The EU Pesticide Blacklist



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Acronyms

| | 1 |
|---------|---|
| ARfD | Acute Reference Dose |
| AOEL | Acceptable Operator Exposure Level |
| a.i. | (pesticide) active ingredient |
| ADI | Acceptable Daily Intake |
| BCF | Bioconcentration Factor |
| Cal P65 | California's Proposition 65 - the Safe Drinking Water and Toxic Enforcement Act |
| CMR | Carcinogenicity, Mutagenicity, Reproductive and developmental toxicity |
| DAR | Draft Assessment Reports |
| EC50 | Effective Concentration, 50% |
| ECHA | European Chemical Agency |
| EFSA | European Food Safety Authority |
| EU | European Union |
| EUDB | EU Pesticide Database |
| FAO | United Nation Food and Agriculture Organization |
| GHS | Globally Harmonized System |
| GUS | Groundwater Ubiquity Score |
| HHPs | Highly Hazardous Pesticides |
| IARC | International Agency for Research on Cancer |
| JMPM | The FAO/WHO Joint Meeting on Pesticide Management |
| LC50 | Lethal Concentration, 50% |
| LD50 | Lethal Dose, 50% |
| LOAEL | Lowest observed adverse effect |
| LR50 | Lethal Rate, 50% |
| NOAEL | No Observed Adverse Effect Levels |
| NOEL | No Observed Effect Levels |
| PAN | Pesticide Action Network |
| POEA | Polyethoxylated Tallow Amines |
| SDS | Safety Data Sheet |
| TLI | Toxic Load Indicator |
| US-EPA | United States Environmental Protection Agency |
| WHO | World Health Organization |

Foreword by publisher

The third edition of "The Blacklist of Pesticides" focuses on the 520 active ingredients authorized for use in the European Union. This catalogue of pesticides is not just a list of substances classified according to their potential human health and environmental hazard but foremost a tool to identify and discourage the use of pesticides with high toxicity. Since no criteria has been adopted yet to define endocrine disrupting chemical (EDC) pesticides the blacklist could not cover all potentially EDC pesticides. The list will in the future be broadened to include all pesticides with endocrine disrupting properties.

The study is an essential tool for producers, retailers and others in the food chain to immediately ban the most hazardous pesticide agents from the production chain. This first step is a vital one towards minimizing and ultimately replacing synthetic pesticides in farming with non-chemical practices where pests and diseases can be effectively managed.

Compared to the two previous versions of "The Blacklist of Pesticides", this new one takes into account extra criteria for hazard evaluation, updates all existing data and supplements the content with new material. For instance, further criteria to assess environmental impacts such as toxicity to aquatic and beneficial organisms have been added. New criteria have been included to judge pesticides' environmental fate, such as plant half life, leaching potential and volatility.

Greenpeace is active in putting pressure to reduce pesticide contamination of our food and the environment. Exceedances of the maximum residue levels have decreased but there are still several reasons for concern. Greenpeace and food safety agencies have repeatedly detected highly hazardous substances in end-products and the environment.

The overall use of pesticides in agriculture has not decreased at all, with overwhelming consequences for the environment. Numerous hazardous active substances are still being used on a large scale in European fields. Substances that can cause cancer, damage genes or disrupt the hormonal balance keep contaminating our soils and waters and affecting biodiversity and people, especially pesticides users, who are directly exposed to them.

Greenpeace has been calling for years to end the use of synthetic chemical pesticides in agriculture, starting from the most hazardous ones. This present study identifies which of the many pesticide agents currently authorized in the European market are the most dangerous and should be replaced as a matter of priority.

Another growing problem is multiple contamination by different pesticides. No toxicologist is able to predict now what kind of impact such pesticide cocktails of potentially harmful substances could have on human health or the environment. Such a striking lack of scientific knowledge about these risks highlights the need for urgent application of the precautionary principle. Multiple contamination must be avoided and, as an immediate first step, significantly reduced.

Unless under specific circumstances few of the pesticides on the blacklist are allowed in organic farming, but as Greenpeace recognizes that those which are used could cause problems it has called for more research so they can be replaced ecologically. Despite these concerns Greenpeace

strongly believes that organic farming is on a progressive path towards effective sustainable farming, positively contributing to better soil, water, wildlife, environment and health compared to industrial agricultural practices.

Greenpeace regularly conducts testing of pesticide residues from our fields to the plate, working with farmers, retailers and politicians to reduce the overall use of pesticides and boost the adoption of ecological farming practices.

- 1. As a first step phasing out the 101 pesticides with a cut-off criteria for human health
- 2. As a second step phasing out the 62 pesticides with 2 cut-off environmental criteria
- 3. As a third step phasing out the remaining 36 pesticides, which are listed because of their high overall score.

Phasing out the most damaging pesticides must be seen only as a first move in the right direction. Long term we urgently need to move away from chemical pesticides. It is of great importance to avoid simplistic substitution effects such as using a less harmful substance, but in higher quantities. Pesticides should not be substituted with other pesticides but with better, more ecological farming practices.

Greenpeace calls on politicians, market actors, farmers and the research community to adopt the necessary changes that would drive agriculture away from its current dependency on synthetic chemical pesticides and fertilizers towards ecological farming practices.

Only ecological farming is able to protect ecosystems, food diversity and security.

01 Introduction

In February 2008, Greenpeace Germany published for the first time an evaluation of basically all marketed pesticide active ingredients globally. In 2010, the list was updated and evaluation parameters were added and modified. One of the objectives for developing such a list was to provide the organization with the necessary scientific basis to campaign on the reduction of pesticide residues in food. The list was aimed at German retailers which internally maintain negative/positive lists.

The initial idea was to have only one list with a scoring system (highest score= highest overall toxicity), with a pesticide with one unwanted property e.g. mutagenicity, but a low score for acute toxicity and environmental parameters would score better than a pesticide with higher scores in less severe categories.

According to this, the outcome of the Greenpeace evaluation was three different lists:

- a black list where a pesticide met one of several toxicity cut-off criteria or scored very high in the total ranking
- a grey list where pesticides, which did not meet cut-off criteria, were evaluated by a complex scoring system based upon 17 parameters
- a yellow list which contained all pesticides where not enough data was available.

After 2010, the original scoring system was used independently from Greenpeace by Lars Neumeister to develop an instrument called "Toxic Load Indicator" (TLI). The TLI is designed as an open source scoring system.

For the creation of a revised European Pesticide Blacklist for Greenpeace, the scoring system as applied for determining the Toxic Load Indicator and two additional criteria previously used (endocrine disruption, immunotoxicity [Sensitization]) are assessed to evaluate pesticides authorized for use in the European Union. The highest possible score for a pesticide active ingredient would be 176 points (see Annex 2).

02 Database

The European Commission maintains an online pesticide database (EC 2016), which allows a complete data download and contains numerous information such as the authorization status, the hazard classification and data on some toxicological parameters (ADI, ARfD and AOEL values). A complete list of authorized pesticide active ingredients is also available in Annex I of the consolidated version (17th of September 2015) of Regulation (EU) No 540/2011. The Annex contains chemical identifiers such as CAS number, CIPAC number and the chemical name. Both data references were merged to create a starting list of EU approved pesticides. They usually do not contain all commonly marketed derivates (salts, esters, isomers etc.)¹. Therefore, the list was edited accordingly using national authorization data.

Currently, about 520² active ingredients (a.i.)are authorized for used in the European Union. As can be seen in Figure 1, the majority of all authorized pesticides are of chemical-synthetic origin (64%). Inorganic substances, organisms and viruses, plant extract and pheromones together represent about 28%. The following figure shows the distribution of the currently approved pesticide by "chemical" type.

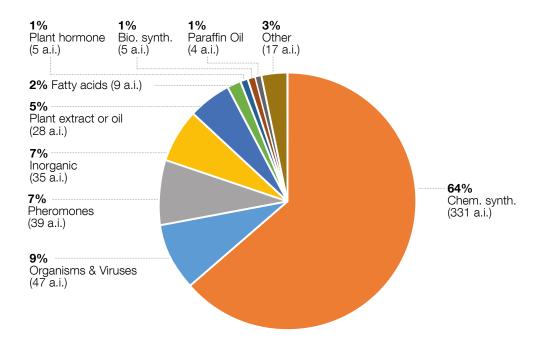


Figure 1: Distribution of all 520 currently approved pesticides (EU) by "chemical" type (own evaluation)

¹ For example: glufosinate is listed, but the marketed formulation contains the salt glufosinate-ammonium.

² The number depends on how the active ingredients are counted. The EU tables do not contain all marketed derivatives but in some cases the basic substance is not market relevant. We identified 520 relevant substances, including several marketed derivates and provisional authorizations.

The current list of approved pesticide active ingredients contains about³ 110 "low risk"⁴ pesticides. "Low risk" pesticide is the short term for pesticides active ingredients which either fulfill the criteria for indications of no harmful effects set by Commission Regulation (EC) No 1095/2007 or meet requirements set in point 5 of Annex II of Regulation (EC) 1107/2009 and were which were authorized under the former Directive 91/414/EEC (about 105 pesticides, mainly through Directive 2008/127/EC and 2008/113/EC) or under the current Regulation (EC) No 1107/2009 (five pesticides). With Regulation (EC) No 1107/2009 "Low-risk active substances" became a regulatory term.

Most of these "low risk" pesticides are pheromones, plant extracts or oils, organisms/viruses and inorganic substances, which together constitute over 70% of the "low risk" pesticides. Altogether, about 21% of all authorized pesticides are authorized as "low risk" pesticides.

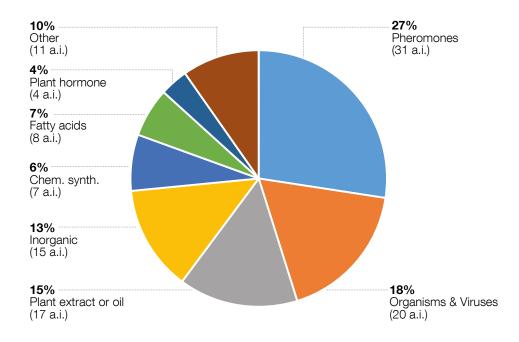


Figure 2: Distribution of the currently approved "low risk" pesticides (EU) by "chemical" type (own evaluation)

³ There are several groups which may contain several substances like "Repellents by smell of animal or plant origin/ fish oil", "Fat distillation residues" or "Straight Chain Lepidopteran Pheromones".

⁴ Commission Regulation (EC) No 1095/2007 (4) as well as Annex II of Council Regulation (EC) No 1107/2009 define criteria for "low-risk active substances".

03 Blacklist Criteria

Compared to the previous version of the Blacklist, the criteria/parameters for defining a black listed pesticide and for the scoring system are different. Table 1 shows a comparison between the previous and the revised parameters.

| Nr. | Criteria | Indicator | Applied 2010 (black listed [BL] and/or score) | Applied 2016 (black listed [BL] and/or score) |
|-----|-------------------------|--|---|---|
| 1 | Health hazards | Acute toxicity (short term toxicity user) | BL & Scoring | BL & Scoring |
| 2 | | Carcinogenicity | BL & Scoring | BL & Scoring |
| 3 | | Mutagenicity | BL & Scoring | BL & Scoring |
| 4 | | Reproductive and Developmental toxicity | BL & Scoring | BL & Scoring |
| 5 | | Operator Toxicity (Acceptable Operator Exposure Level) and/ or Chronic Toxicity (long term toxicity, expressed as ADI) (minimum value) | Scoring | BL & Scoring |
| 6 | | Immunetoxicity | Scoring | Scoring |
| 7 | | Acute toxicity (short term toxicity consumer expressed as ARfD) | BL & Scoring | No |
| 8 | | Neurotoxicity | BL | No |
| 9 | | Corrosive properties | Scoring | No |
| 10 | | Explosive properties | Scoring | No |
| 11 | Endocrine Disruption | Endocrine effects on human health and environment | BL & Scoring | BL & Scoring |
| 12 | Environmental | Aquatic toxicity (Algea) | No | BL & Scoring |
| 13 | toxicity | Aquatic toxicity (Invertebrate, Fish) | BL & Scoring | BL & Scoring |
| 14 | | Toxicity to birds | BL & Scoring | BL & Scoring |
| 15 | | Toxicity to beneficial organism (predator, parasitoid) | No | BL & Scoring |

Table 1 Parameters evaluated by Greenpeace 2010 and 2016

| 16 | Environmental | Toxicity to honey bees | BL & Scoring | BL & Scoring |
|----|---------------|--|--------------|--------------|
| 17 | toxicity | Toxicity to earth worm (indicator for soil dwelling organisms) | BL & Scoring | No |
| 18 | Environmental | Bioaccumulation | BL & Scoring | BL & Scoring |
| 19 | fate | Persistence | BL & Scoring | BL & Scoring |
| 20 | | Leaching potential | No | Scoring |
| 21 | | Volatility | No | Scoring |
| 22 | | Plant Halflife | No | Scoring |

Similar to the previous approach, a pesticide rating the maximum of ten (blacklist criterion) in one of the health hazard categories is black listed.

In the category "Environmental toxicity" and "Environmental fate", the previous approach used in 2010 is maintained: A pesticide qualifies as a black list pesticide when it scores highest of ten (cutoff criterion) in at least two of the following categories:

- Aquatic toxicity (Algae)
- Aquatic toxicity (Invertebrate [Daphnia], Fish)
- Toxicity to birds
- Toxicity to honey bees
- Toxicity to beneficial organism (commonly insect predators, parasitoids)
- Persistence
- Bioaccumulation

The criteria are revised as follows:

In the previous evaluation system, the environmental toxicity and the environmental behavior of pesticides were, compared to human health, under-represented. Now more information on ecotoxicity and environmental behavior is considered.

2 The evaluation for the acute toxicity has changed to the new GHS (as implemented by EU Regulation (EC) No 1272/2008) and the changed WHO classification (WHO 2009). Instead of individual GHS hazard classifications, the Acute Risk Category is used for the assessment. The highest Acute Risk Category for a given pesticide reflects the highest toxicity among all exposure pathways (oral, dermal, inhalation) and is used for the blacklist assessment. In the criterion acute toxicity, these adjustments generate for some highly toxic substances a lower score than before. However, the high toxicity of these substances (specifically to pesticides users) is now reflected in the new criterion "Acceptable Operator Exposure Level" (AOEL) (see below).

Neurotoxicity is not directly reflected anymore because of a lack of consistent data especially in the field of developmental neurotoxicity and a lack of specificity. About 30% of all newly authorized active ingredients appeared on the market after 2005 and they are not reflected by older or newer reviews on neurotoxicity (see for example Mokarizadeh et al. 2015; Corsini et al 2012; Grandjean 2013; Bjørling-Poulsen et al. 2008). Furthermore, scientific articles on neurotoxicity often assign specific effects to a whole group of pesticides (such as organophosphate, pyrethroids, dithiocarbamates etc. – see for example Shelton et al. 2014, Bjørling-Poulsen et al. 2008). That ample approximation only allows a "Yes" or "No" evaluation and does not reflect that individual pesticides within these groups may be more toxic than others.

B

An internal comparison of NOELs (No Observed Effect Levels) for effects on the nervous system and/or the thyroid⁵ (based on the Draft Assessment Reports (DARs) created for the authorization procedure, EFSA 2014) with the EU ADI (EU DB (2016)) values showed that the ADIs seem to represent a useful indicator for specific neurotoxic effects under investigation (see Annex 3). The ADI is therefore used to reflect known neurotoxic effects, but also other potential chronic effects since it is based on results of a large number of toxicity tests.

In addition, the ADI is set for almost all active ingredients (while the ARfD is not), and the ADI is generally lower than the ARfD and thus more protective in most cases. The AOEL is newly introduced as evaluation criterion, it is derived in a very similar way to the ADI and correlates well with it. The ADI is in most cases (>75%⁶), lower than or equal to the AOEL, but in some cases ADI are not set, if consumer exposure is not anticipated. The AOEL presents risks to pesticides users better than the ADI. When both values exist, the lower value is used for the evaluation.

The acute earthworm toxicity was replaced by toxicity to beneficial organisms (parasitoids, invertebrate predator) important for natural pest control. Pesticides disrupting natural pest control can have severe effects on the agro-ecosystem and lead to even more pesticide use (see Reuter & Neumeister 2015). Additionally, the data on acute earthworm toxicity are less differentiated: Most values for Active Ingredients authorized in the EU given are ">500" or ">1000" (mg/kg; LC50 14 days) and the commonly tested compost worm (*Eisenia fetida*) is a rather insensitive test species (Shahla & D'Souza 2010, Pelosi et al. 2014).

Regarding the acute bird toxicity, the oral lethal dose for 50% of the tested bird population is used. The previously applied Hazardous Dose developed by Mineau et al. 2001 was not updated since its publication, and thus does not reflect pesticide newly marketed since 2001.

6 The evaluation for the aquatic toxicity is now based on lethal concentration for 50% of the tested populations (fish or invertebrate) and reduction of algae growth for 50% of the tested populations. For the ranking, the toxicity scale of the US EPA⁷ is used. The previously applied Risk Phrases according to Directive 67/548/EEC were not very differentiated and did not allow a ranking below an LC/EC50 of 1 mg/L.

⁵ Bjørling-Poulsen et al. 2008 relates changes in the thyroid function to neurotoxicity.

⁶ ADI and AOEL values were downloaded from the EU Pesticide Database (EU DB 2016) and compared.

⁷ https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/technical-overview-ecological-risk-assessment-0

The criterion "Explosive" became obsolete in the EU context, explosive pesticides are not authorized.

The scaling changes from a 0-5 ranking to the 1-2-5-8-10. That emphasizes higher toxicity and gives less weight to data gaps which have the default value of 5 out of 10 instead of 3 out of 5.

O The previous Greenpeace blacklists evaluated pesticides marketed globally, for example in the USA. In order to achieve a good data coverage for the global list, some reference lists from US governmental or state authorities had been used (EPA TRI List; California's Proposition 65 List). These lists do not match completely with the list of EU authorized pesticides⁸. In addition, the EPA-TRI (2016) listings represent the lowest LOAEL in a specific effect category independent from the height of the dose causing that critical effect⁹. Reference doses (such as the ADI) derived from a NOAEL allow a better evaluation, because they are based on studies which delivered doses without an observed effect. The new Blacklist criteria apply the ADI instead of EPA-TRI and Californian Proposition 65 (OEHHA 2015) listings. A pre-check showed that all pesticides classified as "developmental toxin" by OEHHA (2015) or by EPA-TRI (2016) score "high" to "very high" under the criterion ADI/AOEL.

For the new Blacklist, all underlying data can be found in publicly available online databases and lists – the Pesticide Properties Database maintained by the University of Hertfordshire (Lewis et al. 2016) as well as the EU Pesticide Database are accessible online (refer to EU DB (2016)) and contain all data used for the Blacklist evaluation¹⁰.

⁸ Only 61 EU authorized pesticide are on the US EPA TRI List: https://www.epa.gov/toxics-release-inventory-triprogram/tri-listed-chemicals and only 40 EU authorized pesticide are on the Prop 65 List http://oehha.ca.gov/ prop65/prop65_list/Newlist.html.

⁹ The primary purpose of the US Toxic Release Inventory is the monitoring of emissions; the categorization of potential health effects serves as additional information.

¹⁰ For this evaluation a Microsoft Access Database containing the pesticides property database and the bio-pesticides property database was obtained (on 25.02.2016) from University of Hertfordshire.

04 Scoring

In order to identify pesticides which may have a high total toxicity, but do not meet blacklist criteria, the scoring system is used to calculate a sum of scoring points based on toxicological and environmental data for all authorized pesticide active ingredients. The scoring system is described in detail in Annex 2.

Figure 3 gives a graphical overview of the criteria used for the scoring.



Figure 3: Criteria evaluated in the scoring system

05 Results

Overall, the Blacklist contains 209 pesticide active ingredients (a.i.), which represent about 40% of all authorized pesticides in the European Union. Among these, 173 pesticides have such a high toxicity in at least one category that they meet the Blacklist cut-off criteria. Of these, 35 active ingredients meet at least one health cut-off criterion, 62 active ingredients meet at least two of the six selected environmental criteria and 76 active ingredients meet health and environmental criteria.

The following graph shows the number of pesticides by number of cut-off criteria, for example:

- two pesticides meet seven cut-off criteria,
- another two pesticides meet six cut-off criteria,
- and another nine pesticides meet five cut-off criteria.

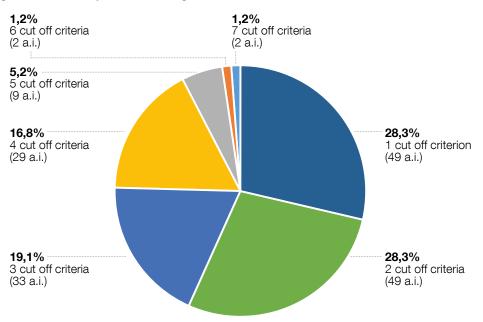


Figure 4: Number of pesticide meeting "cut-off" criteria

Pesticides not meeting cut-off criteria were evaluated using the scoring system (see Annex 2) and were sorted by the total score. As in the previous blacklist the ten percent (n = 36 pesticides) with the highest score were added to the Blacklist. All pesticides classified as "Blacklist" pesticides are listed in Annex 1.

06 Limitations

The parameters to identify a Blacklist pesticide are limited to those for which data are publicly available and standardized testing procedures exist. That ensures maximum transparency, but has some limitations:

Scope

Adverse effects of pesticide use occur mainly through three factors or a combination thereof:

- 1. Scale of usage
- 2. Misuse and
- 3. Chemical properties including toxicity.

The first two factors are not addressed by this Blacklist, and a Blacklist is not the most suitable instrument to address these factors. A Blacklist is just one tool in a "pesticide reduction toolbox" and needs to be accompanied by other measurements (see for example Reuter & Neumeister 2015, Chapter Pesticide use and risk reduction).

Reliance on authorization data

The scoring of the Blacklist is largely based on the outcome of the European pesticide authorization and chemical registration process. Many data for these assessments derive originally from manufacturers who are obliged to submit data dossiers. The involved governmental risk assessment in these processes has some serious flaws (see for example: Knäbel et al. (2012); Knäbel et al. (2014) and Stehle & Schulz 2015 and further below). In some areas (eco-toxicity, environmental fate) independent research and regional monitoring, but also commonly observed effects (like the bee population decline) can trigger re-assessment of substances or the adjustment of the risk assessment. The attention to neo-nicotinoid pesticides due to their high bee toxicity caused, for example, a re-evaluation of imidacloprid and acetamiprid which resulted in the knowledge that both are developmental neurotoxins and require lower toxicological thresholds (EFSA 2013).

The situation is more complicated regarding potential chronic effects on human health. In order to observe such effects long term tests with mammals are usually needed, but these tests are not common among independent researchers (also for ethical reasons). Sometimes they conduct a long-term experiment with one particular pesticide, but a systematic independent assessment of all pesticides is not available.

The IARC assesses existing evidence on potential carcinogenic effects from independent research, but that is a very slow process: In the last 16 years only five pesticides were evaluated and at the time this was done all of them had been on the market for several decades.

Endocrine disruption

In 2000, the European Commission published a screening of chemicals for their potential to disrupt the endocrine system (EC 2000). The list was later prioritized (EC 2004, EC 2007) but never

updated. In Regulation (EC) No 1107/2009 a preliminary identification of endocrine disruptors was published. For the assessment of effects of the endocrine system, the old list and the preliminary "definition" by Regulation (EC) No 1107/2009 are used. That is a rather limited approach, because pesticides entering the market after 2000 were not included in the early screening and the preliminary "definition" by Regulation (EC) No 1107/2009 has a narrow scope. However, validated data which would allow a better ranking of endocrine disrupting effects do not exist. The TEDX List of Potential Endocrine Disruptors¹¹ presents results from literature reviews and "should not be used as a method of ranking or prioritizing."

Developmental Immuno- and Neurotoxicity

Developmental Immunotoxicity (DIT) and Developmental Neurotoxicity (DNT) - while recognized to be of high importance – are not covered by risk assessment required for authorization (Hessel et al. 2015, Grandjean 2013, EFSA 2013). There are no systematic data on these two effects, therefore the Blacklist cannot consider these for evaluation today. A better risk assessment and more data are urgently needed in these areas. Developmental neurotoxicity can cause very serious effects on brain development, including learning and behavior, and adverse effects on the developing immune system can lead to life-long health problems.

Aquatic toxicity

The data for the environmental toxicity are based on endpoints for acute toxicity for a limited number of species. These species might not be the most sensitive species. Daphnia magna for example, as a standard test species for aquatic toxicity, seems to be particularly insensitive against neonicotinoids, which show high toxicity to other aquatic invertebrates (Morissey et al. 2015).

Insect toxicity

The evaluation for the Blacklist is reduced to a few species (usually one predatory mite and one parasitoid). That is not representative for all other species. Prabhaker et al. (2007 & 2011) tested the acute toxicity of nine insecticides to four parasitoid species, and it seems toxicity is species and pesticide specific. The toxicity to the most sensitive species compared to the most insensitive species can vary by a factor of more than 20.000, and a pesticide with lower toxicity to three parasitoids can show very high toxicity to the fourth.

Pesticide preparations

While the active ingredient is usually the effective (and most toxic) compound in a pesticide product, adjuvants added to the tank or "inert¹²" ingredient can enhance toxicity and change environmental behavior. Bonmatin et al. (2015) showed that commercial formulations may contain "inerts" that increase the solubility of the active substance, and one research group consistently found commercial pesticides products to have a higher leaching potential than the actual active ingredient (ibid. see also Krogh et al. 2003).

Brühl et al. (2013) have recently shown that juvenile frogs oversprayed with a fungicide product at recommended label rates caused surprisingly high mortality rates. The commercially available product Headline (pyraclostrobin and 67% naphta solvent) caused 100% mortality just after 1 hour

¹¹ http://endocrinedisruption.org/endocrine-disruption/tedx-list-of-potential-endocrine-disruptors/overview

^{12 &}quot;Inert Ingredients" are for example: solvents, surfactants, and emulsifiers. They have a big variety of functions like preventing caking or foaming, extending product shelf-life, or allowing herbicides to penetrate plants to maintain and enhance the effect of the active ingredient.

at the label rate, the formulation with the lower (< 25%) naphta content revealed 20% mortality at the label rate. Other products caused 40% mortality in only 10% of the label rate. Earlier investigations confirm the relatively high amphibian toxicity of certain strobilurin fungicides (Hooser et al. 2012; Belden et al. 2010). Both studies show the outstandingly high toxicity of the product "Headline". Publicly available toxicity information for pesticide formulations is generally limited to some acute effects. Information about the inert ingredients in pesticide formulations is not publicly available due to corporate confidentiality. In the EU, only ingredients classified as dangerous substances according to Regulation (EC) No 1272/2008 have to be specified, e.g. in the Safety Data Sheet (SDS) of the formulation.

Co-formulants (adjuvants) of glyphosate, polyethoxylated tallow amines (POEA) are long known to be of high toxicity and Germany decided to withdraw authorization for such substances¹³.

Human chronic toxicity

Pesticide classification for human chronic toxicity is often retrospective. Epidemiological evidence for chronic effects of pesticides exists only for pesticides which are on the market for longer. That means pesticides which are not on the Blacklist are not automatically "harmless" – in many cases science has not yet focused on them.

Classification data delay

The process of classification and labeling by the European Chemical Agency (ECHA) seems to be particularly slow. More than 130 synthetic pesticides authorized for use in the EU are not classified according to Regulation (EC) No 1272/2008/EC¹⁴ (incl. amendments). Among those unclassified pesticides are some which are on the market for decades (terbuthylazine, oxyfluorfen, bromadiolone, metiram) and some newer ones which seem to pose severe risks for human health and/or the environment (thiacloprid, emamectin benzoate). Missing classifications can lead to an over- or underestimation in the scoring system, because a default score of five is applied.

Cumulative Effects

The assessment for the Blacklist focuses on the individual pesticide active ingredients. Cumulative effects of marketed products containing one or several active ingredients, inerts, co-formulants, and/or tank mixes which may contain even more chemicals are excluded. Pesticides and other chemicals commonly occur together in the human body as well as in the environment (e.g. Reuter & Neumeister 2015), but an evaluation of potential cumulative effects would require an exposure assessment, because it is impossible to evaluate each combination of each chemical.

¹³ BVL: http://www.bvl.bund.de/DE/04_Pflanzenschutzmittel/06_Fachmeldungen/2011/2011_12_05_Fa_streichung_ zusatzstoffe.html

¹⁴ Regulation (EC) No. 1272 / 2008 on the classification, labelling and packaging of substances and mixtures.

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Annex 1:

| | Greenpeace Blacklist | | Man | nm | al to | oxic | ity | | | | | | l Toxi , Pers | istenc | e |
|----|---------------------------|-------|-------------------------------|----|-------------|--------------|-----------|-----|-------|--------------|-------|-----|------------------|-----------------|-------------|
| - | Active Ingredient | Score | Acute Tox. Carcinomenicity | | Repro. Tox. | Mutagenicity | AOEL /ADI | EDC | Algae | Daphnia/Fish | Birds | Bee | Beneficial | Bioaccumulation | Persistence |
| | Fumigants | | • - | - | | _ | • | | | | | | | | |
| 1 | Aluminum phosphide | | | | | | | | | 10 | | 10 | | | |
| 2 | Metam-Potassium | | 1(| 0 | | | | | | | | | | | |
| 3 | Metam-sodium | | 1(| 0 | | | 10 | 10 | | | | | | | |
| 4 | Phosphine | 82,8 | | | | | | | | | | | | | |
| 5 | Sulfuryl fluoride | 77,5 | | | | | | | | | | | | | |
| | Fungicides | ,- | | | | | | | | | | | | | |
| 6 | Ametoctradin; BAS 650 F | | | | | | | | | 10 | | | 10 | | |
| 7 | Amisulbrom | | | | | | | | | 10 | | | | | 10 |
| 8 | Benthiavalicarb-isopropyl | | 1(| 0 | | | | | | | | | | | |
| 9 | Bixafen | | | | | | | | | 10 | | | | 10 | 10 |
| 10 | Bordeaux mixture | | | | | | | | | 10 | | | | | 10 |
| 11 | Boscalid | 80,1 | | | | | | | | | | | | | |
| 12 | Bupirimate | 74,7 | | | | | | | | | | | | | |
| 13 | Captan | 77 | | | | | | | | | | | | | |
| 14 | Carboxin | | | | | | 10 | | | | | | | | |
| 15 | Chlorothalonil | | 1(| 0 | | | 10 | | | 10 | | | | | |
| 16 | Copper hydroxide | | | | | | | | 10 | 10 | | | | | 10 |
| 17 | Copper oxychloride | | | | | | | | | | | | 10 | | 10 |
| 18 | Cyflufenamid | 78,7 | | | | | | | | | | | | | |
| 19 | Cyproconazole | 82,4 | | | | | | | | | | | | | |
| 20 | Cyprodinil | 80,4 | | | | | | | | | | | | | |
| 21 | Difenoconazole | 80,7 | | | | | | | | | | | | | |
| 22 | Dimoxystrobin | | | | | | 10 | 10 | | 10 | | | | | 10 |
| 23 | Disodium phosphonate | | | | | | | | | | | | 10 | | 10 |
| 24 | Dodine | | | | | | | | 10 | 10 | | | | | |
| 25 | Epoxiconazole | | 1(| 0 | 10 | | 10 | | | | | | | | 10 |
| 26 | Famoxadone | | | | | | 10 | | 10 | 10 | | | 10 | 10 | |
| 27 | Fenbuconazole | | | | | | 10 | | | | | | | | |
| 28 | Fenpropidin | | | | | | | | 10 | | | | 10 | | |
| 29 | Fenpropimorph | | | | | | 10 | | | | | | | | |
| 30 | Fluazinam | | | | | | 10 | | | 10 | | | | 10 | |
| 31 | Fludioxonil | 77,6 | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |

A grey italic 10 is for information only - no cut-off criterion (see Chapter "Blacklist Criteria").

| | Greenpeace Blacklist 2016 | | N | lamr | nal 1 | toxi | city | | | | | | l Toxi , Pers | istenc | e |
|----------|------------------------------|-------|------------|-----------------|-------------|--------------|-----------|-----|-------|--------------|-------|-----|------------------|-----------------|-------------|
| 2 | | Canad | Acute Tox. | Carcinogenicity | Repro. Tox. | Mutagenicity | AOEL /ADI | EDC | Algae | Daphnia/Fish | Birds | Bee | Beneficial | Bioaccumulation | Persistence |
| | Active Ingredient | Score | 4 | 0 | œ | 2 | ◄ | ш | ٩ | | • | 8 | | Ξ | ₽. |
| 32 | Fluopicolide | 81,6 | | | | | | | | | | | | | |
| 33 34 | Fluopyram Fluoxastrobin | 76,6 | | | | | | | | | | | | | |
| 35 | | 74,7 | | | | | 10 | | | | | | | | 10 |
| | Fluquinconazole | | | | | | 10 | | | | | | 10 | | 10 |
| 36 | Fluxapyroxad Fuberidazole | | | | | | 10 | | | | | | 10 | | 10 |
| 37 | Imazalil | | | 10 | | | 10 | | | | | | | | 10 |
| 38 | | | | 10 | | | | | | | | | | | 10 |
| 39 | Ipconazole | 74,4 | | 10 | | | | | | | | | | | |
| 40 | Iprodione | | | 10 | | | | | | | | | | | 10 |
| 41 | Iprovalicarb | | | 10 | | | | | | 10 | | | | | 10 |
| 42 | Isopyrazam | | | | | | | | | 10 | | | | | 10 |
| 43 | Kresoxim-methyl Mancozeb | | | 10 10 | | | | 10 | | 10 | | | | | |
| 44 | Maneb | | | 10 | | | | 10 | 10 | | | | | | |
| 45 | | | | 10 | | | | 10 | 10 | 10 | | | | | |
| 46 | Mepanipyrim | | | 10 | | | 10 | | | 10 | | | | 10 | |
| 47 | Meptyldinocap | 77.0 | | | | | 10 | | | 10 | | | | 10 | |
| 48 | Metalaxyl Metiram | 77,9 | | 10 | | | | 10 | | | | | | | |
| 49 50 | Metrafenone | | | 10 | | | | 10 | | | | | | 10 | 10 |
| | | 70.0 | | | | | | | | | | | | 10 | 10 |
| 51 52 | Myclobutanil Penconazole | 79,9 | | | | | | | | | | | | | |
| 52 | | 84,9 | | | | | | | | | | | | | |
| 53 | Pencycuron Picoxystrobin | 73,6 | | | | | | | | 10 | | | 10 | | |
| 55 | Prochloraz | | | | | | | | 10 | 10 | | | 10 | | 10 |
| 56 | Propiconazole | | | | | | | | 10 | | | | 10 | | 10 |
| 57 | Propineb | | | 10 | | | 10 | | | | | | 10 | | 10 |
| 58 | Proquinazid | 70 0 | | 10 | | | 10 | | | | | | | | |
| 59 | Proquinazio | 78,2 | | | | | | | | 10 | | | | 10 | |
| 60 | Pyrimethanil | 74 7 | | | | | | | | 10 | | | | 10 | |
| 61 | Quinoxyfen | 74,7 | | | | | | | | 10 | | | 10 | 10 | 10 |
| 62 | Sedaxane | | | 10 | | | | | | 10 | | | 10 | 10 | 10 |
| 63 | Spiroxamine | | | 10 | | | | | 10 | | | | 10 | | 10 |
| 64 | Tebuconazole | 70 0 | | | | | | | 10 | | | | 10 | | |
| -04 | | 78,9 | | | | | | | | | | | | | |

| | Greenpeace Blacklist | | Μ | lamn | nal t | oxio | city | | | | | | l Toxi , Pers | city, istenc | e |
|----|------------------------|-------|------------|-----------------|-------------|--------------|-----------|-----|-------|--------------|-------|-----|------------------|-----------------|-------------|
| 2 | 2016 | | Acute Tox. | Carcinogenicity | Repro. Tox. | Mutagenicity | AOEL /ADI | EDC | Algae | Daphnia/Fish | Birds | ē | Beneficial | Bioaccumulation | Persistence |
| | Active Ingredient | Score | ĕ | - | Å | Ē | Ă | Ш | A | õ | ä | Bee | | Bi | Å |
| 65 | Terrazole; Etridiazole | | | 10 | | | | | | | | | 10 | | |
| 66 | Tetraconazole | | | | | | 10 | | | | | | 10 | | 10 |
| 67 | Thiophanate-methyl | | | 10 | | | | | | | | | | | |
| 68 | Thiram | | | | | | | 10 | | 10 | | | | | |
| 69 | Tolclofos-methyl | 77,2 | | | | | | | | | | | | | |
| 70 | Triadimenol | 80,6 | | | | | | | | | | | | | |
| 71 | Triazoxide | | | | | | 10 | | | 10 | | | | | 10 |
| 72 | Trifloxystrobin | | | | | | | | 10 | 10 | | | 10 | | |
| 73 | Triflumizole | | | | | | | | | | | | 10 | 10 | |
| 74 | Triticonazole | | | | | | | | | | | | 10 | | 10 |
| 75 | Ziram | | | | | | 10 | | | 10 | | | | | |
| | Herbicides | | | | | | | | | | | | | | |
| 76 | 2,4-DB | | | | | | | 10 | | | | | | | |
| 77 | Aclonifen | | | | | | | | | | | | | 10 | 10 |
| 78 | Amitrole* | | | | | | 10 | 10 | | | | | 10 | | 10 |
| 79 | Benfluralin | | | | | | 10 | | | 10 | | | 10 | 10 | |
| 80 | Bifenox | | | | | | | | 10 | | | | 10 | 10 | |
| 81 | Bromoxynil | 78,2 | | | | | | | | | | | | | |
| 82 | Chlorotoluron | | | | | | | 10 | | | | | | | 10 |
| 83 | Cyhalofop-butyl | | | | | | 10 | | | | | | 10 | | |
| 84 | Diclofop | | | | | | 10 | | | | | | | | |
| 85 | Diflufenican | | | | | | | | 10 | 10 | | | | 10 | 10 |
| 86 | Diquat dibromide | | | | | | 10 | | | | | | 10 | | 10 |
| 87 | Diuron | | | 10 | | | 10 | | 10 | | | | | | |
| 88 | Ferrous sulfate | | | | | | | | | 10 | | | | 10 | 10 |
| 89 | Flufenacet | | | | | | 10 | | 10 | | | | 10 | | 10 |
| 90 | Flumioxazin | | | | 10 | | 10 | | 10 | | | | | | |
| 91 | Fluometuron | | | | | | 10 | | | | | | | | 10 |
| 92 | Fluorochloridone | | | | | | | | 10 | | | | | | 10 |
| 93 | Foramsulfuron | | | | | | | | | | | | 10 | | 10 |
| 94 | Glufosinate-ammonium | | | | 10 | | 10 | | | | | | 10 | | |
| 95 | Glyphosate | | | 10 | | | | | | | | | | | |
| 96 | Haloxyfop-R | | | | | | 10 | | | | | | 10 | | |

A grey italic 10 is for information only - no cut-off criterion (see Chapter "Blacklist Criteria"). * Authorization expired. Maximal period of grace: 30.09.2017

| | Greenpeace Blacklist 016 | | М | lamr | nal t | toxi | city | | | | | | l Toxi , Pers | city, istenc | e |
|-----|-----------------------------|-------|------------|-----------------|-------------|--------------|-----------|-----|-------|--------------|-------|-----|------------------|-----------------|-------------|
| 2 | Active Ingredient | Score | Acute Tox. | Carcinogenicity | Repro. Tox. | Mutagenicity | AOEL /ADI | EDC | Algae | Daphnia/Fish | Birds | Bee | Beneficial | Bioaccumulation | Persistence |
| 97 | Haloxyfop-R-methyl | | | | | | 10 | | | 10 | | | 10 | | |
| 98 | Imazaquin | | | | | | | | | | | | 10 | | 10 |
| 99 | Isoproturon* | 73,7 | | | | | | | | | | | | | |
| 100 | Isoxaflutole | , | | 10 | | | | | | | | | | | |
| 101 | Lenacil | | | | | | | | 10 | | | | | | 10 |
| 102 | Linuron | | | | 10 | | 10 | 10 | | | | | 10 | | |
| 103 | Metazachlor | 77,2 | | | | | | | | | | | | | |
| 104 | Metobromuron | | | | | | 10 | | | | | | | | |
| 105 | Metribuzin | | | | | | | 10 | | | | | | | |
| 106 | Oryzalin | | | 10 | | | | | | | | | | | |
| 107 | Oxadiazon | | | 10 | | | 10 | | 10 | | | | | | 10 |
| 108 | Oxyfluorfen | | | 10 | | | 10 | | | | | | | 10 | |
| 109 | Pendimethalin | | | | | | | | 10 | | | | 10 | 10 | |
| 110 | Penoxsulam | 74,7 | | | | | | | | | | | | | |
| 111 | Picloram | | | | | | | 10 | | | | | | | 10 |
| 112 | Picolinafen | | | | | | | | 10 | | | | | 10 | |
| 113 | Profoxydim | | | | | | 10 | 10 | | | | | | | |
| 114 | Propaquizafop | 75,7 | | | | | | | | | | | | | |
| 115 | Propyzamide | | | | | | | | | | | | 10 | | 10 |
| 116 | Prosulfocarb | | | | | | 10 | | | | | | | 10 | 10 |
| 117 | Prosulfuron | | | | | | | | 10 | | | | | | 10 |
| 118 | Pyraflufen-ethyl | | | 10 | | | | | 10 | | | | 10 | | |
| 119 | Quinoclamine | | | | | | 10 | | | 10 | | 10 | | | |
| 120 | Quizalofop-P-ethyl | | | | | | 10 | | | | | | | | |
| 121 | Quizalofop-p-tefuryl | | | | 10 | | | | | | | | | | |
| 122 | Sulcotrione | | | | | | 10 | | | | | | | | |
| 123 | Tembotrione | | | | | | 10 | | | | | | 10 | | 10 |
| 124 | Terbuthylazine | | | | | | 10 | | | | | | | | |
| 125 | Topramezone | | | | | | 10 | | | | | | | | 10 |
| 126 | Tralkoxydim | | | | | | 10 | | | | | | | | 10 |
| 127 | Tri-allate | | | | | | | | 10 | 10 | | | | 10 | 10 |
| 128 | Triclopyr | 74,6 | | | | | | | | | | | | | |

A grey italic 10 is for information only - no cut-off criterion (see Chapter "Blacklist Criteria"). * Authorization expired. Maximal period of grace: 30.09.2017

| | ireenpeace Blacklist 016 | | Μ | lamr | nal t | toxid | city | | Environmental Toxicity, Bioaccumulation, Persistence 동 | | | | | e | |
|-----|-----------------------------|-------|------------|-----------------|-------------|--------------|-----------|-----|--|--------------|-------|-----|------------|-----------------|-------------|
| 2 | Active Ingredient | Score | Acute Tox. | Carcinogenicity | Repro. Tox. | Mutagenicity | AOEL /ADI | EDC | Algae | Daphnia/Fish | Birds | Bee | Beneficial | Bioaccumulation | Persistence |
| | Insecticides; Acaricides | | | | | | | | | | | | | | |
| 129 | Abamectin | | 10 | | | | 10 | | | 10 | | | | | |
| 130 | Acrinathrin | | | | | | 10 | | 10 | 10 | | 10 | 10 | 10 | |
| 131 | Beta-cyfluthrin | | | | | | 10 | | | 10 | | 10 | 10 | 10 | |
| 132 | Bifenazate | | | | | | 10 | | | | | | | | |
| 133 | Bifenthrin | | | | | | 10 | 10 | | 10 | | 10 | 10 | 10 | 10 |
| 134 | Buprofezin | 86,6 | | | | | | | | | | | | | |
| 135 | Chlorantraniliprole | | | | | | | | | 10 | | | | | 10 |
| 136 | Chlorpyrifos | | | | | | 10 | | | 10 | | 10 | 10 | 10 | |
| 137 | Chlorpyrifos-methyl | | | | | | | | | 10 | | 10 | 10 | 10 | |
| 138 | Clofentezine | | | | | | | | | 10 | | | | | 10 |
| 139 | Clothianidin | | | | | | | | | | | 10 | 10 | | 10 |
| 140 | Cyhalothrin, gamma | | | | | | 10 | | | 10 | | 10 | 10 | 10 | |
| 141 | Cypermethrin | | | | | | | | | 10 | | 10 | 10 | 10 | |
| 142 | Cypermethrin, alpha | | | | | | | | | 10 | | 10 | 10 | 10 | |
| 143 | Cyromazine | 73,6 | | | | | | | | | | | | | |
| 144 | Deltamethrin | | | | | | 10 | 10 | | 10 | | 10 | 10 | 10 | |
| 145 | Diflubenzuron | | | | | | | | | 10 | | | 10 | | |
| 146 | Dimethoate | | | | | | 10 | | | | | 10 | 10 | | |
| 147 | Emamectin benzoate | | | | | | 10 | | 10 | 10 | | 10 | | | 10 |
| 148 | Esfenvalerate | | | | | | | | 10 | 10 | | 10 | 10 | 10 | |
| 149 | Ethoprophos | | 10 | 10 | | | 10 | | | | 10 | | 10 | | |
| 150 | Etofenprox | | | | | | | | | 10 | | 10 | 10 | | |
| 151 | Etoxazole | | | | | | | | | 10 | | | | 10 | |
| 152 | Fenamiphos | | | | | | 10 | | | 10 | 10 | 10 | 10 | | |
| 153 | Fenazaquin | | | | | | 10 | | | 10 | | 10 | | 10 | |
| 154 | Fenoxycarb | | | 10 | | | | | | | | | | | |
| 155 | Fenpyroximate | | | | | | 10 | | | 10 | | | 10 | 10 | |
| 156 | Fipronil | | | | | | 10 | | | | | 10 | 10 | | 10 |
| 157 | Flubendiamide | | | | | | 10 | | | 10 | | | | | 10 |
| 158 | Flupyradifurone | 74,2 | | | | | | | | | | | | | |
| 159 | Formetanate | | | | | | 10 | | | 10 | | 10 | 10 | | |
| 160 | Hexythiazox | | | 10 | | | 10 | | | | | | | 10 | |

| | Greenpeace Blacklist | | N | lamr | nal t | oxic | city | | Env Bioaco | | | l Toxi , Pers | | e |
|-----|-------------------------------|-------|------------|-----------------|-------------|--------------|-----------|-----|-----------------------|-------|-----|------------------|-----------------|-------------|
| 2 | Active Ingredient | Score | Acute Tox. | Carcinogenicity | Repro. Tox. | Mutagenicity | AOEL /ADI | EDC | Algae Danhnia/Eich | Birds | Bee | Beneficial | Bioaccumulation | Persistence |
| 161 | Imidacloprid | | - | 0 | - | - | • | | | | 10 | 10 | | 10 |
| 162 | Indoxacarb | | | | | | 10 | | | | 10 | 10 | 10 | |
| 163 | Lambda-cyhalothrin | | | | | | 10 | 10 | 1(|) | 10 | 10 | 10 | 10 |
| 164 | Lufenuron | | | | | | | - | 1(| | _ | - | 10 | |
| 165 | Malathion | | | 10 | | | | | 1(|) | 10 | 10 | | - |
| 166 | Metaflumizone | | | _ | | | | | | | 10 | 10 | 10 | 10 |
| 167 | Methiocarb | | | | | | | | 1(|) 10 | 10 | 10 | | |
| 168 | Methomyl | | | | | | 10 | | 1(|) | 10 | 10 | | |
| 169 | Methoxyfenozide | 75,1 | | | | | | | | | | | | |
| 170 | Milbemectin | ,. | | | | | | | 1(|) | 10 | 10 | | |
| 171 | Paraffin oil (cont. >3% DMSO) | | | 10 | | | | | | | | | | |
| 172 | Phosmet | | | | | | | | 1(|) | 10 | 10 | | |
| 173 | Pirimicarb | | | 10 | | | | | 1(|) | | | | 10 |
| 174 | Pirimiphos-methyl | | | | | | 10 | | 1(|) | 10 | 10 | 10 | |
| 175 | Pymetrozine | | | 10 | | | | | | | | | | |
| 176 | Pyrethrum | | | | | | | | 1(|) | 10 | | | |
| 177 | Pyridaben | | | | | | 10 | | 1(|) | 10 | 10 | | |
| 178 | Pyridalyl | | | | | | | | 1(|) | | | 10 | 10 |
| 179 | Pyriproxyfen | 73,8 | | | | | | | | | | | | |
| 180 | Spinetoram | | | | | | 10 | | | | 10 | 10 | | 10 |
| 181 | Spinosad | | | | | | | | | | 10 | 10 | | |
| 182 | Spirodiclofen | | | 10 | | | 10 | | 1(|) | | 10 | | |
| 183 | Spiromesifen | | | | | | | | 1(|) | | | 10 | |
| 184 | Sulfoxaflor | | | | | | | | | | 10 | 10 | | |
| 185 | Tau-fluvalinate | | | | | | 10 | | 1(|) | | 10 | 10 | |
| 186 | Tebufenozide | | | | | | 10 | | | | | | | 10 |
| 187 | Tebufenpyrad | | | | | | | | 1(|) | | 10 | 10 | |
| 188 | Teflubenzuron | | | | | | | | 1(|) | | 10 | 10 | 10 |
| 189 | Tefluthrin | | | | | | 10 | | 1(|) | 10 | | 10 | |
| 190 | Thiacloprid | | | 10 | | | | | | | | 10 | | |
| 191 | Thiamethoxam | | | | | | | | | | 10 | 10 | | |
| 192 | Triflumuron | | | | | | | | 1(|) | | | 10 | |
| 193 | zeta-Cypermethrin | | | | | | | | 1(|) | 10 | | | |

| | Greenpeace Blacklist | | Μ | lamn | nal t | oxio | ity | | В | | | | | l Toxi , Pers | city, istenc | e |
|-----|---------------------------|-------|------------|-----------------|-------------|--------------|-----------|-----|---|-------|--------------|-------|-----|------------------|-----------------|-------------|
| 2 | 016 Active Ingredient | Score | Acute Tox. | Carcinogenicity | Repro. Tox. | Mutagenicity | AOEL /ADI | EDC | : | Algae | Daphnia/Fish | Birds | Bee | Beneficial | Bioaccumulation | Persistence |
| | Nematicides | | | | | | | | | | | | | | | |
| 194 | Fosthiazate | | | | | | 10 | | | | | 10 | 10 | | | |
| 195 | Oxamyl | | | | | | 10 | | | | | 10 | 10 | 10 | | |
| | Plant Growth Regulators | | | | | | | | | | | | | | | |
| 196 | 1-methylcyclopropene | | | | | | 10 | | | | | | | | | |
| 197 | Aluminum sulfate | | | | | | 10 | | | | | | | | | 10 |
| 198 | Chlorpropham | | | | | | | | | | | | | 10 | | 10 |
| 199 | Clodinafop-propargyl | | | | | | 10 | | | | | | | 10 | | |
| 200 | Daminozide | | | 10 | | | | | | | | | | | | |
| 201 | Flumetralin | | | | | | | | | | 10 | | | | 10 | 10 |
| 202 | Paclobutrazol | 82,7 | | | | | | | | | | | | | | |
| 203 | Sodium 2-nitrophenoxide | | | | | | 10 | | | | | | | | | |
| 204 | Sodium 4-nitrophenoxide | | | | | | 10 | | | | | | | | | |
| 205 | Sodium 5-nitroguaiacolate | | | | | | 10 | | | | | | | | | |
| 206 | Sodium silver thiosulfate | | | | | | 10 | | | | | | | | | |
| | Rodenticides | | | | | | | | | | | | | | | |
| 207 | Bromadiolone | | 10 | | | | 10 | | | | | | | | 10 | |
| 208 | Calcium phosphide | 80,3 | | | | | | | | | | | | | | |
| 209 | Difenacoum | | | | | | 10 | | | | 10 | | | | 10 | 10 |

Annex 2

The Pesticide Blacklist Scoring System

The scoring system translates classification and/or toxicological endpoints or certain chemical properties into a numerical score. The scoring is usually 1-2-5-8-10 and relates to the toxicity or the chemical properties/environmental behavior of the pesticides. A high score relates high toxicity or a critical classification or in the case of environmental fate to critical effects (mobility, persistence).

Without balanced weighting, the highest possible score for a pesticide active ingredient would be 168 points (16 parameters with the highest possible score of 10 plus one parameter with maximum score of 8). The lowest possibly score would be 17. However, because the mammalien/human toxicity group includes one more criterion for evaluation (immunotoxicity), a factor of 1,16 was applied to the ecotoxicity to outweight the inbalance between ecotoxicity and human toxicity. The highest possible score for a pesticide active ingredient is therefore 176 points.

Mammalian toxicity

Acute Toxicity Score

| All Exp. | Oral | | Inhalation | | | |
|----------------------|---------|--------------------|--------------------|--------------------|---------------------------|-------|
| GHS Acute Cat. | WHO* | LD50 (mg/kg bw) | Gases (ppm/V) | Vapours (mg/l) | Dusts and Mists (mg/l) | Score |
| 1 | la | ≤5 | LD50 ≤ 100 | LD50 ≤ 0,5 | LD50 ≤ 0,05 | 10 BL |
| 2 | lb | 5 < LD50 ≤ 50 | 100 < LD50 ≤ 500 | $0,5 < LD50 \le 2$ | 0,05 < LD50 ≤ 0,5 | 8 |
| 3 | П | 50 < LD50 ≤ 300 | 500 < LD50 ≤ 2500 | 2 < LD50 ≤ 10 | 0,5 < LD50 ≤ 1 | 5 |
| 4 | Ш | 300 < LD50 ≤ 2000 | 2500 < LD50 ≤ 2000 | $10 < LD50 \le 20$ | 1 < LD50 ≤ 5 | 2 |
| ** | U | > 2000 | > 2000 | > 20 | > 5 | 1 |
| ACTIVE I | NGREDIE | ENTS WITHOUT DATA | | | | 5 |

* The WHO Classification includes **dermal** toxicity, if higher than oral toxicity.

** Active ingredients evaluated by GHS Regulation (EC) No 1272/2008 and not classified in any acute toxicity category.

The GHS Classification reflects three exposures: oral, **dermal** and inhalation. The highest toxicity across all pathways is used.

GHS Classification supersedes WHO and other LD50 data.

References

EC (2008): Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union L 353/1 and its amendments.

IPCS/WHO (2009): The WHO recommended classification of pesticides by hazard and guidelines to classification 2009, International Programme on Chemical Safety (IPCS) & World Health Organization (WHO), Geneva.

Carcinogenicity Classification and Scoring

| GHS CLASSIFI- CATION | EPA CLASSIFI- CATION 2005 | EPA CLASSI- FICATION 1999 DRAFT | EPA CLASSIFI- CATION 1996 | EPA CLASSIFI- CATION 1986 | IARC CANCER CLASSIFI- CATION | SCORE |
|--|---|---|------------------------------------|--|--|-------|
| Known human carcinogens' (category 1a) | Carcinogenic to humans | Carcinogenic to humans | Known/likely | Human carcinogen | Group 1 The agent (mixture) is carcinogenic to humans. | 10 BL |
| Presumed human carcinogens' (category 1b) | Likely to be carcinogenic to humans | Likely to be carcinogenic to humans | | Group B – probable human carcinogen Group B1 is reserved for agents for which there is limited evidence of car- cinogenicity from epidemiologic studies Group B2 is used for agents for which there is "sufficient: evidence from animal studies and for which there is "inade- quate evidence" or "no data" from epidemiologic studies. | Group 2a The agent (mixture) is probably carcinogenic to humans. | 10 BL |
| Suspected human carcinogens (category 2) | Suggestive evidence of carcinogenic potential | Suggestive evidence of carcinoge- nicity, but not sufficient to assess human carcinogenic potential | | Group C – possible human carcinogen | Group 2b The agent (mixture) is possibly car- cinogenic to humans. | 8 |
| | Inadequate information to assess carcinogenic potential | Data are inadequate for an assessment of human carcinogenic potential. | Cannot be determined | Group D – not classifiable as to human carcinogenicity | Group 3 The agent (mixture or exposure circum- stance) is not classifiable as to its car- cinogenicity to humans. | 5 |

| Active ingredients evaluated by ghs regulation 1272/2008/ ec and not classified in any carci- nogenicity category. | Not likely to be carcino- genic to humans. | Not likely to be carcinoge- nic to humans | Not likely | Group E – evidence of non- carcinogenicity for humans | Group 4 The agent (mixture) is probably not carcinogenic to humans. | 1 |
|---|---|---|------------|--|--|---|
| ACTIVE INGREDIENTS WITHOUT DATA | | | | 5 | | |

References:

EC (2008): Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union L 353/1 and its amendments.

IARC (2015): Agents reviewed by the IARC Monographs, Volumes 1– 112 (by CAS Numbers). International Agency for Research on Cancer (IARC). Last updated: 7.April 2015. Lyon, France.

US EPA (2006–2014): Chemicals Evaluated for Carcinogenic Potential. Science Information Management Branch, Health Effects Division Office of Pesticide Programs, U.S. Environmental Protection Agency (US EPA). April 26 2006; September 12 2007, September 24 2008; September 03 2009, November 2012, September 2013, October 2014.

US EPA (2015): Annual Cancer Report 2015. Chemicals Evaluated for Carcinogenic Potential. Office of Pesticide Programs, U.S. Environmental Protection Agency (US EPA).

Mutagenicity

| GHS | Description | Score |
|-------------|---|-------|
| Category 1A | The classification in Category 1A is based on positive evidence from human epidemiological studies. | 10 BL |
| | Substances to be regarded as if they induce heritable mutations in the germ cells of humans. | |
| Category 1B | The classification in Category 1B is based on: | 10 BL |
| | positive result(s) from in vivo heritable germ cell mutagenicity tests in mammals; or | |
| | positive result(s) from in vivo somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. It is possible to derive this supporting evidence from mutagenicity/genotoxicity tests in germ cells in vivo, or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of germ cells; or | |
| | positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people. | |
| Category 2 | Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans | 8 |
| | Active ingredients evaluated by GHS Regulation 1272/2008/EC and not classified in any mutagenicity category. | 1 |
| | ACTIVE INGREDIENTS WITHOUT DATA | 5 |

Reference:

EC (2008): Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union L 353/1 and its amendments.

Reproductive and developmental toxicity

| GHS | Description | Score |
|-------------|---|-------|
| Category 1A | Known human reproductive toxicant The classification of a substance in Category 1A is largely based on evidence from humans | 10 BL |
| Category 1B | Presumed human reproductive toxicant The classification of a substance in Category 1B is largely based on data from animal studies. | 10 BL |
| Category 2 | Suspected human reproductive toxicant Substances are classified in Category 2 for reproductive toxicity when there is some evidence from humans or experimental animals, possibly supplemented with other information. | 8 |
| | Active ingredients evaluated by GHS Regulation (EC) No 1272/2008 and not classified in any category for reproductive toxicity. | 1 |
| | ACTIVE INGREDIENTS WITHOUT DATA | 5 |

Reference:

EC (2008): Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union L 353/1 and its amendments

Operator Toxicity AOEL/ADI (Acceptable Operator Exposure Level/Acceptable Daily Intake)

| AOEL/ADI-Wert [mg/kg body weight] | Score |
|--|-------|
| AOEL/ADI < 0,01 | 10 BL |
| $0,01 \leq AOEL/ADI < 0,1$ | 8 |
| $0,1 \leq AOEL/ADI < 1$ | 5 |
| $1 \leq AOEL/ADI < 10$ | 2 |
| AOEL/ADI >= 10 or "not appl." or. "n.n." | 1 |
| ACTIVE INGREDIENTS WITHOUT DATA | 5 |

References:

EC (2016) : EU Pesticides database. European Commission. http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN

EC (2015) EU Pesticides database. European Commission. http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN

Immunotoxicity

| GHS | Score |
|---|-------|
| H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H317: May cause an allergic skin reaction. | 8 |
| Active ingredients evaluated by GHS Regulation (EC) No 1272/2008 and not classified as H317 or H343. | 2 |
| Active ingredients without data | 5 |

Reference:

EC (2008): Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union L 353/1 and its amendments.

Endocrine Disruption

| EU Classification | Score |
|---|-------|
| Endocrine disruptor or potential endocrine disruptor according to EU Category 1 ("At least one study showing endocrine disruption in an intact organism") or 'Suspected human reproductive toxicant' (Category 2) AND 'Suspected human carcinogens' (Category 2) according to Regulation (EC) No 1272/2008. | 10 BL |
| Endocrine disruptor or potential endocrine disruptor according to EU Category 2 ("Potential for endocrine disruption") | 8 |
| EU Category 3 (No scientific basis for inclusion in list) | 1 |
| Active ingredients without data | 5 |

References:

EC (2000): Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption - preparation of a candidate list of substances as a basis for priority setting. European Commission. Delft.

EC (2004): Commission Staff Working Document SEC (2004) 1372 on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706). Europäische Kommission. Brüssel.

EC (2007): Commission staff working document on the implementation of the "Community Strategy for Endocrine Disrupters" - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706), (COM (2001) 262) and (SEC (2004) 1372), SEC(2007) 1635. European Commission (EC), Brussels, 30.11.2007.

EC (2008): Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union L 353/1 and its amendments.

Environmental toxicity

Acute toxicity Algae

| EC50 (growth) mg/l (ppm) | Footprint 'narrative' | Score |
|--------------------------|-----------------------|-------|
| ≤ 0,01 | Highly toxic | 10 |
| > 0,01 - ≤ 10 | Moderately toxic | 5 |
| >10 | Low toxicity | 1 |
| ACTIVE INGREDIENTS | 5 | |

References:

Lewis KA, Tzilivakis J, Warner D & Green A (2016): An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, In Press. doi:10.1080/108070 39.2015.1133242.

University of Hertfordshire (2015): The Bio-Pesticides Database (BPDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

University of Hertfordshire (2015): The Veterinary Substance Database (VSDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

Acute toxicity Daphnia and Fish*

| LC50 or EC50 (acute) mg/l (ppm) | US EPA 'narrative' | Score |
|---------------------------------|----------------------|-------|
| ≤ 0,1 | very highly toxic | 10 |
| > 0,1 - ≤ 1 | highly toxic | 8 |
| >1 - ≤ 10 | moderately toxic | 5 |
| > 10 - ≤ 100 | slightly toxic | 2 |
| > 100 | practically nontoxic | 1 |
| ACTIVE INGREDIENTS | 5 | |

*The highest score is applied, when scores differ between the two species groups.

References:

Lewis KA, Tzilivakis J, Warner D & Green A (2016): An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, In Press. doi:10.1080/108070 39.2015.1133242.

University of Hertfordshire (2015): The Bio-Pesticides Database (BPDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

University of Hertfordshire (2015): The Veterinary Substance Database (VSDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

Acute toxicity birds

| LD50 (oral) | US EPA 'narrative' | Score |
|------------------|----------------------|-------|
| ≤ 10 | very highly toxic | 10 |
| > 10 to \le 50 | highly toxic | 8 |
| > 50 to ≤ 500 | moderately toxic | 5 |
| > 500 to ≤ 2000 | slightly toxic | 2 |
| > 2000 | practically nontoxic | 1 |
| ACTIVE INGREDIE | 5 | |

References:

Lewis KA, Tzilivakis J, Warner D & Green A (2016): An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, In Press. doi:10.1080/108070 39.2015.1133242.

University of Hertfordshire (2015): The Bio-Pesticides Database (BPDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

University of Hertfordshire (2015): The Veterinary Substance Database (VSDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015

Beneficial organisms

| Lethal Rate (50%) in gramm/hectar | Percent effect (mortality, beneficial capacity) | Footprint 'narrative' | Score | |
|--|---|-----------------------|-------|--|
| < 5 | > 79 | Harmful | 10 | |
| > 5 to ≤ 40 | - | - | 8 | |
| > 40 to ≤ 110 | 30 - 79 | Moderately harmful | 5 | |
| > 110 to ≤ 500 | - | - | 2 | |
| > 500 | < 30 | Harmless | 1 | |
| ACTI | VE INGREDIENTS WITHOUT | DATA | 5 | |
| Data for most sensitive species are used for the TLI | | | | |

References:

Lewis KA, Tzilivakis J, Warner D & Green A (2016): An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, In Press. doi:10.1080/108070 39.2015.1133242.

University of Hertfordshire (2015): The Bio-Pesticides Database (BPDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

University of Hertfordshire (2015): The Veterinary Substance Database (VSDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

Honey bees (Apis mellifera)

| LD50 (µg/bee) | US EPA 'narrative' | Score |
|-------------------|----------------------|-------|
| < 2 | Highly toxic | 10 |
| 2 – 11 | Moderately toxic | 5 |
| > 11 | Practically nontoxic | 1 |
| ACTIVE INGREDIENT | 5 | |

References:

Lewis KA, Tzilivakis J, Warner D & Green A (2016): An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, In Press. doi:10.1080/108070 39.2015.1133242.

University of Hertfordshire (2015): The Bio-Pesticides Database (BPDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

University of Hertfordshire (2015): The Veterinary Substance Database (VSDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

Environmental fate and transport

Bioaccumulation

| Bioconcentration Factor (BCF) | LogP KOW | Score* |
|---|-----------|--------|
| > 500 | > 5 | 10 |
| > 400 - ≤ 500 | > 3 - ≤ 5 | 8 |
| > 300 - ≤ 400 | > 2 - ≤ 3 | 5 |
| > 200 - ≤ 300 | > 1 - ≤ 2 | 2 |
| ≤ 200 | < 1 | 1 |
| ACTIVE INGREDIENTS WITHOUT DATA | | 5 |
| *Bioconcentration Factor (BCF) supersede Log P KOW data | | |

References:

Lewis KA, Tzilivakis J, Warner D & Green A (2016): An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, In Press. doi:10.1080/108070 39.2015.1133242.

University of Hertfordshire (2015): The Bio-Pesticides Database (BPDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2013.

University of Hertfordshire (2015): The Veterinary Substance Database (VSDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2013.

Persistence in soil, sediments and water

| Halflife soil and/or sediment (days) | Halflife in Water (days) | Score |
|--------------------------------------|--------------------------|-------|
| > 90 | > 50 | 10 |
| > 80 ≤ 90 | > 40 ≤ 50 | 8 |
| > 70 ≤ 80 | > 30 ≤ 40 | 5 |
| > 60 ≤ 70 | > 20 ≤ 30 | 2 |
| > 50 ≤ 60 | > 10 ≤ 20 | 1 |
| ≤ 50 | ≤ 10 | 1 |
| Elements | | 1 |
| ACTIVE INGREDIENTS WITHOUT DATA | | 5 |

References:

Lewis KA, Tzilivakis J, Warner D & Green A (2016): An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, In Press. doi:10.1080/108070 39.2015.1133242.

University of Hertfordshire (2015): The Bio-Pesticides Database (BPDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

University of Hertfordshire (2015): The Veterinary Substance Database (VSDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

Leaching potential

| GUS Index (function of soil half-life and soil binding) | Footprint 'narrative' | Score |
|--|-----------------------|-------|
| > 2,8 | High leachability | 10 |
| 2,8 - 1,8 | Transition state | 5 |
| < 1,8 | Low leachability | 1 |
| ACTIVE INGREDIENTS WITHOUT DATA | | 5 |

Primary References:

Lewis KA, Tzilivakis J, Warner D & Green A (2016): An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, In Press. doi:10.1080/108070 39.2015.1133242.

University of Hertfordshire (2015): The Bio-Pesticides Database (BPDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

University of Hertfordshire (2015): The Veterinary Substance Database (VSDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2015.

Secondary reference (when data are not available in Primary Reference):

CDPR (2015): 2014 Status Report Pesticide Contamination Prevention Act. California Environmental Protection Agency.- California Department of Pesticide Regulation. Environmental Monitoring Branch.

Volatility

| Vapour pressure (mm HG) at 20-25°C | Score |
|---|-------|
| > 0,01 | 10 |
| < 0,01 to > 0,0001 | 5 |
| < 1 x 10 ⁻⁴ - > 1 x 10 ⁻⁶ | 5 |
| < 1 x 10 ⁻⁶ - > 1 x 10 ⁻⁸ | 2 |
| < 1 x 10 ⁻⁸ | 1 |
| ACTIVE INGREDIENTS WITHOUT DATA | 5 |

References:

Lewis KA, Tzilivakis J, Warner D & Green A (2016): An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, In Press. doi:10.1080/108070 39.2015.1133242.

University of Hertfordshire (2015): The Bio-Pesticides Database (BPDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2013.

University of Hertfordshire (2015): The Veterinary Substance Database (VSDB) developed by the Agriculture & Environment Research Unit (AERU), University of Hertfordshire, 2011-2013.

Half-life on plants

| Half-life on plant (days) | Score |
|---|-------|
| > 3,8 | 10 |
| > 1 - < 3,8 (or post-emergency herbicide) | 5 |
| < 1 (or pre-emergency herbicide) | 1 |
| ACTIVE INGREDIENTS WITHOUT DATA | 5 |

Primary Reference:

Fantke P & Juraske R (2013): Variability of Pesticide Dissipation Half-Lives in Plants. Environ. Sci. Technol. (47): 3548–3562. dx.doi.org/10.1021/es303525x

Secondary Reference (when data are not available in Primary Reference):

Lewis KA, Tzilivakis J, Warner D & Green A (2016): An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, In Press. doi:10.1080/108070 39.2015.1133242.

Scoring for "low risk" compounds

EU Commission Regulation (EC) No 1095/2007 (4) as well as Annex II of Regulation (EC) No 1107/2009 define criteria for "low-risk active substances". Pesticides which were authorized in the EU because they meet these criteri receive a default total score of 17 in the Blacklist Scoring System – the lowest possible total score. The score cannot be lower, because even a low-risk substance may present some potential risk.

Annex 3

Comparison of toxicological thresholds for specific effects with the ADI as used for the Blacklist

Database

NOEL ("*No Observed Effect Level*") values for repeated dosing for selected effects on the nervous system and the thyroid collated by EFSA in the framework of the "cumulative risk assessment". The goal of that assessment was to identify pesticides with common toxicological mechanisms, and presents a review of all data from the authorization process regarding specific endpoints and specific target organisms.

All data are available at: http://www.efsa.europa.eu/en/efsajournal/pub/3293

Pesticides active ingredients (a.i.) were investigated with the following results:

- ▶ 84 a.i. with effects on nervous system (517 studies delivered NOELs, repeated dose)
- 110 a.i. with effect on thyroid (745 studies delivered NOELs, repeated dose)

Important note:

NOEL ("*No Observed Effect Level*") values are normally more protective than NOAEL ("*No Observed Adverse Effect Level*") values. ADI values are commonly derived by dividing NOAEL values by two uncertainty factors 10 and 10 (=100).

Methods

Comparison of the EFSA NOELs for specific effects with the ADI as used for the Blacklist. The EFSA NOELs (repeated dose) were divided by 100 to create values ("NOEL-ADIs") comparable with the ADIs.

For comparison, the Blacklist scoring system for the ADI (refer to Annex 2, table AOEL/ADI) was applied to the NOEL-ADIs, and then divided by the scores for the ADIs used for the Blacklist. Results greater than 1 would mean that the ADI used for the Blacklist is weaker than the NOEL-ADI. Results smaller than 1 would mean that the Blacklist ADIs are stricter than the "NOEL-ADI" so they would be more protective for the effects under scope.

Results

In 98% of all studies analyzed by EFSA the blacklist score is equal (66%) or stricter (32%) than the score for the NOEL-ADI. For 2% of the studies, the NOEL-ADI results in a stricter score than the blacklist ADI which concerns 10 pesticides. The reason for this is that for these 10 pesticides very different results for the NOEL values were found by EFSA (between 5 and 35).

For Buprofezin for example, 15 NOELs were found, they range from 0.9 mg/kg bw per day to 1000 mg/kg bw per day for the same target organ Since EFSA reviewed all available data for the focus of the project, the cumulative risk assessment, also studies were considered which would not be part of standard risk assessment, e.g. studies with humans. For that reason, the stricter NOEL-ADIs for 10 pesticides found by EFSA are not used for the Blacklist.

Conclusion

The ADIs used as Blacklist Criteria seem to be strict enough for covering effects on the nervous system concerning selected repeated dose effects derived from EU Draft Assessment Reports (DARs).

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