Bundesinstitut für Risikobewertung

Study on the transparent approval of plant protection products: Manufacturers should submit all available studies on an active substance

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In order to ensure comprehensive consumer and user protection, both plant protection products and their active substances are tested and assessed for possible adverse health effects before they are approved. The respective procedures within the European Union (EU) are among the strictest in the world. A Swedish study published in the scientific journal "Environmental Health" has now investigated the question of whether studies that were available to the U.S. Environmental Protection Agency (EPA) were also made known to the corresponding EU authorities. These studies examine whether the development of the nervous system can be impaired by active substances used in plant protection products. Out of 35 studies on developmental neurotoxicity (DNT - the technical term), nine were not made available to the EU authorities.

According to the corresponding EU regulation, the submission of a study on developmental neurotoxicity is not mandatory for the evaluation of active substances, depending on the data available. However, if there are indications of possible adverse health effects, these must be clarified and corresponding data collected and submitted. Irrespective of this the German Federal Institute for Risk Assessment (BfR) is of the opinion that generally all available studies on an active substance should be submitted for approval as to have a solid data basis for the assessment.

Link to the study: https://ehjournal.biomedcentral.com/articles/10.1186/s12940-023-00994-9

The studies and dossiers to be submitted for the evaluation of a plant protection product active substance are laid down in Regulation (EU) No 283/2013[1] . According to point "*5.6.2. developmental toxicity studies*", these studies must always be submitted ("*developmental toxicity studies must always be performed*"). With regard to developmental neurotoxicity studies (DNT studies), it is stated that *"[...] If observations in other studies or the mode of action of the test substance indicate, further studies or information may be required to provide information on the postnatal manifestation of effects, such as developmental neurotoxicity. [...]"* Therefore, although the submission of a DNT study is not required as a standard, it is mandatory when there is evidence of a possible developmental neurotoxic effect.

BfR is of the opinion that, from a scientific point of view, all available studies on an active substance should be submitted and assessed to allow for a robust assessment and in order to reduce possible uncertainties.. Therefore, when acting as an assessor within the EU peer review process and in its function as Rapporteur Member State (RMS) BfR generally cross-checks the assessment reports of other international risk assessment agencies such as the U.S. EPA for studies that were not made available in the EU.

About the BfR

The Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the German Federal Ministry of Food and Agriculture (BMEL). The BfR advises the Federal Government and the Federal States (“Laender”) on questions of food,

chemicals and product safety. The BfR conducts independent research on topics that are closely linked to its assessment tasks

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