



Questions and answers on the EFSA conclusion

What studies and data were included in the EFSA peer review?

EFSA looked at all available studies and data relevant to the representative uses of glyphosate in Europe. This includes publicly available studies and those generated by industry. This expert report is the most complete scientific report on the risk assessment of glyphosate. It considered all relevant scientifically valid studies that have been conducted on glyphosate during the last 40 years, including the recent work of the WHO organization IARC.

What conclusions came out of the EFSA review on glyphosate?

EFSA has concluded that glyphosate does not demonstrate carcinogenic or mutagenic properties and has no toxic effect on fertility, reproduction or embryonal development. The report also states that glyphosate poses minimal risk to non-target plants and animals when used appropriately.

These conclusions are consistent with the outcome of previous regulatory evaluations of glyphosate around the world, all of which support the conclusion that glyphosate poses no unacceptable risk when used responsibly.

Why is there divergence between EFSA's position on glyphosate and that of WHO organization IARC?

EFSA has concluded that glyphosate is unlikely to pose a carcinogenic hazard. At first glance, this position seems to contradict the findings of IARC which, according to its own evaluation, categorised glyphosate as a Class 2A carcinogen in March 2015.

In order to understand the divergence in opinion, it is important to note the following elements:

- The EFSA report is more comprehensive and complete. EFSA reviewed all available relevant data on glyphosate including the data of IARC, while the IARC review was limited to published studies.
- IARC assesses the carcinogenic properties of substances (such as glyphosate, red meat and many others) based on single effects and not in the context of real life scenarios. It does not evaluate the likelihood that a substance presents a risk for consumers, operators or the environment and is therefore not an equivalent comparison to comprehensive assessments health risks. This is the task of regulatory authorities (such as EFSA in Europe and the EPA in the USA) which consider both the hazards posed by the substances evaluated and the



likelihood of the most extreme exposures likely to arise presenting risks to human health.

- The size of the dose and its duration (i.e. exposure) are critical factors that must be considered to identify real health risks for consumers. EFSA recommends maximum residue levels (MRLs) to ensure that levels of residues in food are not harmful to consumer health.
- Traces of glyphosate which have occasionally been measured in food are not a cause of concern, since they are far less than the levels judged safe from a consumer health perspective, taking account of all population sectors including children and the elderly.

Why did EFSA establish an acute reference dose (ARfD) for glyphosate?

The acute reference dose value represents the amount of the substance which can be ingested, within a short time frame (one meal or one day), without posing any risk to health. EFSA has set an acute reference dose (ARfD) for glyphosate at a value of 0.5mg/kg of body weight.

Although this is the first time such a value has been set for glyphosate, it is common practice for risk assessors (in this case EFSA) to establish ARfD reference values for active substances found in plant protection products.

Toxicological reference values such as ARfDs are used when checking that proposed Maximum Residue Levels (MRLs) permitted in food and feed are set at levels that are safe from a consumer health perspective.

What was EFSA's recommendation about co-formulants?

Glyphosate is the active substance present in a wide range of different herbicides. Plant protection products which are placed on the market also contain other substances, known as co-formulants. These include diluents, surfactants and binding agents.

The other substances present in herbicide products containing glyphosate are regulated under the European chemical regulation REACH, which has been established to ensure a high level of protection for consumers and the environment.

A common group of co-formulants called surfactants are not unique to formulations containing glyphosate. They can also be found in an array of household and cosmetic products such as detergents and shampoos.

EFSA conclusions confirmed that glyphosate poses no unacceptable risk to human health or the environment. However, it recommended that Member States further assess the genotoxic potential of individual product formulations. In line with the current regulatory framework, it will be up to



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individual countries to decide if this is necessary.

It is important to note that EFSA's recommendation on formulations does not necessarily signify that the authority has any specific concerns regarding the safety of plant protection products containing glyphosate.

How can we guarantee the safety of formulated products?

The approval process which ultimately allows plant protection products to be placed on the market in Europe is a phased process.

Firstly, **the active substance** is subject to a risk assessment at EU level. **Individual formulations** (products) then undergo a thorough safety evaluation and registration process at national level.

The data evaluated by Member States, as well as evaluation and decision-making criteria, are prescribed by EU legislation on plant protection products. Therefore, the same high standards apply in each Member State. However, individual Member States are best placed to assess the impact of local agricultural practices, climate and soils on the performance and safety profiles of individual products.

Please refer to www.glyphosate.eu for further information