Criminal Complaint Against Bayer for Concealing Glyphosate Risks to Pregnant Women

Threat of re-approval based on misinformed risk assessment

Brussels, Vienna, September 27, 2023 - In a <u>submission</u> made today to the Vienna Public Prosecutor's Office, GLOBAL 2000 and other member organisations of the European Pesticide Action Network (PAN) revealed that the <u>consortium</u> led by Bayer - like Monsanto before it - failed to submit unfavourable studies and/or data on the carcinogenic and neurotoxic effects of glyphosate in the application for re-approval of glyphosate. The complainants argue that this may have influenced the risk assessment conducted by authorities in favour of reauthorization. They are calling on EU member state governments to reject the reauthorization of glyphosate in the upcoming vote on October 12.

Health Risks for Pregnant Women and Infants

The EU Pesticide Regulation requires pesticide manufacturers to report all studies on potentially harmful effects of glyphosate in their authorization applications, including studies commissioned by them and those from the scientific literature. However, Bayer's current authorization application lacked the majority of <u>publications</u> that indicate harmful effects on the nervous system (neurotoxicity) from glyphosate, including an <u>epidemiological study</u> that found an increased risk of autism spectrum disorders in children when their mothers were exposed to glyphosate during pregnancy or in their first year of life.

Of particular concern is the reproach, raised by two Swedish scientists and confirmed by EFSA, that a developmental neurotoxicity (DNT) study commissioned by a member of the consortium (Syngenta) was withheld from EU authorities. This 'DNT-study' showed significant behavioural impairment in young rats when their mothers were exposed to glyphosate during pregnancy. The scientists emphasise that the DNT study was deemed "acceptable for regulatory purposes" by the U.S. Environmental Protection Agency (U.S. EPA), and that the adverse effects identified in the study occurred at a dose that is currently considered safe by EU authorities.

Investigations Against Bayer-Monsanto Since 2019

The criminal complaint submitted today to the Vienna Public Prosecutor's Office is a follow up to an earlier <u>submission from July 17, 2019</u>, by Attorney Josef Unterweger on behalf of GLOBAL 2000, PAN Europe, Generations Futures, and PAN Germany. In the submission, not made public before in order not to disturb the investigation. Therein, the complainants <u>detailed</u> their suspicion that Monsanto, during the previous authorization process, misrepresented or failed to disclose unfavorable data and study results to conceal health risks associated with glyphosate.

"This approach seems to be repeated in the current approval process", Unterweger said. As an example, he refers to internal Monsanto emails (see: Analysis Section 3.1.1, page 48ff) that demonstrate how the glyphosate manufacturer commissioned a study in 2002 to convince German regulatory authorities that their assumption of dermal absorption of glyphosate was too high. However, when the interim report of this study revealed a significantly higher value for dermal glyphosate absorption than assumed by the authorities, Monsanto promptly terminated the study, fearing it had the potential to "blow up the Roundup risk evaluation."

Concealing Glyphosate's Neurotoxicity?

The DNT study also has significant potential to 'blow up' the glyphosate risk assessments. "It shows harmful effects at a dose currently considered safe by the authorities" says Helmut Burtscher-Schaden, Biochemist at GLOBAL 2000: "The late submission of this study, however, put the European authorities in a dilemma. If they recognize the DNT study as 'acceptable for regulatory purposes', it will turn their previous human toxicological evaluation upside down, with significant reduction in health reference values for dietary and occupational glyphosate exposure. Yet they chose the easy way out. The authorities declared the DNT study as 'unacceptable' and 'not relevant' and gave glyphosate a thumbs up. However, this decision does the least justice to its mandate of protecting human health."

"Observing the growing scientific evidence linking glyphosate to neurotoxicity is deeply alarming. Yet, pesticide companies, in blatant violation of EU law, concealed critical neurotoxicity data without repercussions. The assessment continued, and the Commission along with Member States are now pushing to keep glyphosate on the market, ignoring clear evidence of its potential harm," stated Dr Angeliki Lysimachou from Pesticide Action Network (PAN) Europe.

As a result, there is a looming reauthorization proposal of glyphosate that member states are invited to vote on October 12 or 13, based on a flawed risk and hazard assessment influenced by the suppression of unfavourable information from manufacturer studies and published scientific literature. Therefore, the organisations are appealing to the European Member States to reject the reauthorization of glyphosate.

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