. https://doi.org/10.1016/j.envint.2019.105267

being the Rapporteur for Glyphosate. It is therefore inconsistent not to consider biodiversity for other pesticides as EFSA does.

This is the more the case now the German Environmental Agency (UBA) developed an approach[24] which can serve as an interim solution for the time the old, outdated Guidelines are not revised. EFSA should not hide behind "*holistic approaches on the condition of regulatory changes'*. The UBA-method is available, and shall, according to Art.4, be considered as the most recent insights available. Waiting for a revision of the Terrestrial Guideline, as you like to do, will take many years and a continued lacking protection of terrestrial organisms till 2030 and beyond. Germany's request to use the approach was dismissed by you and raises questions about EFSA's intentions.

Also Swedish KEMI published a report[25] on methods how to assess the effects of pesticides on biodiversity. The report concludes that "*While plenty of papers suggest that current risk assessment methodologies are insufficient to safeguard biodiversity, few papers have actually compared how well different environmental risk methodologies protect biodiversity. The current risk assessment methods are based on short term laboratory studies, on single test species, or on simplified communities in mesocosm experiments, which provide information on acute toxicity. The validity and usefulness of such laboratory studies have been criticized for not including variation in space and time, interactions with other stressors and indirect effects caused by competition and trophic interactions between populations. This hampers the possibility of using them to assess effects on biodiversity in field situations*".

It is long overdue that EFSA finally takes Art.4.3.e.iii of Regulation (EU) 1107/2009 as a priority and starts evaluating and protecting biodiversity.

We urge you to start taking indirect effects on biodiversity into account and adopt the UBA-proposal as an interim solution.
We are looking forward to your reply,

Sincerely yours,
Hans Muilerman,
Pesticide Action Network.

[24] IMPACT OF PESTICIDES ON IN-FIELD NONTARGET PLANTS AND ARTHROPODS WITH CONSEQUENCES FOR ´FOOD-WEB-SUPPORT´ – EXPANDED RISK ASSESSMENT METHOD FOR NATIONAL PRODUCT AUTHORISATION IN GERMANY, UBA, 2022.
[25] KEMI, Methods for assessing the effects of plant protection products on biodiversity, 2020