



In glyphosate review, WHO cancer agency edited out “non-carcinogenic” findings

DECISION TIME: The European Union is considering whether to allow the continued use of the weedkiller glyphosate. France has said it would like to phase it out. Some farmers say such a move would damage their business. Above, a French farmer harvests wheat in a field in northern France. REUTERS/Pascal Rossignol

When the International Agency for Research on Cancer assessed the best-selling weedkiller glyphosate, significant changes were made between a draft of its report and the published version. The agency won't say who made the changes or why.



LONDON – The World Health Organization's cancer agency dismissed and edited findings from a draft of its review of the weedkiller glyphosate that were at odds with its final conclusion that the chemical probably causes cancer.

Documents seen by Reuters show how a draft of a key section of the International Agency for Research on Cancer's (IARC) assessment of glyphosate - a report that has prompted international disputes and multi-million-dollar lawsuits - underwent significant changes and deletions before the report was finalised and made public.

IARC, based in Lyon, France, wields huge influence as a semi-autonomous unit of the WHO, the United Nations health agency. It issued a report on its assessment of glyphosate - a key ingredient in Monsanto Corp's top-selling weedkiller RoundUp - in March 2015. It ranked glyphosate a Group 2a carcinogen, a substance that probably causes cancer in people.

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That conclusion was based on its experts' view that there was "sufficient evidence" glyphosate causes cancer in animals and "limited evidence" it can do so in humans. The Group 2a classification has prompted mass litigation in the United States against Monsanto and could lead to a ban on glyphosate sales across the European Union from the start of next year.



studies that IARC decided there was “sufficient” evidence of carcinogenicity.

One effect of the changes to the draft, reviewed by Reuters in a comparison with the published report, was the removal of multiple scientists' conclusions that their studies had found no link between glyphosate and cancer in laboratory animals.

In one instance, a fresh statistical analysis was inserted - effectively reversing the original finding of a study being reviewed by IARC.

In another, a sentence in the draft referenced a pathology report ordered by experts at the U.S. Environmental Protection Agency. It noted the report “firmly” and “unanimously” agreed that the “compound” – glyphosate – had not caused abnormal growths in the mice being studied. In the final published IARC monograph, this sentence had been deleted.

Draft version

and the incidence of renal tubule

23 adenoma or carcinoma (combined) was 1/49 (2%), 0/49 (0%), 1/50 (2%), 3/50 (6%). The report

24 from the PWG also indicated they firmly believe and unanimously concur with the original

25 pathologist that the incidences of renal tubular-cell neoplasms in this study are not compound

26 related. The EPA (1991d) stated they did not feel that this lesion was compound related.

Published report

and the incidence of adenoma

or carcinoma (combined) of the renal tubule was 1/49 (2%), 0/49, 1/50 (2%), 3/50 (6%) [$P = 0.034$, trend test for combined]. [The Working Group considered that this second evaluation indicated a significant increase in the incidence of rare tumours, with a dose-related trend, which could be attributed to glyphosate. [Chandra & Frith](#)



BEFORE & AFTER: A draft of IARC’s assessment of glyphosate (top) cited animal research findings that the compound didn’t cause tumours; the published version concluded the opposite.

Reuters found 10 significant changes that were made between the draft chapter on animal studies and the published version of IARC’s glyphosate assessment. In each case, a negative conclusion about glyphosate leading to tumours was either deleted or replaced with a neutral or positive one. Reuters was unable to determine who made the changes.



on its website advising the scientists who participate in its working groups “not to feel pressured to discuss their deliberations” outside the confines of IARC.

Reuters contacted 16 scientists who served in the IARC expert working group that conducted the weedkiller review to ask them about the edits and deletions. Most did not respond; five said they could not answer questions about the draft; none was willing or able to say who made the changes, or why or when they were made.

The chairman of the IARC sub-group tasked with reviewing evidence of glyphosate’s effect on laboratory animals was Charles Jameson, an American toxicologist. In testimony as part of personal-injury lawsuits against Monsanto in the United States, Jameson told lawyers for Monsanto he did not know when, why or by whom the edits had been made.

Monsanto is facing multiple legal claims in the U.S. from plaintiffs who allege glyphosate gave them or their loved ones cancer. Jameson is an expert witness for the plaintiffs. He did not respond to questions for this article.

Scott Partridge, Monsanto’s vice president of global strategy, told Reuters the changes to the draft showed how “IARC members manipulated and distorted scientific data” in their glyphosate assessment.

IARC declined to comment.



PARIS PROTEST: In September, French farmers staged a demonstration on the Champs-Elysees avenue in Paris, France, to protest against a possible ban on glyphosate. REUTERS/Philippe Wojazer

“IARC would like to reiterate that draft versions of the Monographs are deliberative in nature and confidential.”

Statement posted by IARC on its website after Reuters inquired who had made certain changes to a draft of its assessment of glyphosate

Numerous national and international agencies have reviewed glyphosate. IARC is the only one to have declared the substance a probable carcinogen. Compared with other agencies, IARC has divulged little about its review process. Until now, it has been nearly impossible to see details, such as draft documents, of how IARC arrived at its decision.

The European Food Safety Authority (EFSA) said that in its assessment of the weedkiller, the scientific decision-making process “can be traced from start to finish.” Jose Tarazona, head of EFSA’s pesticides unit, told Reuters: “Anyone can go to EFSA’s website and review how the



thinking.”

In the United States, the Environmental Protection Agency published a full 1,261-page transcript of a three-day scientific advisory panel meeting on its ongoing evaluation of the carcinogenic potential of glyphosate in December 2016.

No such record of the deliberations behind IARC’s monographs is published.

In a previous response to questions about the transparency of the IARC process, the agency’s director, Chris Wild, referred Reuters to a letter in which he said his agency’s assessments are “widely respected for their scientific rigour, standardised and transparent process.” Wild also said IARC’s methods are intended to allow scientists to engage in free scientific debate at its monograph meetings.

DELETIONS AND ADDITIONS

IARC says its working group scientists are selected for “their expertise and the absence of real or apparent conflicts of interest.” For the panel that evaluated glyphosate and four other pesticides in what is known as IARC’s Monograph 112, scientists from 11 countries met at the agency’s headquarters in Lyon for a week-long meeting starting on March 3, 2015. The meeting “followed nearly a year of review and preparation” by IARC staff and working group members, “including a comprehensive review of the latest available scientific evidence,” IARC said in a statement at the time.



INFLUENTIAL: The headquarters of the International Agency for Research on Cancer (IARC) in Lyon, France. The agency's assessments can have far-reaching impact. REUTERS/Robert Pratta

In June, Reuters reported how the chairman of the IARC working group was aware of new data showing no link between glyphosate and cancer in humans, but the agency did not take it into account because it had not been published.

No drafts of IARC's glyphosate assessment have surfaced before. However, a draft was obtained by Monsanto as part of the legal proceedings in the United States. Reuters reviewed chapter 3, the section on animal studies, which is the only section no longer covered by a confidentiality order of the court.

The glyphosate review in IARC's Monograph 112 runs to 92 pages; the chapter on animal studies consists of just over 10 pages. Reuters has not seen any other sections of the draft and cannot say whether they also underwent significant edits.

In comparing draft and final versions of chapter 3, Reuters found that in several instances comments in the draft were removed; the comments noted that studies had concluded glyphosate was not carcinogenic. They were replaced in the final version with the sentence: "The Working Group was not able to evaluate this study because of the limited experimental data provided in the review article and supplemental information."



Non-significant increases in tumour incidences versus controls

16 were noted for skin keratoacanthoma in high-dose males, and mammary gland fibroadenoma
17 in low- and mid-dose females [The authors concluded that glyphosate was not carcinogenic
18 in Sprague Dawley rats].

Published report

Non-significant increases in tumour incidences compared with controls were noted for skin keratoacanthoma in males at the highest dose, and for fibroadenoma of the mammary gland in females at the lowest and intermediate doses. [The Working Group was unable to evaluate this

study because of the limited experimental data provided in the review article and supplemental information.]



DRAFT & FINAL: A draft of IARC's assessment (top) said the scientists conducting this rat study found that glyphosate didn't cause cancer. The final version omitted that sentence.

This sentence was inserted six times into the final version. Each time it replaced a contrary conclusion, noted in the draft, by the original investigators on the study being considered, such as: "The authors concluded that glyphosate was not carcinogenic in Sprague Dawley rats"; "The authors concluded that glyphosate technical acid was not carcinogenic in Wistar rats"; and "The authors concluded that glyphosate was not carcinogenic in CD-1 mice in this study."

Reuters also found changes to the conclusions and statistical significance of two mouse studies. These studies were cited in IARC's ultimate finding of "sufficient" evidence that glyphosate causes cancer in animals.

One edit concerned a 1983 study in mice. IARC's published monograph contains a fresh statistical analysis calculation as part of its review of that study. The original investigators found no statistically significant link between glyphosate and cancer in the mice. IARC's new calculation reached the opposite conclusion, attributing statistical significance to it.



conclusion that glyphosate was probably carcinogenic.

In further discussion of the same 1983 study, IARC's final published report refers to expert pathologists on a panel commissioned to re-analyse the work of the original investigators. The IARC draft notes that these pathologists "unanimously" agreed with the original investigators that glyphosate was not related to potentially precancerous tissue growths in the mice. IARC's final report deletes that sentence.

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Reviewing a second mouse study, the IARC draft included a comment saying the incidence of a type of animal cancer known as haemangiosarcoma was "not significant" in both males and females. IARC's published monograph, by contrast, inserts a fresh statistical analysis calculation on the data in male mice, and concludes that the findings were statistically significant.

INFLUENTIAL MONOGRAPH

IARC's assessment that glyphosate is a probable human carcinogen is an outlier. In the 40 or so years since the weedkiller first came to the market, glyphosate has been repeatedly scrutinised and judged safe to use.

A year after IARC issued its evaluation, a joint United Nations and World Health Organization panel reviewed the potential for glyphosate in food to cause cancer in people. It concluded the weedkiller was "unlikely to pose a carcinogenic risk to humans."

The U.S. Environmental Protection Agency, which first assessed glyphosate in the 1980s and has reviewed it several times since, says it has "low toxicity for humans." The European Food Safety Authority and the European Chemicals Agency, which advise the 28 members of the EU, have also assessed glyphosate within the past two years and ruled it safe.



It is weighing heavily on a pending European Union decision – due by the end of the year and possibly to be made next week - on whether glyphosate should be relicensed for sale across the 28 member states. France, one of the bloc's agricultural powerhouses, has said it wants the weedkiller phased out and then banned, provoking protests by its vocal farmers, who argue glyphosate is vital to their business.



UNDER FIRE: The key ingredient of Monsanto's popular Roundup weedkiller is glyphosate, which the EU is considering whether to re-license. Here RoundUp atomisers are displayed at a garden shop near Paris, France. REUTERS/Charles Platiau

A failure to renew glyphosate's licence by the end of the year would see an EU ban kick in on Jan. 1, 2018.

In the United States, Monsanto – the firm that first developed and marketed glyphosate - is facing litigation in California involving at least 184 individual plaintiffs who cite the IARC assessment and claim exposure to RoundUp gave them a form of cancer known as non-Hodgkin lymphoma. They allege Monsanto failed to warn consumers of the risks. Monsanto denies the allegations. The case is ongoing.



investigations into American taxpayer funding of IARC. The investigations are ongoing.

In Europe, IARC has become embroiled in a public spat with experts at the European Food Safety Authority, which conducted its own review of glyphosate in November 2015 and found it “unlikely to pose a carcinogenic hazard to humans.”



SCIENTIST: Kurt Straif, head of IARC's monograph programme, seen in front of IARC's building in Lyon, France, in 2016.
REUTERS/Robert Pratta

With IARC monograph meetings, some outside observers are selected and allowed to witness proceedings, but they are banned from talking about what goes on. Journalists are generally not allowed in.

Last year, Reuters reported on an email sent by IARC to the experts on its glyphosate working group in which the agency advised them not to discuss their work or disclose documents. The email said IARC “does not encourage participants to retain working drafts or documents after the monograph has been published.”



programme, Kurt Straif, and to Kathryn (Kate) Guyton, the staffer responsible for the glyphosate review. IARC responded by posting the following message on its website:

“Members of the IARC Monograph Working Group which evaluated glyphosate in March 2015 have expressed concern after being approached by various parties asking them to justify scientific positions in draft documents produced during the Monographs process. IARC would like to reiterate that draft versions of the Monographs are deliberative in nature and confidential. Scientists should not feel pressured to discuss their deliberations outside this particular forum.”

IARC answered none of Reuters’ specific questions about changes to the draft.



INVESTIGATION: The U.S. Capitol Dome in Washington. A Congressional committee is examining U.S. funding of the International Agency for Research on Cancer. REUTERS/Jonathan Ernst

Glyphosate Battle

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