5.3. Human health

Parameter	Source	Thresholds
Health data	Health data interpretation depends on the specific issue but, because the PPDB has an international focus and different countries use different asessment and classification processes, we use a 'weight of evidence' approach considering all of the information we have identified. This might mean (in rare cases) that our data varies from that in a particular document.	
Carcinogenicity	There are multiple different classification systems that classify substances according to their potential carcinogenicity, each of which use different criteria and types of evidence. Sometimes these schemes do not agree on whether or not a substance is a carcinogen. They also tend to use different terminology making the landscape confusing. In the PPDB we consider all the available information from multiple sources (e.g. CLP data; US EPA, US NTP, OSHA, IARC, publications) and use a rule base to classify the data into four classes: Yes (majority of our data sources agree the substance is carinogenic), No (majority of our data sources agree the substance is not carinogenic), Possible (data is conflicting/ambiguous or there is insufficient data to make a sound judgement), No data (we have not identified any useful information).	
Genotoxicity	For genotoxicity the majority of our data that classifies a pesticide into a specific genotoxicity type (Chromosome aberration, DNA damage/repair, Gene mutation and Genome mutation) has been taken (with EFSA approval) from the EFSA Genotox database. Other data has come from various data sources including regulatory dossiers and tends to be broader. Similar to carcinogenicity, we use a 4 point classification system: **1.** Positive (the substance has been classified as a genotoxin), **2.** Ambiguous (the data and information we have is inconclusive), **3.** Negative (substance has not been classified as a genotoxin), **4.** No data (we have not identified any useful information).	
Endocrine disruption	For endocrine distruption our data interpretation follows Commission Regulation (EU) 2018/605 and similar regulations for US, Canada and Australia. We don't consider specific endpoints but just whether or not regulatory dossiers consider the substance an endocrine disrupter.	
ADI (mg kg^{-1} bw)	The acceptable daily intake is the amount of a substance that can be ingested every day of an individual's entire lifetime, in the practical certainty, on the basis of all known facts, that no harm will result. SF – refers to the safety factor applied.	

AOEL (mg kg^{-1})	The acceptable operator exposure level is the maximum amount of active **substance** to which the operator may be exposed without any adverse health effects. SF – refers to the Safety Factor applied.	
ARfD (mg kg^{-1})	The Acute Reference Dose, is a toxicological benchmark used to assess short-term exposure risks to chemicals—especially in food and drinking water. It is the estimated amount of a substance that can be ingested in **one meal or one day** without posing a significant health risk to the consumer	
AAOEL (mg kg^{-1})	The Acute Acceptable Operator Exposure Level is a health-based guidance value used in the risk assessment of pesticides, specifically to evaluate short-term (acute) exposure risks for people who handle or apply these substances—like farmers, agricultural workers, or pesticide applicators. It represents the maximum amount of a pesticide's active substance that an operator can be exposed to in a single day without experiencing adverse health effects.	
Dangerous substances directive	This Directive requires Member States to introduce measures to eliminate (List I) or to reduce (List II) pollution of the aquatic environment from certain listed substances identified in its Annexes.	
MRL's - maximum residue limits	These limits can change and the data given here is usually that proposed by EFSA. Data may not be complete. See EU database for further information.	
Drinking water MAC	Maximum Admissible Concentration of the chemical in drinking water. The MAC for a chemical is derived from its ADI. The EU Drinking Water Directive imposes a maximum admissible concentration (EU MAC) for any individual pesticide compound of 0.1 mg l^{-1}.	
WHO Toxicity class	WHO Guidelines 2004. Based on rat LD50 & physical state of the pesticide. See note 4.	See note 2.

Notes

1. Consistent with EU Guidance. (9188/VI/97 rev. 8.) and

   I. Kerle EA, Jenkins JJ & Vogue PA (1996), Understanding pesticide persistence and mobility for groundwater and surface water protection. Oregon State University. EM 8561.

   II. Rao PSC & Hornsby AG (2004) Behaviour of pesticides in Soils and water. University of Florida. See http://edis.ifas.ufl.edu/SS111.

   III. See also Note 3 below.

2. Several relevant references which include:

   I. Van der Werf , HMG (1996) Assessing the impact of pesticides on the environment. Agriculture, Ecosystems & Environment, 60, 81-96.

   II. Jury WA, Spencer WF, & Farmer WJ (1984) Behaviour assessment model for trace organics in soil. III Application of screening model. J. Environ Qual. 13, 573-579.

III. Kerle EA, Jenkins JJ & Vogue PA (1996) Understanding pesticide persistence and mobility for groundwater and surface water protection. Oregon State University. EM 8561.

3. Table below has been extracted from:

I. Goss, D & Wauchope RD (1990) The SCR/ARS/CES Pesticide Properties Database. II using it with Soils data in a screening Procedure. In D.L. Weigmann Ed., Pesticides in the next decade: the challenge ahead, Virginia Resources Research Centre, Blacksburg, VA, USA pp471-493.

Potential for Particle-bound transport	Criteria
High	DT50 >= 40 days & Koc >= 1000 DT50 >= 40 days, Koc >= 500 & solubility <= 0.5 mg/l
Low	DT50 <= 1 day DT50 <= 2 days & koc <= 500 DT50 <= 4 days, Koc <= 900 & solubility >= 0.5 mg/l DT50 <= 40 days, Koc <= 500 & solubility >= 0.5 mg/l DT50 <= 40 days, Koc <= 900 & solubility >= 2 mg/l
Medium	All other

4. Classification given below has been extracted from the WHO Guidelines document: The WHO recommended classification of pesticides by hazard & guidelines to classification. (2004). See http://www.who.int/publications/en/

- Class Ia: extremely hazardous
- Class Ib: highly hazardous
- Class II: moderately hazardous
- Class III: slightly hazardous
- O: Obsolete
- NL: Not listed

5. Thresholds used have been selected to be consistent with industry guidelines, were developed, and are consistent with regulatory thresholds used in both the UK and EU. Alternative classification systems are in use. In particular, that published by the FAO (https://www.fao.org/3/X2570E/X2570E06.htm) may be useful.

6. The EU (Uniform Principles) (Annex VI of Directive 91/414/EEC) guidelines have been adopted have set toxicity:exposure (TER) ratios for algae and aquatic plants at 1/10th of those for fish and daphnids. The same ratio has been applied here.

6a Algae growth tests can provide both acute and chronic endpoints due to the rapid growth of most algae species. Typically, four endpoints may be reported from the study: ErC50, EbC50, ErC10 and NOEC. Within the PPDB we report acute algae growth endpoints as EC50 or ErC50. However, biomass (EbC50) or yield (EyC50) data may be reported in the absence of growth rate data. Similarly we report chronic algae growth endpoints as NOEC or ErC10. It is the end users choice how these endpoints are categorised within risk assessments.

7. In EU pesticide regulatory risk assessments 'hazard quotients' are used to determine the need for additional studies to assess risk to beneficial arthropods. Hazard quotients (HQ) are determined by dividing the Predicted Environmental Concentration (PEC) of the active substance by the median lethal rate (LR50). HQ values less than 2.0 are considered to be low risk to beneficial arthropods and additional

(higher tier) data are not required. Values greater than 2.0 trigger additional data requirements. As the PEC is not known we are unable to provide an interpretation.

8. SCI-GROW is a screening model used by the US EPA to estimate pesticide concentrations in vulnerable groundwater. The model provides an exposure value that can be used to determine the potential risk to the environment and to human health from drinking water contaminated with the pesticide. The SCI-GROW estimate is based on environmental fate properties of the pesticide (aerobic soil degradation half-life and linear adsorption coefficient normalised for soil organic carbon content), the maximum application rate, and existing data from small-scale prospective ground-water monitoring studies at sites with sandy soils and shallow ground water.

   SCI-GROW estimates represent worse case estimates. For this reason, it is not appropriate to use SCI-GROW concentrations for national or regional exposure estimates. Nor is this indicator an alternative to a scientific risk assessment. Values given are based on a standard 1 kg ha^{-1} or 1 L ha^{-1} application rate and should be adjusted to the actual application rate used

   For more information see: http://www.epa.gov/oppefed1/models/water/scigrow_description.htm.

9. The distribution of a pesticide between the solution and absorbed phases can often be described by the "Freundlich equation", an equation that is used to describe a wide variety of adsorption data from every area of science. The equilibrium concentration and adsorbed pesticide amounts are determined experimentally. The Log10 of the quantity of adsorbed pesticide is plotted against the equilibrium concentrations. Often the relationship obtained is approximately linear and can be described by the Freundlich equation: Q=KC1/n, where Q is the adsorbed amount of pesticide (µg kg-1), C is the equilibrium concentration (µg l-1), and kf and n are the experimental parameters unique to the isotherm. The parameter n is greater than 1, the larger it is the more non-linear the equation becomes.

10. The availability of the pesticide in the soil can depend on the amount of soil organic carbon (SOC). The toxicity endpoint value may therefore be corrected for the difference in SOC of the test soil and the reference soil. This means that the toxicity endpoint value is divided by the percentage organic matter in the standard test soil and multiplied by the percentage organic matter in the reference soil. Uncorrected values are quoted herein unless otherwise stated e.g. '(corr)'.

11. Data is very limited and is presented in the literature in a variety of formats. Therefore, neither a standard format nor interpretation can be provided.