

**Einheitliche Grundsätze zur Sicherung des Gesundheitsschutzes für den Anwender von Pflanzenschutzmitteln (Einheitliche Grundsätze Anwenderschutz) - Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection), Lundehn, J.-R.; Westphal, D.; Kieczka, H.; Krebs, B.; Löcher-Bolz, S.; Maasfeld, W.; Pick, E.-D., Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Heft 277 (1992)**

Plant protection products are authorised according to the Plant Protection Act (Pflanzenschutzgesetz) if the respective products meet the requirements of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. Member States have to ensure that the preparations have no harmful effects on human or animal health, neither directly nor indirectly, with regard to intended uses.

Appropriate stipulations in the authorisation procedure ensure the compliance with the conditions above. In this context an Aceptable (tolerable) Operator Exposure Level (AOEL) of the active substance (a.s.) has to be taken into particular account for the risk assessment of plant protection products, i.e. the estimated exposure values (based on experimental field data) are compared with this reference dose.

According to Article 65 on the labelling of the product the nature of any special risks as well as safety precautions for the protection of humans have to be indicated, by means of standard phrases. Beyond that, specific instructions for operator protection could be required in the directions for use for the purpose of preventive health protection.

The specific instructions are primarily derived from the toxicological properties of the plant protection product – mainly from its acute properties - reflected by the corresponding classification and labelling according to Council Directives 67/548/EEC and 1999/45/EC as well as Regulation No 1272/2008/EC (mandatory for pesticide formulations by 2015).

In order to protect operators against possible hazards resulting from intended uses of plant protection products estimated exposure has to be compared with the relevant reference dose (AOEL) derived from toxicological studies. In the scope of this predictive operator exposure model (German model, see EXCEL-spreadsheet for more details) dermal and inhalation exposure can be calculated separately based on experimentally derived values in relation to defined conditions of use for different working steps (mixing/loading or application), for different types of product formulation (e.g. liquid or solid) and for different use conditions (use pattern and application techniques, e.g. field crop tractor-mounted application technique).

In certain cases the results of the risk assessment may indicate the need for additional specific instructions for operator protection against possible hazards from exposure. If the AOEL is exceeded, measures to reduce exposure will be required considering verified reduction coefficients of specific personal protective equipment according to respective guidelines (Federal Office of Consumer Protection and Food Safety (BVL) 2006, Personal protective equipment for handling plant protection products - Guidelines for requirements concerning personal protective equipment in plant protection).