

Brussels, 30/04/2020

EFSA's pilot studies on Cumulative Risk Assessment – A source of concern

Fifteen years have passed since EU law (EC 396/2005) called to evaluate the impact of pesticide mixtures on human health. To our disappointment EFSA's pilot studies presented yesterday seem *unfit for purpose* to ensure that pesticides mixtures cause no impact to human health and particularly to the most vulnerable groups in our population.

The EFSA [studies](#) examine the risk of dietary exposure to pesticides mixtures for acute effects on the nervous system and chronic effects on the thyroid, and they're completely hypothetical: no experimental studies using pesticide mixtures have taken place at any step of the assessment.

They conclude that "consumer risk from dietary cumulative exposure" is - with varying degrees of certainty - "below the threshold that triggers regulatory action"

When examined in detail they raise major concerns on their adequacy to objectively and independently assess the toxicity of mixtures.

During [the public consultation last November](#), PAN Europe had raised major concerns about the process being "based on -unfit for purpose- experimental studies and numerous far-fetched assumptions" leading to an "underestimation of the potential harm that pesticides may cause".

PAN Europe's environmental toxicologist Dr. Angeliki Lyssimachou says "*the most sensitive tests, which examine endocrine-related diseases following low-dose, continuous exposures, during sensitive or vulnerable periods of life-time have not been taken into account.*"

According to [EFSA's latest report](#) over 65% of common fruits like table grapes, strawberries, cherries and pears, contain two or more pesticide residues. A goji berry from China contained 29 pesticides. Numerous scientific studies have raised alarms on [the health impact of chemical mixtures](#), including [pesticides](#), highlighting the need for regulatory measures to address exposure to mixture of chemicals.

Unsurprisingly, EFSA received criticism¹ for reaching a misleading conclusion in the draft studies², since important data to cover exposures of all age ranges and vulnerable groups were missing. EFSA correctly decided to delete these conclusions from the final version of the reports. Other relevant factors such as previous

¹ See results of public consultation: [nervous system](#) and [thyroid](#)

² Conclusions at the two pilot studies that were deleted following the public consultation:

- Thyroid: "*Overall, taking account of the available data and the uncertainties involved, it is concluded that cumulative exposure to pesticides that have chronic effects on the thyroid does not exceed the threshold for regulatory consideration established by risk managers*".
- Nervous system: "*Overall, taking account of the available data and the uncertainties involved, it is concluded that cumulative exposure to pesticides that have acute effects on the nervous system does not exceed the threshold for regulatory consideration established by risk managers.*"



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exposure to pesticides, non-dietary exposures and exposures to other chemicals were, according to EFSA “outside the scope of the studies”.

What is of concern is industry’s involvement in the development of the tools that have been used in the assessment. The Dutch National institute for public health (RIVM) developed the probabilistic models used in the exposure assessments under EU projects ACROPOLIS and now EuroMix, with the same experts that have been removed from EFSA panels due to conflicts of interest³, as partners. Many of the methods developed in collaboration with these experts (e.g. margin of exposure, considering potency of chemicals in cumulative risk assessment groups, probabilistic modelling) now form part of EFSA’s Cumulative risk assessment pilot studies.

Hans Muilerman, Chemicals coordinator at PAN Europe adds “*EFSA has clearly adopted an industry-designed system that ensures a safe outcome and protects the pesticide industry’s profit*”

Ironically, on the other side of the chemicals regulation Sweden and the Netherlands [are discussing with EU member states](#) the idea of implementing a mixture assessment factor (MAF) under REACH to account for combined exposures from unintentional mixtures.

“*In a time where reducing pesticide dependency is [a political priority](#), regulators have to stop pretending that pesticide cocktails are safe. An additional safety factor for mixtures must urgently be placed in the pesticide safety assessment, which will inevitably reduce what levels of pesticide residues in food are considered safe*” Dr. Lyssimachou adds.

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³ See industry involvement section: <https://www.pan-europe.info/blog/efsa%E2%80%99s-pilot-studies-cumulative-risk-assessment-institutions%E2%80%99-toxic-smoothie-mix>

Pesticide Action Network (PAN) Europe is a network of NGOs working to reduce the use of hazardous pesticides and have them replaced with ecologically sound alternatives. We work to eliminate dependency on chemical pesticides and to support safe sustainable pest control methods. Our network brings together 40 consumer, public health, and environmental organisations, and women’s groups from across Europe.