GREENPEACE

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Glyphosate – the case for classification as Category 1B carcinogen

Greenpeace submission to the ECHA consultation on glyphosate

In March 2015, the International Agency for Research on Cancer (IARC) announced that it had classified glyphosate as *probably carcinogenic to humans* putting it into IARC Category 2A. The classification was based on *sufficient evidence* of carcinogenicity in animals, *limited evidence* of carcinogenicity in humans and *strong evidence* of two mechanisms through which carcinogenicity can be invoked, genotoxicity and oxidative stress. The full rationale for this classification was presented in IARC Monograph 112.

The EU's carcinogen classification is based on an evaluation of the strength of evidence of carcinogenicity (see point 1 below) coupled with additional considerations (discussed under point 2 below).

(1) Strength of evidence

In the European Union, classification in Category 1B (*presumed human carcinogen*) is based on animal experiments for which there is *sufficient evidence* to demonstrate animal carcinogenicity. Scientific judgement may warrant a classification in Category 1B also based on *limited evidence* of carcinogenicity in humans in addition to *limited evidence* of carcinogenicity in experimental animals. (Regulation 1272/2008, Table 3.6.1)

The criteria for *sufficient* and *limited* strength of evidence are directly derived from IARC:

Limited evidence of carcinogenicity in humans is given when a positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence. (Regulation 1272/2008, Annex I: 3.6.2.2.3.)

The IARC Working Group identified a positive association for Non-Hodgkin Lymphoma based on high quality case-control studies. It found that this constitutes *limited evidence* in humans since causality is credible but could not be fully established based on the evidence. (IARC Monograph 112)

Sufficient evidence of carcinogenicity in animals is given when a causal relationship has been established between the agent and an increased incidence of malignant neoplasms in (a) two or more species of animals or (b) two or more independent studies in one species carried out at different times or in different laboratories or under different protocols. (Regulation 1272/2008, Annex I: 3.6.2.2.3.)

The IARC Working Group identified a significant positive trend for renal tumours in male CD-1 mice. It found a significant positive trend for hemangiosarcoma in male CD-1 mice in another study. It also found a significant increase in the incidence of pancreatic islet cell adenomas in two studies in male Sprague-Dawley rats. In one of these rat studies, thyroid gland adenomas in females and liver adenomas in males were also increased. The IARC Working Group found that this constitutes *sufficient evidence* in animals. (IARC Monograph 112)

Therefore, based on the strength of evidence ascertained in the IARC Monograph, insofar as RAC confirms these findings, an EU classification as Category 1B carcinogen is warranted.

In addition to the above-mentioned findings in animal studies, the Dossier Submitter (DS) identified further evidence of carcinogenicity in studies that were not considered by IARC. These findings are consistent with those reviewed in the IARC Monograph, according to experts. (Comments submitted under this consultation by Peter Clausing, PAN Germany, and Christopher J. Portier)

(2) Additional considerations

Further factors can be considered as either increasing or decreasing the level of concern for human carcinogenicity. Importantly, there is a requirement for more complete information to decrease than to increase the level of concern. (Regulation 1272/2008, Annex I: 3.6.2.2.5.)

The DS has described several factors that would decrease the concern. However, independent scientists have found these factors to be insufficiently documented to effectively decrease the level of concern. (Portier et al, 2016, Differences in the carcinogenic evaluation of glyphosate between IARC and EFSA, comments submitted under this consultation by Peter Clausing, PAN Germany, and Christopher J. Portier)

In the interest of public health, Greenpeace urges the members of the Risk Assessment Committee (RAC) to confirm the evaluation of the IARC Working Group. In particular, we ask the members to acknowledge the limited evidence of carcinogenicity in humans, as well as the strong and consistent evidence of carcinogenicity in animals. We ask the members to critically review the considerations brought forward by the DS to decrease the level of concern.

Glyphosate is widely used in the EU, and human exposure practically inevitable. It merits careful evaluation of the evidence to ensure proper classification, and regulation, in order to prevent unnecessary, widespread suffering.

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