Sensitive populations, especially children, are the measure of all things in scientific risk assessment

BfR Communication No. 006/2016, 4 March 2016

Children are considered to be especially sensitive to potentially harmful substances. This is taken into account in the assessment of the health risks of pesticidal active ingredients and in the setting of health-based limit values. For this purpose, toxicological limit values such as the ADI (Acceptable Daily Intake of a substance) and the ARfD (Acute Reference Dose), which are established by international panels of experts, are compared to the exposure of children. This also applies to the risk assessment of glyphosate.

Glyphosate is an active ingredient in a range of pesticides approved in Germany and worldwide. The use of these pesticides can lead to residues in food. Provided that the legal maximum levels are not exceeded, the occurrence of such residues is safe in terms of health effects and hence legally permitted. From a scientific perspective, the detection of glyphosate in low concentrations in urine is to be expected. Indeed it shows that glyphosate is rapidly excreted, predominantly via urine.

Across all foods studied within the framework of the German food monitoring programme over the last six years, approximately 1400 samples were tested for glyphosate. This sample base is too limited to allow any reliable statement on the actual exposure levels of the German population. In total, residues were detected in 24 of the tested samples. In both children and adults, glyphosate exposure amounts to less than 1 % of the ADI value.

When the product is used correctly and in line with its intended purpose, no health risks for children are to be expected from glyphosate. The risk assessment in approval and licensing procedures ensures that the highest expected intake quantity is taken into account for all affected sections of the population. This includes children. The assessment by BfR has been clearly confirmed by the European Member States experts in the conclusion of the European Food Safety Authority (EFSA).

Regarded as especially sensitive to potentially harmful substances, children must be subject to special protection. This is taken into consideration in the assessment of the health risk of active ingredients in insecticides and pesticides and also when setting health-based limit values. For this purpose, the toxicological limit values such as the ADI (Acceptable Daily Intake of a substance) and the ARfD (Acute Reference Dose) are compared to the exposure levels for children. When deriving those toxicological limit values which apply to the entire life span, the weakest (i.e. most sensitive) link within the affected section of population is taken into account as well.

Residues from approved pesticidal active ingredients in food are permissible up to the defined maximum residue levels and are harmless in terms of their health effects. It is true that humans and animals can ingest low quantities of glyphosate from food and feed. However, since glyphosate is rapidly excreted, it is to be expected that traces of this active ingredient are to be found in the urine of humans and animals. The glyphosate concentrations detected in urine so far do not, however, indicate levels that raise concerns for consumer health. Due to constantly improving analytical methods, ever smaller amounts of substances can be detected. Whereas in 1960 it was possible to detect substances at the ppm level (i.e. parts per million = \(10^6\) = 0.000001), by 2015 the detection levels have been lowered, thanks to the development of new devices (modern gas chromatography coupled...
with high-resolution mass spectrometry), to a precision range of ppq (parts per quadrillion = $10^{-15} = 0.000000000000001$) (see graph in german).

Regarding the question as to whether the defined maximum residue levels for active pesticide ingredients are safe for children, specific toxicological data with relevance to children in addition to the safety factor used to derive the ADI are taken into consideration. The same applies to the Acute Reference Dose. The exposure estimate incorporates consumption data specific to children, since in proportion to their body weight, they eat 3 to 4 times more than adults.

**Further information is available on the BfR website under the heading “glyphosate”:**

Documents on glyphosate published by the BfR
http://www.bfr.bund.de/en/a-z_index/glyphosate-193962.html

Questions and Answers on Residues of Plant Protection Products in

The EFSA explains risk assessment of glyphosate

Glyphosate in Urine - Concentrations are far below the range indicating a potential health hazard