#HEALTH NEWS OCTOBER 5, 2017 / 8:00 AM / 14 DAYS AGO

EU set to delay vote on weed-killer glyphosate

Reuters Staff

2 MIN READ

BRUSSELS (Reuters) - Health experts from European Union countries are expected to discuss whether or not to extend the license for herbicide glyphosate at a meeting starting on Thursday, but will only vote on the issue later this year.

FILE PHOTO: Monsanto Co's 'Roundup For Lawns' is shown for sale in Encinitas, California, U.S., June 26, 2017. The product photographed does not contain glyphosate. REUTERS/Mike Blake

Europe has been debating for two years whether to allow the weed-killer, used in Monsanto's Roundup, with no clear majority of countries for or against a license extension andconcerns that it is carcinogenic.

The EU granted an 18-month extension in July 2016 pending further scientific study after failing to agree on a proposed 15-year license renewal.

The European Chemical Agency concluded in March that glyphosate, one of the world's most heavily used weed killers, should not be classified as causing cancer.

FILE PHOTO: People take part in a protest against a planned $66 billion takeover of the U.S. seeds company Monsanto by

Bayer and Monsanto's glyphosate herbicides, outside the European Commission headquarters in Brussels, Belgium July 19, 2017. REUTERS/Yves Herman

The European Commission is now proposing a 10-year extension, but said this will only pass if supported by a clear majority of member states. The standing committee on plant animal food and feed (PAFF), meeting on Thursday and Friday, had been expected to vote on the license for glyphosate but that vote will not now take place.

"Depending on how the discussions evolve there will be another meeting to discuss it and a possible vote. A decision should be taken by the end of the year when the current authorization expires," a Commission spokeswoman said.

"There will be a meeting of PAFF on October 23 but the agenda is not finalised yet so we don't know if glyphosate will be on the agenda or not."

France, which is opposed to a 10-year extension, has put forward the idea of a shorter extension for glyphosate with a view to phasing it out.

"We are working with the member states to find a solution, but the current proposal is for 10 years," the spokeswoman said.

Reporting by Philip Blenkinsop. Editing by Jane Merriman

Our Standards: The Thomson Reuters Trust Principles.

#HEALTH NEWS OCTOBER 19, 2017 / 10:38 AM / UPDATED AN HOUR AGO

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

EPA-HQ-2018-0008760072579

Kate Kelland

14 MIN READ

LONDON (Reuters) - 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.

FILE PHOTO: A French farmer drives his combine harvester as he harvests wheat in a field during sunset in Trescault, near Cambrai, northern France, August 5, 2015. To match Special Report WHO-IARC/GLYPHOSATE REUTERS/Pascal Rossignol/File Photo

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.

EPA-HQ-2018-0008760072580

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.

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.

The edits identified by Reuters occurred in the chapter of IARC's review focusing on animal studies. This chapter was important in IARC's assessment of glyphosate, since it was in animal 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.

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 tumors was either deleted or replaced with a neutral or positive one. Reuters was unable to determine who made the changes.

IARC did not respond to questions about the alterations. It said the draft was "confidential" and "deliberative in nature." After Reuters asked about the changes, the agency posted a statement 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.

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 assessment evolved over time. So you can see clearly how experts … appraised each and every study and also how comments from the public consultation were incorporated into the scientific 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 rigor, standardized 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.

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.

EPA-HQ-2018-0008760072583

FILE PHOTO: External view of the International Agency for Research on Cancer (IARC) in Lyon, France, June 12, 2017. To match Special Report WHO-IARC/GLYPHOSATE REUTERS/Robert Pratta/File Photo

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."

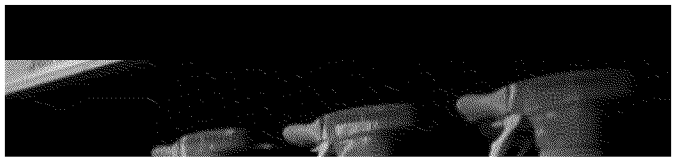
This sentence was inserted six times into the final version. Each time it replaced a contrary conclusion, noted in the draft, by the original investigators on the study being considered, such as: "The authors concluded that glyphosate was not carcinogenic in Sprague Dawley rats"; "The authors concluded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

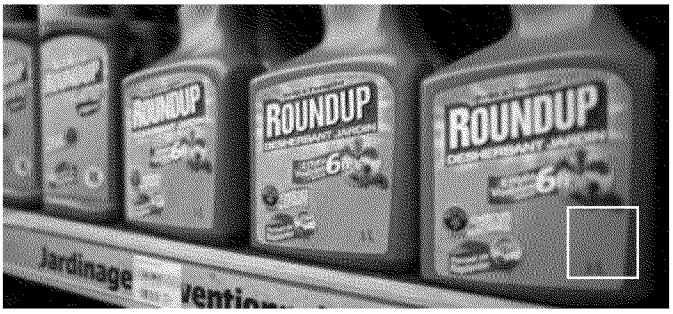
One edit concerned a 1983 study in mice. IARC's published monograph contains a fresh statistical analysis calculation as part of its review of that study. The original investigators found no statistically significant link between glyphosate and cancer in the mice. IARC's new calculation reached the opposite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

This new calculation was inserted into the final published assessment, but was not in the draft version seen by Reuters. The change gave the working group more evidence on which to base its 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 reanalyze 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.



Reviewing a second mouse study, the IARC draft included a comment saying the incidence of a type of animal cancer known as



Slideshow (4 Images)

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 scrutinized 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.

But IARC's Monograph 112 has had great influence.

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.

A failure to renew glyphosate's license by the end of the year would see an EU ban kick in on

EPA-HQ-2018-0008760072586

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.

Members of the U.S. Congress, concerned about what they described as IARC's "inconsistent" standards and determinations for classifying substances as carcinogenic, last year launched 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."

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."

Reuters sent questions about the draft version of the glyphosate assessment to members of the IARC working group that assessed the herbicide as well as to the head of IARC's monograph program, 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.

By Kate Kelland. Editing By Richard Woods

Our Standards: *The Thomson Reuters Trust Principles.*

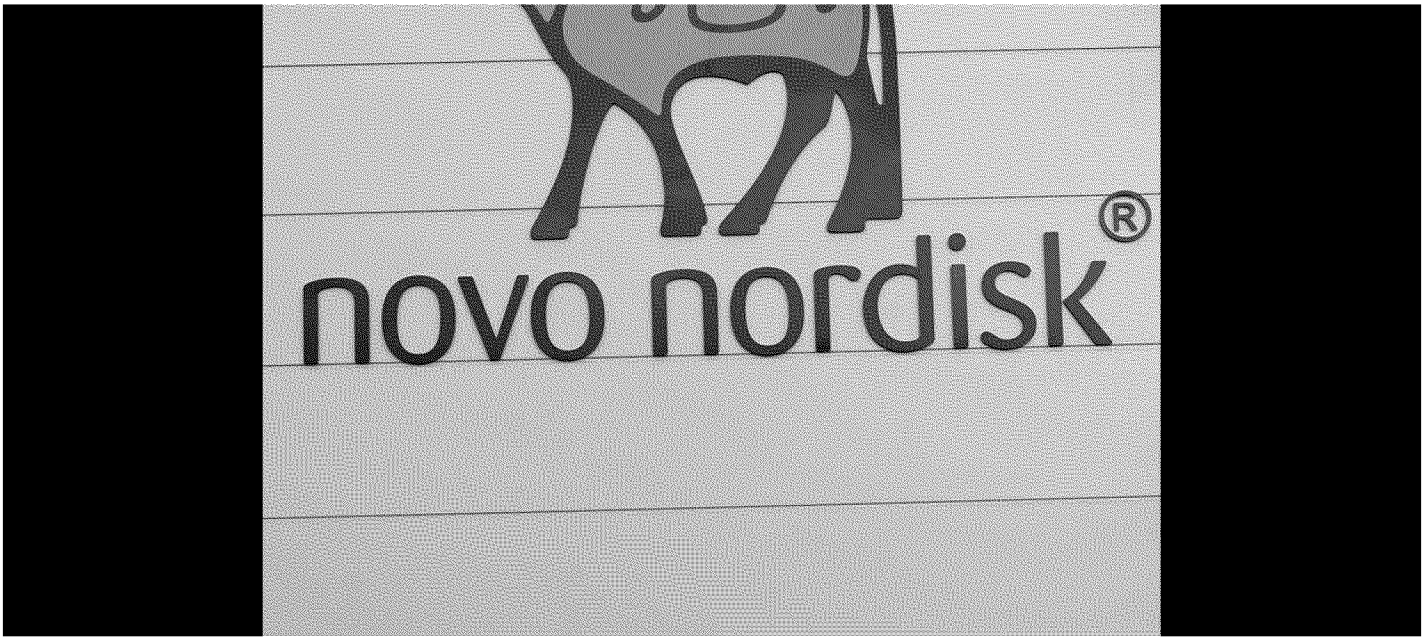
#HEALTH NEWS OCTOBER 18, 2017 / 4:36 PM / UPDATED 11 HOURS AGO

Novo Nordisk takes aim at Eli Lilly with U.S. backing of new diabetes drug

Toni Clarke, Jacob Gronholt-Pedersen

4 MIN READ

WASHINGTON/COPENHAGEN (Reuters) - Denmark's Novo Nordisk will take aim at Eli Lilly in the growing diabetes market after an advisory panel to the U.S. Food and Drug Administration (FDA) gave the green light to its semaglutide drug.



FILE PHOTO: The logo of Danish multinational pharmaceutical company Novo Nordisk is pictured on the facade of a production plant in Chartres, north-central France, April 21, 2016. REUTERS/Guillaume Souvant

Shares in Novo Nordisk rose almost 3 percent in early trading on Thursday, after the panel late on Wednesday concluded semaglutide is effective, reasonably safe and should be approved by the FDA.

The panel voted 16-0 with one abstention in favor of the drug being approved. It would compete with others in a class known as glucagon-like peptide-1 (GLP-1) analogs, which imitate an intestinal hormone that stimulates the production of insulin.

The FDA, due to decide on the drug by Dec. 5, typically follows the recommendations of its advisors.

“This should pave the way for a timely approval,” Chief Scientific Officer Mads Krogsgaard Thomsen said in an interview.

Novo Nordisk expects semaglutide, administered through a once-weekly injection, will take market share from Eli Lilly’s once-weekly Trulicity, which in turn has been taking share from Novo Nordisk’s once-daily Victoza.

"When you have the best (drug), if you cannot win market share, you should do be doing something other than supplying medicine to people," said Thomsen.

Novo will also target some 95 percent of the around 30 million diabetics in the United States who currently don't use GLP-1 drugs, he said.

PRICE RANGE

Novo plans to price semaglutide, which has yet to get a brand name, in a similar range as existing GLP-1 drugs, possibly with a small premium, Thomsen said, adding Novo Nordisk is also developing an oral form of semaglutide that it aims to launch in 2020.

Analysts on average expect annual semaglutide sales to reach $3.17 billion by 2023, with sales of Trulicity, which was approved in the United States in late-2014, rising to $3.71 in 2023, according to Thomson Reuters data.

"We believe semaglutide will be a formidable competitor for Lilly's Trulicity," Alex Arfaei, an analyst at BMO Capital Markets, said in a research note.

Panelists discussed data showing semaglutide was associated with an initial worsening of diabetic retinopathy, a condition caused by damage to blood vessels in the retina due to high blood sugar levels. The damage can cause progressive deterioration in vision, potentially leading to blindness.

But they found that the benefit of reducing blood sugar overall offset this risk, which the company argues is transient. Thomsen said most panel members supported Novo's ambition that the drug's label will to carry a standard warning, similar to insulins, regarding diabetic retinopathy. The FDA will decide on the final label.

The drug has also been shown to reduce cardiovascular risks, although it was unclear whether the FDA will include that in the label.

Most panel members pointed to the need of a larger post-approval study of the drug, a study that will be initiated next year, Thomsen said, without giving further details on the scope of the study.

Reporting by Toni Clarke; Additional reporting by Stine Jacobson in Denmark; Editing by Richard Chang and David Holmes

Our Standards: *The Thomson Reuters Trust Principles.*

Apps Newsletters Reuters Plus Advertising Guidelines Cookies Terms of Use Privacy

All quotes delayed a minimum of 15 minutes. See here for a complete list of exchanges and delays.

© 2017 Reuters. All Rights Reserved.