Toxicological Assessment of Pesticides -Evaluation of Consumer Risk in the EU

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Historically, the assessment of plant protection products (PPP) for human health hazard and risk has been generating a quite rich data package. The hazard risk assessment includes the evaluation of acute, short-, medium and long-term animal studies. Also genotoxicity and reproductive toxicity studies are required in any case, as well as neurotoxicity and immunotoxicity studies if indicated.

Along with the assessment of the active substances, the toxicological relevant environmental and plant/livestock metabolites are also the subject of interest in this process. Likewise, a detailed scrutiny of impurities is warranted, and if found relevant, these impurities are strongly restricted and further monitored in phytopharmaceutical products put on the EU-market.

The PPP-regulation further forbids the placing on the market of “known or presumed” carcinogenic, mutagenic or reprotoxic active substances (or metabolites thereof), as well those exhibiting endocrine disrupting behaviour. Post-approval, the possibility exists to conduct a comparative assessment for products containing substances of high environmental and human health concern.

The whole assessment should permit the establishment of reliable consumer reference doses. Residue definitions are set in order to perform both human risk assessment and monitoring.

From the exposure side, a proposal is made to establish maximal residue levels (MRL’s).

The consumer risk assessment is performed taking into account the anticipated residue levels and EU-consumption data in validated calculation models.

Whereas the risk evaluation process is limited per active substance, the regulation foresees the development of a cumulative risk assessment. Both the scientific basis and the status of the process are discussed.