

Bayer comments on the UNEP report 'An Assessment Report on Issues of Concern: Chemicals and Waste Issues Posing Risks to Human Health and the Environment'

Bayer, December 18, 2020.

Glyphosate

Page 77

UNEP report excerpt:

- **After the IARC's conclusion, other governmental institutions also conducted their own reassessments or assessed glyphosate for the first time (see Table B4–1 in the Annex and references therein). The different assessments reached seemingly different conclusions. Many concluded that glyphosate is not carcinogenic (e.g. US EPA 2015; EFSA 2015; Australian Pesticides and Veterinary Medicines Authority [APVMA] 2016; New Zealand Environmental Protection Authority 2016; ECHA 2017; Health Canada 2017; US EPA 2017), whereas some others agreed with the conclusion of the IARC (e.g. California Office of Environmental Health Hazard Assessment [OEHHA] 2017; US ATSDR 2019).**

Bayer comment:

- The statement that following the IARC classification, “different assessments reached *seemingly* different conclusions” is misleading. In fact, there is overwhelming consensus among leading health regulators around the world that glyphosate is not carcinogenic.
- Most recently, in January 2020, the U.S. Environmental Protection Agency (EPA) stated “*EPA considered a significantly more extensive and relevant dataset than the International Agency on the Research for Cancer (IARC). EPA's database includes studies submitted to support registration of glyphosate and studies EPA identified in the open literature. For instance, IARC only considered eight animal carcinogenicity studies while EPA used 15 acceptable carcinogenicity studies. EPA does not agree with IARC's conclusion that glyphosate is 'probably carcinogenic to humans.'* EPA's cancer classification is consistent with other international expert panels and regulatory authorities, including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, European Chemicals Agency, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan and the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Meeting on Pesticide Residues (JMPR).”
- Indeed, IARC's opinion is inconsistent with the conclusions of regulatory authorities and other experts around the world, who have assessed all the studies examined by IARC and many more. IARC is an outlier even within the World Health Organization (WHO). IARC is one of four programs within the WHO that has evaluated the safety of glyphosate and is the only one to find an association between glyphosate and carcinogenicity. The WHO's International Programme on Chemical Safety and Joint FAO/WHO Meeting on Pesticide Residues (JMPR) both found that glyphosate is not carcinogenic, and the WHO's Guidelines for Drinking-Water Quality found that glyphosate does not present a hazard to human health.¹

¹ References: a) International Programme on Chemical Safety: Guidelines for drinking water quality - IPCS. 1994. Glyphosate. Environmental Health Criteria 159. Geneva, Switzerland: World Health Organization. ISBN 92-4-157159-4;

- Regarding the ATSDR report: The ATSDR report does not draw conclusions about whether glyphosate can or cannot cause cancer. Rather, it contains a summary of eight national and international agency assessments of carcinogenicity (table 2-13, page 126) that, with the one exception of IARC, conclude that glyphosate is not carcinogenic. The table reinforces the safety of glyphosate, as regulators around the world who have reviewed the extensive science on glyphosate continue to conclude that it is safe for use and is not carcinogenic. And, IARC remains the outlier. The ATSDR profile also notes that ‘most studies found no association between exposure to glyphosate-based products and risk of cancer.’”
- Regarding OEHHA: OEHHA reviewed glyphosate in 2007 and concluded it is not likely to cause cancer. OEHHA’s own regulations require it to list substances that IARC has assigned certain classification. OEHHA did not assess the carcinogenicity of glyphosate when it chose to list glyphosate as carcinogenic under Proposition 65 solely on the basis of IARC’s classification.

Page 77

UNEP excerpt:

- **ECHA (2017) concluded that glyphosate is toxic to aquatic life with long-lasting effects (classification of Aquatic chronic 2).**

Bayer comment:

- The ECHA classification is based on a hazard assessment and not a risk assessment that considers environmental exposure levels to glyphosate. When the endpoint (NOEC = 1 mg glyphosate/L) used for the classification is put into the context of an environmental risk assessment, that considers worst-case environmental glyphosate exposure levels, negligible chronic aquatic risk has been concluded (EFSA, 2015).

EFSA. 2015. Renewal assessment report on glyphosate. 31 October 2015. RMS: Germany, Co-RMS: Slovakia. Available from: <http://dar.efsa.europa.eu/darweb/provision>

Page 77

UNEP report excerpt:

- **Glyphosate-containing airborne particles can be transported away from the original source by wind, with transport distances depending on particle size and weather conditions.**

Bayer comment:

- Glyphosate is not volatile, is rapidly oxidized in the atmosphere, and long-term transport via air can be excluded (EFSA, 2015). Glyphosate can bind to soil particles and be transported by air and wind. However, inhalation exposure of glyphosate from particles containing glyphosate represents negligible risk when exposure is compared in inhalation toxicity endpoints for glyphosate. In addition, DT₅₀ values for glyphosate in sediment range from 34 to 76 days and does

b) JMPR: FAO and WHO. 2016. Pesticides residues in food 2016. Special session of the Joint FAO/WHO meeting on pesticide residues. FAO plant production and protection paper. Food and Agriculture Organization of the United Nations, World Health Organization. <http://www.fao.org/3/a-i5693e.pdf>.

c) Drinking Water Quality: WHO. 2005. Glyphosate and AMPA in drinking-water. Background document for development of WHO guidelines for drinking-water quality. World Health Organization. WHO/SDE/WSH/03.04/97. https://www.who.int/water_sanitation_health/dwq/chemicals/glyphosateampa290605.pdf

not meet the criterion to be classified as persistent in sediment under established PBT criteria (EFSA, 2015).

EFSA. 2015. Renewal assessment report on glyphosate. 31 October 2015. RMS: Germany, Co-RMS: Slovakia. Available from: <http://dar.efsa.europa.eu/darweb/provision>

Page 77-78

UNEP report expert:

- **Glyphosate may be present as airborne particles due to drift during spraying operations (Ravier et al. 2019) or windblown particles which the co-presence of AMPA can be observed (Chang, Simcik and Capel 2011; for more examples, see Table B4–2 in the Annex).**

Bayer comment:

- Chang et al. measured ambient concentrations of glyphosate and AMPA in surface water, air, and rain. Reporting the levels of glyphosate and AMPA in water and rain is not new as the USGS has been reporting these data since 2001 (Scribner et al., 2007). While the studies for glyphosate in air are limited the levels reported for Chang et al. are consistent with what has been previously reported (Jauhiainen et al., 1991; Humphries et al., 2005; Prouvost et al., 2005) and more recent surveys (Sousa et al., 2019; Ravier et al., 2019).
- Unfortunately, the Chang study perpetuates two misperceptions about glyphosate: (1) that glyphosate detections and levels in the ambient environment are increasing; and (2) that those levels are not safe for human health. In fact, more recent surveys of ambient air are consistent with the levels measured by Chang et al. including sampling in both urban and rural areas in Brazil (Sousa et al., 2019) and France (Ravier et al., 2019) suggesting that ambient levels are not increasing even in agricultural areas. Furthermore, the Chang study reaffirms the safety of this important low-risk product.
- Chang et al. measured ambient concentrations of glyphosate in air with the highest reported air level being 9 ng/m³. Assuming a 24 hr breathing volume of 20 m³, a worst-case human inhalation exposure would be 180 nanomoles (9 ng/m³ x 20 m³) which is 30,420 ng (180 x mol. Wt. of 169). For a 70 kg adult the worst-case inhalation is 434 ng/kg BW versus the oral ADI of 0.5 mg/kg BW or 0.08% of the oral ADI. Assuming 100% inhalation bioavailability, the worst-case inhalation exposure of 434 ng/kg body weight is equivalent to an oral exposure (assuming 20% oral bioavailability) of 434/0.2 = 2,170 ng oral dose, which is still only 4% of the oral ADI.

References

1. De F. Sousa MG, da Silva AC, dos Santos Araújo R, Rigotto RM. Evaluation of the atmospheric contamination level for the use of herbicide glyphosate in the northeast region of Brazil. *Environmental Monitoring and Assessment*. 2019;191:604. DOI: 10.1007/s10661-019-7764-x
2. Jauhiainen A, Räsänen K, Sarantila R, Nuutinen J, Kangas J. Occupational exposure of forest workers to glyphosate during brush saw spraying work. *American Industrial Hygiene Association Journal*. 1991;52(2):61-64. DOI: 10.1080/15298669191364334
3. Humphries D, Byrtus G, Anderson AM. Glyphosate residues. In: Alberta's Atmospheric Deposition, Soils and Surface Waters. Vegreville, Alberta: Water Research Users Group Alberta Environment; 2005

4. Prouvost H, Declercq C. Exposition de la population aux pesticides dans la region Nord-Pas-de-Calais: Apports du programme PHYTO AIR. 2005:78. Project report. Available from: <http://www.orsnpdc.fr/wp-content/uploads/2015/02/05-5.pdf>
5. Ravier S, Désert M, Gille G, Armengaud A, Wortham H, et al. Monitoring of Glyphosate, Glufosinateammonium and (Aminomethyl) phosphonic acid in ambient air of Provence-Alpes-Côte-d'Azur Region, France. Atmospheric Environment. 2019;204:102-109. DOI: 10.1016/j.atmosenv.2019.02.023hal-02059173
6. Scribner EA, Battaglin WA, Gilliom RJ, Meyer MT. 2007. Concentrations of glyphosate, its degradation product, aminomethylphosphonic acid, and glyfosinate in ground- and surface-water, rainfall, and soil samples collected in the United States, 2001-06. U.S. Geological Survey Scientific Investigations report 2007-5122, 111p. Available online at: <http://pubs.usgs.gov/sir/2007/5122/pdf/SIR2007-5122.pdf>

Page 78

UNEP report excerpt:

- **The degradation half-life of glyphosate in soil may vary from a few days up to several months and even years (Vereecken 2005).**

Bayer comment:

- Glyphosate does not meet the criterion to be classified as persistent under established PBT criteria (EFSA, 2015). A more recent review has published predicted levels of glyphosate AMPA in soil and placed these levels derived from the best available data into the context of an ecological risk assessment demonstrating low chronic risk for glyphosate and AMPA to soil macro- and micro-organisms (von Mérey et al. 2015).

EFSA. 2015. Renewal assessment report on glyphosate. 31 October 2015. RMS: Germany, Co-RMS: Slovakia. Available from: <http://dar.efsa.europa.eu/darweb/provision>

von Mérey G, Mehrsheikh A, Manson P, Sutton P, Levine SL. 2016 Glyphosate and aminomethylphosphonic acid chronic risk assessment for soil biota. Environ Toxicol Chem. 35:2742-2752.

Page 78

UNEP report excerpt:

- **In some cases, through drainage water or agricultural runoff, glyphosate and AMPA may also be transported to groundwater.**

Bayer comment:

- Glyphosate and AMPA have been concluded to be below the EU groundwater threshold value of 0.1 µg/L, indicating that the use of glyphosate as intended is not likely to pose an unacceptable risk to groundwater via leaching (EFSA, 2015).
- Horth (2012) provided a review of glyphosate and AMPA monitoring results for surface waters from all 27 EU Member States. The outcome of the assessment demonstrates that the risk for direct and indirect effects to aquatic organisms from the intended uses of glyphosate is acceptable.

EFSA. 2015. Renewal assessment report on glyphosate. 31 October 2015. RMS: Germany, Co-RMS: Slovakia. Available from: <http://dar.efsa.europa.eu/darweb/provision>

Horth, H. 2012. Survey of glyphosate and AMPA in groundwaters and surface waters in Europe. BVL report number 2310291.

Page 79

UNEP report expert:

- **Note that one study detected elevated levels of different heavy metals such as arsenic and lead in glyphosate-based herbicide formulations on the French market, and thus, the use and disposal of such formulations may also result in exposure to these heavy metals (Defarge et al. 2018).**

Bayer comment:

- Arsenic is a naturally occurring element and is present in soils at an average concentration of 5 parts per million (ppm) (ATSDR, 2007). That level is approximately 10 times greater than the levels reported for concentrated Roundup-branded herbicides.
- Arsenic co-occurs with phosphate in the environment and arsenic is naturally found in the soil and water. Consequently, arsenic may be present in many foods including grains, fruits, and vegetables where it is present due to absorption through the soil and water. Arsenic is absorbed by plants regardless of whether they are grown under conventional or organic farming practices and the data show there is no difference in the amount of arsenic found in organic versus conventionally grown food (FDA, 2020).
- Defarge et al. compared the amounts of arsenic present in concentrated glyphosate formulation to the drinking water standard (10 ppb). However, concentrated pesticide products are not intended for use as drinking water and the WHO or other standards do not apply to products other than drinking water.

Agency for Toxic Substance and Disease Registry (ATSDR). 2007. Toxicological Profile for Arsenic. <https://www.atsdr.cdc.gov/ToxProfiles/TP.asp?id=22&tid=3>

U.S. Food and Drug. 2020. Arsenic in Food and Dietary Supplements.

<https://www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements>

Page 81

UNEP report excerpt:

- **For example, in 2017, California (US) added glyphosate to its “Proposition 65 list” under the Safe Drinking Water and Toxic Enforcement Act of 1986, as a substance known to the state to cause cancer, and thus the state requires businesses to provide warnings to consumers about significant exposure to glyphosate (OEHHA 2017).**

Bayer comment:

- California does not require businesses to provide warnings to consumers regarding glyphosate. In June 2020, a U.S. federal judge ruled that such a warning label would be false and misleading because the weight of evidence is that glyphosate does not cause cancer. The judge issued a permanent injunction against California, barring them from requiring a warning for glyphosate under Proposition 65 as a cancer-causing chemical.

Page 79

UNEP report excerpt:

- **However, studies on human exposure are limited. In particular, a recent review highlights the paucity of data on glyphosate levels among individuals exposed occupationally, para-occupationally or environmentally; the authors concluded that as such, it is challenging to fully understand the extent of exposure overall and in vulnerable populations such as children.**

Bayer comment:

- An important biomonitoring article that characterized applicator and farm family exposures should have been included in this section (Acquavella et al. 2004) was omitted. None of the systemic doses estimated in this study approached the USEPA or EFSA reference doses for glyphosate. A more recent review article has reviewed glyphosate exposure in the general population and applicators (Solomon et al. 2016). The conclusions from this comprehensive and critical review is that glyphosate exposures are less than the reference dose and the acceptable daily intakes proposed by several regulatory agencies, thus supporting a conclusion that human exposures were within regulatory limits.

Acquavella JF, Alexander BH, Mandel JS, Gustin C, Baker B, Chapman P, Bleeke M. 2004. Glyphosate biomonitoring for farmers and their families: results from the Farm Family Exposure Study. *Environ Health Perspect.* 112(3):321-6.

Solomon KR. 2016. Glyphosate in the general population and in applicators: a critical review of studies on exposures. *Crit Rev Toxicol.* 46(sup1):21-27.

Page 82

UNEP report excerpt:

- **While effects such as biodiversity and weed resistance may seem to be local or regional in scale, the widespread nature of the use of glyphosate and glyphosate-tolerant crops and of glyphosate contamination in many parts of the world makes this an international issue (FAO 2012).**

Bayer comment:

- This statement misrepresents the cited reference. The cited reference does not mention biodiversity. The cited reference is guidance for slowing the development of pests resistant to a range of pest controls.

Page 79

UNEP Report Excerpt:

- **Monitoring of urine concentrations also suggests higher exposure of populations in the US than in Europe (Niemann et al. 2015) and a considerable increase of exposure at least in some regions over time (e.g. Niemann et al. 2015; Conrad et al. 2017; Mills et al. 2017). One study shows that local reductions in glyphosate applications could be correlated to decreases in levels in young people in the general population (Conrad et al. 2017).**

Bayer comment:

- Niemann et al. (2015) provides a comprehensive discussion of reliability of using urine to determine exposure and put it into context by comparing it to health-based guidance. They reviewed seven reports of studies in which samples of urine from human subjects were collected and analyzed and the data indicate exposure to glyphosate is <1% of the ADI.
- Conrad et al. (2017) used random 24-hr urine samples from 20 males and 20 females that were 20 to 29 years old and samples were collected yearly from 2001 through 2015 from a town in Northeastern Germany. 31.8% of the samples had quantifiable concentrations of glyphosate and the data suggests that concentrations of glyphosate in urine increased from 2001 to 2011 but declined after 2012. All the samples tested were at or below 0.1% of the ADI.
- Mills et al. (2017) tested urine samples from older adults and concluded that the number of detects and the mean values were elevated over time. Regardless, using the mean value for urinary glyphosate, the exposure of glyphosate is 0.01% of the ADI indicating a reasonable expectation of safety.

Neonicotinoids

The neonic section emphasises how extensively they have been assessed by regulatory authorities, and there are further assessments underway in several countries. They are registered in more than 120 countries and, with uses increasing it follows that exposure is also increasing, and appropriate restrictions are applied. These insecticides would not be used and assessed so widely if they did not bring benefits to farmers and other users, but the section completely ignores these benefits.

The text notes that the recent (2018) EFSA peer review reports on imidacloprid, thiametoxam and clothianidin showed their use may result in a high risk for bees in specific circumstances. It neglected to mention that high risks were identified in only 5% of more than 500 different scenarios, and none of these were for honeybees.

There is an error in reporting the EFSA conclusions on thiacloprid which was NOT identified as an endocrine disruptor. The ED assessment was not completed.

Section 4.7.2 addresses presence in the environment but remains very vague with “may” result in, etc., and treating all neonicotinoids as the same when, in fact, their properties differ greatly with respect to movement in soil, persistence etc.

As with the specific scenarios and high risk, the mention of two countries that have banned one or more neonicotinoids and the removal of some products from the US market is not placed into context of where the products remain approved and suitable risk mitigation measures applied. It is correct that France has banned neonicotinoids (the EU has not but did introduce restrictions on outdoor uses). However, France has just changed its national law to allow emergency uses where alternatives have failed to protect sugar beet from devastating losses due to yellow virus transmitted by aphids. The 12 products banned in the US, recently, were either of negligible use or not in use any longer.