Brussels, 30.11.2021

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Drawing attention to EFSA's unscientific, biased, and flawed chemical cocktail policy. Towards the implementation of a Mixture Assessment Factor.

To: World Health Organisation, To: Dr Tedros Adhanom Ghebreyesus, the Director-General of WHO To: Dr Patrick Amoth, the Executive Board of WHO and its Chair To: The Chemical Safety and Health Unit

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To: Organisation for Economic Co-operation and Development (OECD) To: Mr. Mathias Cormann, the Secretary-General of the OECD To: The members of the OECD Council To: OECD Environment Directorate, Environment, Health and Safety Division

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Concern: Your cooperation with the European Food Authority EFSA on the risk assessment of chemical cocktails.

Dear Mr. Ghebreyesus, Mr. Amoth and Mr. Cormann,

With this letter we would like to give you some background information on the work of the EU Food Authority EFSA regarding pesticide cocktails and its attempt to 'sell' its risk assessment system to you through its 'international' workshop' (18-20 October 2021)¹. We believe that you are not aware of the details of EFSA's policy which is designed by the pesticide industry. We, therefore, feel it is imperative to share with you some facts alongside our views on the matter. In addition to demonstrating why this methodology cannot be supported by your institutions, we respectfully

¹ <u>https://events.efsa.europa.eu/international-workshop-on-risk-assessment-of-combined-exposure-to-multiple-chemicals</u>

call for your support of the mixture assessment method² (developed in the position paper attached to this letter).

The precautionary principle is enshrined in the EU Treaty and in the EU laws, including the one regulating pesticide approval (Art. 1.4 of Regulation (EC) n°1107/2009³). EFSA has been active in the past years to substitute this principle by ideology⁴. This ideology lays out that in case of demonstrated adverse effects of a pesticide, while full proof is lacking, the advantage of the doubt should be given to the industrial applicant and not to the public. EFSA's ideology, therefore, is very similar to the one promoted by industry. This EFSA policy is implemented by selecting external experts with an industry background, who end up regularly being a majority in EFSA working groups⁵. There are instances wherein entire EFSA working groups are composed of an industry taskforce⁶, generally from industry lobby group ILSI⁷, exhibiting complete disregard for independence considerations. Not coincidentally, EFSA management (in charge of scrutinising the external expert's selection) in majority also has an industry background⁸.

The EFSA 'international workshop'⁹ is a case in point. The EFSA employee at the steering wheel for the meeting, Ms. Kleiner (EFSA head of department on risk assessment), worked for many years for industry group ILSI and came through the revolving door to EFSA. She selected, for instance, Mr. Boobis and Mr. Moretto as chair or speaker for this meeting, experts both expelled from EFSA panels for conflicts of interest. This is the same pair of experts who chaired the controversial FAO/WHO meeting on the pesticide Glyphosate¹⁰ without revealing their board membership position at ILSI¹¹. Apart from these two experts who dedicated their entire career to industry front group ILSI, the big majority of speakers/chairs exhibit similar biases. Mr. Schlatter has been active for decades for ILSI¹² and is part of a network with Boobis and other industry-linked experts¹³. He entered EFSA after a 2-year 'cooling-off' period, but with his ideology and positions intact. Mr. Benfenati worked for chemical industry umbrella group CEFIC¹⁴, Mr. Price was an employee of DOW Chemicals till 2015¹⁵. Ms. Testai was part of a pressure group to fight EU law on endocrine

² PAN Europe, <u>How to best address cocktails effects in the Pesticide legislation? Towards the</u> <u>implementation of a Mixture Assessment Factor (MAF)</u>

³ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

⁴ <u>science or ideology?</u>, in the 9 cases/EFSA working groups studied, in none the precautionary principle was applied

⁵ PAN Europe, <u>science or ideology?</u>, in 9 case studies (EFSA working groups on genotoxicity) in 4 cases >90% of the experts had a questionable independence, while in another 4 cases 50% of the experts had a questionable independence (one case intermediate with 75% experts with a questionable independence). ⁶ PAN Europe, <u>Toxic mixture</u>, page 8

⁷ ILSI, the International Life Sciences Institute, an industry funded (not exclusively pesticide industry, but all food and tobacco industries) front group that has offices all over the world and desings risk assessment methods.

⁸ PAN Europe, <u>science or ideology?</u>, in de 13 EFSA management analysed, 11 out of 13 had a questionable independence.

⁹ https://events.efsa.europa.eu/international-workshop-on-risk-assessment-of-combined-exposure-tomultiple-chemicals

¹⁰ <u>https://www.testbiotech.org/en/press-release/glyphosate-science-playground-industry</u>

¹¹ <u>https://www.theguardian.com/environment/2016/may/17/unwho-panel-in-conflict-of-interest-row-over-glyphosates-cancer-risk</u>

¹² PAN Europe, <u>Toxic mixture</u>, page 24

¹³ PAN Europe, <u>Toxic mixture</u>, page 10

¹⁴ <u>https://cefic-lri.org/lri-research-programme/programme-management/emilio-benfenati/</u>

¹⁵ https://slidetodoc.com/a-perspective-paul-price-dow-chemical-company-ppricedow/

disrupting pesticides¹⁶. Ms. Browne is known for having close ties to industry (DOW) and ILSI (HESI¹⁷).

We, therefore, urge you to adopt a strict policy on conflicts of interest. We noted that your publication on the risks of combined exposure to mixtures of chemicals¹⁸ "builds upon the recommendations from the WHO OECD ILSI/HESI International Workshop on Risk Assessment of Combined Exposures to Multiple Chemicals (OECD, 2011)". It is unfair to cooperate with a specific interest group (ILSI) and to allow them such an influence on the outcome of a policy meant to protect the public. Organisations representing the public are side-lined. The tragedy of 'industry writing its own rules'¹⁹, resulting in classifying any pesticide or pesticide cocktail as 'safe' should be put to an end.

The matter discussed in EFSA's international workshop last week was using probabilistic modelling for the risk assessment of pesticide cocktails. This modelling idea was further elaborated in industryinitiated (EU-funded) programs (Acropolis by EU trading umbrella group Freshfel). The main expert of this type of modelling, Mr. Van Klaveren, even promised at the start to "prove that pesticide use is safe" (see flyer Acropolis from 2010²⁰). This type of program was later adopted by EFSA and the outcome can be no surprise. Pesticide cocktails, no matter how high or how many, in food are safe for consumption. By simply changing the input of the computer modelling, any outcome can be reached. In other words, this modelling makes it very easy to manipulate data and tailor the results of the assessment to the needs of the industry, rather than on the level of protection required for consumers. Unsurprisingly, Mr. Van Klaveren was joined by Mr. Boobis, Mr. Moretto and even Ms. Kleiner in his program Acropolis. Unfortunately, these people together with other experts like Ms. Meek can hardly be qualified as independent²¹.

EFSA's method is unscientific, it is biased, it is 'desired-outcome' risk assessment and should be rejected. We hope that you, at WHO and OECD, will refrain from aligning your name and reputation to such work.

With the EU Agency ECHA working on cocktail risk assessment as well, there is more to this. Calls from politicians and the public have been heard very loud for years now to finally start protecting EU citizens against the potential harms of chemical cocktails. This was well reflected in the EU Chemical Strategy for Sustainability where the European Commission introduced the MAF, a multiassessment-factor, as the best way to effectively protect the health of citizens and the environment from cocktail effects. Therefore, ECHA is on its way to develop a risk assessment method building on a MAF, which PAN Europe welcomes. **EFSA now feels that its method is finally (for good reason) questioned. This is the reason why it tries to get you, at WHO and OECD, on board on the probabilistic modelling idea. This is another good reason not to support EFSA** and to look more closely at the implementation of a MAF, in line with the precautionary principle.

¹⁶ Emanuela Testai, Corrado L. Galli, Wolfgang Dekant, Marina Marinovich, Aldert H. Piersma, Richard M. Sharpe, A plea for risk assessment of endocrine disrupting chemicals, Toxicology 314 (2013) 51–59

¹⁷ Katie Coady, Patience Browne, Michelle Embry, Thomas Hill III, Eeva Leinala, Thomas Steeger, Lidka Maślankiewicz, and Tom Hutchinson, Integrated Environmental Assessment and Management — Volume 15, Number 4—pp. 633–647, 2019.

¹⁸ <u>https://www.oecd.org/chemicalsafety/risk-assessment/considerations-for-assessing-the-risks-of-combined-exposure-to-multiple-chemicals.pdf</u>

¹⁹ PAN Europe, <u>Writing IOR</u>, page 60 – 62 with the usual suspects of ILSI experts, Boobis, Moretto, Barlow, Meek, Renwick, Olin, Kleiner, etc.

²⁰ <u>https://businessdocbox.com/66428015-Agriculture/Acropolis-aggregate-and-cumulative-risk-of-pesticides-an-on-line-integrated-strategy-seventh-framework-programme.html</u> – page 5
²¹ <u>Poisonous injection</u>, page 4

Mr. Ghebreyesus, Mr. Amoth and Mr. Cormann, we hope you will consider and eventually share our views on this important matter.

Sincerely yours,

Salomé Roynel and Hans Muilerman On the behalf of PAN Europe

With the support of Javier Souza On the behalf of PAN International

About PAN EUROPE:

Pesticide Action Network Europe (PAN Europe) was founded in 1987 and brings together consumer, public health, environmental organisations, and women's groups from across Europe. PAN Europe is part of the global network PAN International working to minimise the negative effects and replace the use of harmful pesticides with ecologically sound alternatives.