2.6. Human health

Parameter	Explanation
Threshold of Toxicological concern (Cramer class) **NOTE: THIS IS AN INDICATOR & NOT A RISK ASSESSMENT**	Applies to non-cancer health issues and uses a decision tree approach classifying and ranking chemicals according to their expected level of oral systemic toxicity. The decision tree categorises chemicals, mainly on the basis of chemical structure and reactivity, into three classes indicating a high (Class III), medium (Class II) or low (Class I) level of concern. It is a simple toxicity indicator and should not be used if experimental data is available. See Lapenna & Worth, 2011 for more information. (Reference: Lapenna & Worth, 2011 - https://eurl-ecvam.jrc.ec.europa.eu/laboratories-research/predictive_toxicology/doc/EUR_24898_EN.pdf).
Toxicity endpoints for mammals	Oral, dermal and inhalation (and other) values provided.
Acceptable Daily Intake (ADI mg kg^{-1} bw day^{-1})	The amount of chemical in food or drinking-water that can be ingested daily over a lifetime without appreciable health risk to the consumer, on the basis of all the known facts at the time of the evaluation.
Acute Reference Dose (ARfd) (mg kg^{-1} bw day^{-1})	The amount of chemical that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer - as far as evidence suggests.
Acute Acceptable Operator Exposure Level (AAOEL) (mg kg^{-1} bw day^{-1})	This is similar to the AOEL and is the health-based limit for exposure that could occur in a single day. It is comparable with the ARfD for consumption.
Acceptable Operator Exposure Level (AOEL) (mg kg^{-1}bw day^{-1})	This is a health-based limit that is established on the basis of the full toxicological assessment required for regulatory purposes. The risk for operators can be quantified by comparing this value with exposure level during application.
Dermal penetration studies (%)	Mean value of known studies reported. Default value in the absence of further evidence is normally taken as 10%.
Dangerous Substances Directive	This Directive concerns pollution caused by certain dangerous substances discharged into the aquatic environment and aims to regulate potential aquatic pollution. The Directive covered discharges to inland surface waters, territorial waters, inland coastal waters and groundwater. The protection of groundwater is now regulated under a separate Council Directive. Directive 76/464 introduced the concept of list I and list II chemicals. Where the chemical concerned appears on these lists it is given here.
Exposure routes public and occupational	Where identified risks to the public (e.g. bystanders and consumers) and operators/workers are identified. This list is not exhaustive but given for guidance only.
EU MRLs (mg kg^{-1})	MRLs are defined as the maximum concentration of chemical residue likely to occur in or on food, drink and feeding stuffs after the use of chemicals according to Good Practice (GP). GP is defined as the substance being applied in accordance with current regulations, product label recommendations and in keeping with local environmental and other conditions. The values listed here are for guidance only and are often those proposed within regulatory

	documents. More precise information on pesticides and Bio-Pesticides can be found in the EU Database.
Drinking water quality standards	This field gives an indication of the quality standards in place for the protection of drinking water quality and human health.
Drinking water MAC	The Maximum Acceptable Concentration of the chemical in drinking water.
Mammalian dose excretion route and rate	The rate at which a substance is lost from the body and the route of that loss.
Specific health issues	Summary of the main human health concerns across a number of issues. Note this is somewhat subjective as literature is not universally uniform in the way issues are addressed. We have used a 'weight-of-the-evidence' approach erring on the side of caution.
General health issues	Summary of main issues relating to human health. This list is not exhaustive and for guidance only.
Carcinogenicity	There are multiple different classification systems for carcinogenic substances, each of which uses different criteria and types of evidence. Often 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 use a 'weight of evidence' 'worse-case' approach taking 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, No, Possible and No data.
Genotoxicity	The data in the PPDB for genotoxicity is a summary and simplified interpretation of the information in the EFSA genotox database available at: https://data.europa.eu/euodp/data/dataset/database-pesticide-genotoxicity-endpoints. Data has been coded into a 4 x 2-character code; The first character refers to one of four data types are: A: Chromosome aberration; B: DNA damage/repair; C: Gene mutation and D: Genome mutation and the second character is a number 0-3 where 0=No data; 1=a significant majority of the test records (75%+) are positive; 2=the test results have given mixed or ambiguous results; 3= a significant majority of the test records (75%+) are negative. In addition to the EFSA data some less specific data has been collated from other sources. This is coded as 'E' and uses the same numerical coding as given above.
Endocrine disruption	For endocrine distruption our data interpretation tends to follow 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.
General handling issues	General description of any hazards that should be addressed when handling the substances.
CLP classification	The 'CLP' Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures, or simply 'CLP', introduces the United Nations globally harmonised system (UN GHS) for classification and labelling of chemicals into Europe. For further information on this please see other documents available on the PPDB website under Support Information/Other Information.

WHO classification	Toxicity hazard class given by the World Health Organisation (WHO). • Class Ia: extremely hazardous • Class Ib: highly hazardous • Class II: moderately hazardous • Class III: slightly hazardous • O: Obsolete substance • NL: Not listed The system is based on the LD50 endpoint for rats. An ingested solid with a LD50 5mg or less/kg bodyweight is Class Ia, at 5-50 mg/kg Class Ib, at 50-500 mg/kg Class II, and at more than 500 mg/kg Class III. Values may differ for liquid oral agents and dermal agents.
UN Number	Number used world-wide in international commerce and transportation to identify hazardous chemicals or classes of hazardous materials.
Waste disposal & packaging	UN Packing Group and other relevant transport information.