CHRONICALLY UNDERRATED?

A review of the European carcinogenic hazard assessment of 10 pesticides

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INTRODUCTION

Glyphosate, one of the world's most widely used pesticides that has been linked to multiple negative health effects, was reauthorized for a period of five years on the European market in 2017. This decision was a controversial one, particularly as the official assessment on the carcinogenicity of this pesticide was based on a flawed and distorted use of EU guidelines and guidance documents [1]. These criticisms have also raised more general questions about the way European authorities perform carcinogenicity assessments. In an effort to find answers to these questions, we have performed a review of the carcinogenicity sections of the draft Renewal Assessments Reports (RARs) of ten different pesticides.

This report presents the findings of our review and draws conclusions for future improvements of the risk assessment process of pesticide active substances at the European level.

APPROACH

The review focused on how the sections describing the carcinogenicity studies in rats and mice in the EU assessment documents complied with guidelines from the Organisation for Economic Co-operation and Development (OECD) and the EU's own guidance documents. European regulation on the Classification, Labelling and Packaging (CLP) of substances and mixtures (1272/2008) and the regulation on plant protection products (1107/2009) were taken as points of reference. The guidance document from the European Chemicals Agency (ECHA) on the Application of CLP Criteria (2015, 2017) was also taken into account. The ten selected draft RARs were completed between 2015 and 2018. Nine of the ten substances were already classified as suspected human carcinogens (category 2) and one was classified as non-carcinogenic [2].

RESULTS

THE OUTCOME OF OUR REVIEW IS SUMMARISED IN THE TABLE BELOW.

AGREEMENT

For three of the ten pesticides reviewed in the EU renewal assessment reports (RARs), our assessment was in agreement with the classification decided by the European authorities: chlorothalonil and diuron are now proposed as "presumed to have carcinogenic potential for humans" (category 1B) and forchlorfenuron will remain as "suspected human carcinogen" (category 2).

DISAGREEMENT

For three of the ten substances, our assessment was in disagreement with the classification proposed by the authorities: folpet, pirimicarb and thiacloprid. We concluded that these active ingredients should be classified as category 1B instead of its current classification as category 2.

For phosmet, where a severe data gap should have been identified, the authorities accepted an insufficient study that lead to the wrong conclusion that phosmet is not carcinogenic.

INSUFFICIENT INFORMATION

For the last three pesticides reviewed, our review found a severe lack of detail and a widespread deficiency in transparency concerning the description of the carcinogenicity studies in the RARs: captan, chlorpropham, dimoxystrobin. This makes it impossible to come to a conclusion, and demonstrates an urgent need to improve the transparency of authorities' assessment reports.

The most frequent flaw observed through our review was the wrong use of historical control data. Historical control data were used to dismiss study results for dimoxystrobin, folpet, phosmet and pirimicarb.

Summarised below are the conclusions in the Renewal Assessment Reports (RARs) and the results of our review.

PESTICIDE	CATEGORY IN RAR*	AGREED	INSUFFICIENT DETAIL	DISAGREED
Captan	2		X	
Chlorotalonil	1B	X		
Chlorpropham	2		X	
Dimoxystrobin	2		X	
Diuron	1B	X		
Folpet	2			should be 1B
Forchlorfenuron	2	X		
Phosmet	not carcinogenic			severe data gap**
Pirimicarb	2			should be 1B
Thiacloprid	2			should be 1B

* *Category 1B classifies a substance as "presumed to have carcinogenic potential for humans". Category 2 classifies a substance as a "suspected human carcinogen".*

** *Authorities should withhold marketing approval until data gap has been closed*

CONCLUSION

According to our review, the hazard classification proposed by the EU authorities was too weak (category 2 instead of 1B) or based on a flawed database for at least four of the ten compounds reviewed. This means that substances could be authorized for use although they have carcinogenic potential for humans.

In three separate cases, the available documents had a severe lack of transparency which prevented scientific scrutiny. EU authorities (EFSA and the European Commission) and Member States in charge of these assessments must apply guidelines and guidance documents more thoroughly and provide full transparency in the RARs on their evaluation and decision process as stipulated in the revised General Food Law.

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The Pesticide Action Network Germany (PAN Germany) is a nongovernmental organisation informing about the negative consequences of pesticide use and promoting environment-friendly and socially fair alternatives. PAN Germany is part of the PAN International network. Our work comprises critical analyses of pesticides and their use, policy advice practical advice for farmers and consumers. https://pan-germany.org/

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REFERENCES

1. Clausing et al. (2018): Pesticides and public health: a review of the regulatory approach to assessing the carcinogenicity of glyphosate in the European Union. J. Epidemiol. Community Health 72, 668–672.

2. http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN