German Federal Institute for Risk Assessment

Communication 021/2026

8 April 2026

Health hazards posed by genotoxic substances

International experts discuss new approaches to health risk assessment of chemicals

Genotoxic substances induce damage to the genetic material (DNA) and are therefore strictly regulated in the European Union (EU). In particular, for substances that react directly with the DNA, current scientific knowledge does not support to derive a threshold with sufficient certainty below which it can be assumed that there is no increased health risk. The ALARA principle applies to such genotoxic compounds in the EU: intake should be 'As Low As Reasonably Achievable'.

An international group of experts discussed at a symposium at the German Federal Institute for Risk Assessment (BfR) how, in future, new experimental methods and assessment strategies can be used to arrive at a more nuanced scientific judgement in health risk assessment of genotoxic substances. The results of the symposium have now been published in the journal 'Environment International'.

Link to the study:

https://www.sciencedirect.com/science/article/pii/S0160412026000280?via%3Dihub

Chemicals and other external influences (such as ionising radiation) can damage the genetic material (deoxyribonucleic acid, DNA) directly or indirectly. The focus is primarily on substances which, due to their chemical properties, react directly with the building blocks of DNA, thereby damaging the genetic material and potentially leading to diseases such as cancer (DNA-reactive, genotoxic-carcinogenic substances). Due to the serious and irreversible health consequences, such substances pose a particular challenge for risk assessment. Current scientific knowledge suggests that already low concentrations could be potentially harmful to health.

Prospects for future assessment approaches

Currently, the evaluation of genotoxic properties has mostly been limited to identifying the health hazards posed by specific chemicals. For DNA-reactive, genotoxic-carcinogenic substances, health-based guidance values have therefore only been established in exceptional cases, based on particularly comprehensive data. Provided that these limits are not exceeded, health risks can be ruled out with a high degree of certainty. On the other hand, exposure to certain substances in food cannot always be avoided, such as mycotoxins, acrylamide or nitrosamines. Therefore, in this situation, the ALARA principle is applied within the framework of risk management.

In order to characterise the potential health effects more comprehensively and thus obtain a better basis for well-founded risk management decisions, approaches to the quantitative interpretation of genotoxicity data are being discussed in regulatory risk assessment. To facilitate these discussions, the BfR organised an international symposium at which experts from regulatory authorities, academia and industry discussed in detail aspects of the assessment of genotoxic substances, including future assessment concepts.

In the view of most experts, the available data suggest that thresholds could exist also for genotoxic substances. Below these thresholds, significantly increased damage to the genetic material is highly unlikely. This is due to, for example, indirect mechanisms of action that require significant prior damage to other cellular components. Also, repair mechanisms can often repair DNA damage up to a certain level. There may be considerable differences between substances.

Where possible, the previous black-and-white approach (genotoxic vs. non-genotoxic) should be replaced by a more nuanced assessment that takes into account findings regarding the precise mode of action as well as exposure (intake of the substance) in the risk assessment. Such an approach is particularly important for the risk assessment of substances whose exposure cannot easily be avoided. Examples include contaminants in food and certain naturally occurring food constituents.

Human health remains the benchmark

Of course, a shift in thinking must not come at the expense of human health. Existing knowledge gaps must be closed before such concepts can be integrated into regulatory practice as standard. Discussions therefore also focused on the requirements for experimental genotoxicity studies, so that these can be used for quantitative interpretation in the future. New concepts also include non-animal testing methods, which can, for example, help to understand the precise mechanisms of action of a substance, as well as to mathematical methods for modelling dose-response relationships.

The results of the international symposium on ‘Risk assessment of genotoxic compounds: Challenges and Future Perspectives’, which took place at the BfR in February 2024, are summarised in the publication.

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientific, independent institution within the portfolio of the German Federal Ministry of Agriculture, Food and Regional Identity (BMLEH). It protects people's health preventively in the fields of public health and veterinary public health. The BfR provides advice to the Federal Government as well as the Federal States ('Laender') on questions related to food, feed, chemical and product safety. The BfR conducts its own research on topics closely related to its assessment tasks.

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Responsible according to the German Press Law: Dr Suzan Fiack

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