BRUSSELS, 16 JUNE 2021

To: Manuela Tiramani, Head of Pesticides Peer Review Unit, European Food Safety Agency (EFSA)

Re: Additional questions regarding the peer-review status of several pesticide active substances, including endocrine disruption assessment

Dear Mrs Tiramani,

The Health and Environment Alliance (HEAL), Alerte des Médecins sur les Pesticides (AMLP) and Générations Futures thank you for the detailed response you recently sent to our inquiry about the peer-review status of the following six active substances: Cyprodinil, Fenbuconazole, Mepanipyrim, Spinosad, Ziram and Pyrimethanil. Your response triggered further questions, for which we would appreciate additional clarifications.

First of all, we acknowledge that the current lack of data about endocrine disrupting (ED) properties is a general problem under various European regulations, including that of pesticides, and that the generation of such adequate data can be challenging and time-consuming. In the context of the assessment of the afore mentioned substances, we are however surprised at the length of the subsequent process.

Those substances have all been flagged up for their thyroid activity in an EFSA report dating back from 2013 and therefore have long been known as potential priority candidates for further investigation about ED properties. Furthermore, as you are well aware, the finalizing of the scientific criteria for ED properties and accompanying guidance for implementation was a long process, which took several years way passed the Regulation deadline. It however appears that practical aspects of the criteria implementation, starting with the effects of delays stemming from new data generation, have not been anticipated in a way to keep the substance renewal processes within reasonable time-limits. All the substances addressed in our letter have been authorized for a long time and delays in their safety assessment effectively means that they remain on the market until the process is being completed, with important concerns about human health and environmental impacts.

Based on the information you kindly provided in your letter and related annex, we understand that the maximum amount of time for data generation – 30 months – has systematically been granted to industry applicants for the five substances that are under 'stop the clock' provisions. It is however not clear what were the specific reasons for granting each of those substances the maximum delay possible. According to Article 13(3a) of Regulation 844/2012 as amended by Regulation 2018/659, the 'stop the clock period' *"shall be at least of 3 months, shall not exceed 30 months, and shall be justified in relation to the type of information which has to be submitted"*. We would therefore be grateful if you could provide us with additional information about the reasons justifying the use of the longest possible delays under current legal rules for all of those substances.

Furthermore, we also thank you for your clarification as regards the conditions of application of the recent EFSA Transparency Regulation (Regulation 2019/1381). We are aware that Article 11(1) states that *"this Regulation shall not apply to applications under Union law as well as requests for scientific outputs submitted to the Authority before 27 March 2021".* However, the legal text does not specify when the regulation starts to apply in case of additional data requests and suspension of the application process. Considering the objective of this regulation (see recital 12), Article 11 should be interpreted as requiring that any data submitted after 27 March 2021 for the purpose of fulfilling additional data requirements, shall be published following the rules this regulation.

We trust EFSA's commitment to continuously increase the transparency of the authorization and renewal processes of pesticide active substances and we would therefore expect that any safety data provided by industry applicants after the entry into force of this regulation are made available for public scrutiny.

In the context of the assessments of the five substances raised in our exchange, we wish to emphasize that full transparency would significantly help increasing trust in the renewal processes. All those renewals started several years ago, with the most recent expert meetings taking place during the year 2019 - that is two years ago. Due to the recourse to the 'stop the clock' provision, those evaluations will at best be finalized by the middle to the end of 2022 and final decisions on the fate of the substances will be issued at best by the end of 2022, if not in the course of 2023.

In the context of the EU's strong commitments with regards to endocrine disruptors, in particular to strengthen and speed up their identification due to the risks they pose for human health and the environment, the lack of possibility for the public and interested stakeholders to follow those procedures real-time raises legitimate questions about the determination of EU institutions to do so. It also unnecessarily discredits the regulatory work that is currently underway. We therefore very much urge you to make as much information about the state of those assessments public, including all safety information and studies received throughout the process.

We thank you for your response and look forward to continue to exchange in a constructive way.

Yours sincerely,

Natacha Cingotti
Programme Lead, Health and Chemicals
Health and Environment Alliance (HEAL)
On behalf of Alerte des Médecins sur les Pesticides and Générations Futures