TESTIMONY OF

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BEFORE THE

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Good morning Chairman Smith, ranking Member Johnson and members of the committee. My name is Anna Lowit. I serve as the Science Advisor in the Office of Pesticide Programs of the U.S. Environmental Protection Agency. I have a Ph.D. in Environmental Toxicology from the University of Tennessee and have worked at the EPA since 1998. In my role as Science Advisor, I provide advice and guidance to senior management and staff concerning toxicity testing, risk assessment, and science policy issues of national and international importance related to pesticides.

The EPA regulates the manufacture and use of all pesticides in the United States and establishes maximum levels for pesticide residues in food, thereby safeguarding the nation's food supply, workers, and the general public. The EPA implements the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Pesticide Registration Improvement Act (PRIA); and key parts of the Food Quality Protection Act (FQPA) and Federal Food, Drug, and Cosmetic Act (FFDCA), along with the Endangered Species Act. Under these statutes, new pesticides and new

uses of existing pesticides are evaluated before they can enter the market. In addition, existing pesticides are re-evaluated at least every 15 years to determine whether they continue to meet the standard for registration. This program is known as registration review.[1] The EPA must complete registration review by October 1, 2022, for all pesticides registered as of October 1, 2007.

The process the EPA uses for evaluating the potential for human health and ecological effects of a pesticide is called risk assessment. The EPA uses the risk assessment process established by the 1983 National Research Council in the report on "Risk Assessment in the Federal Government: Managing the Process."[2] This process is widely used across the federal government and considers how toxic a chemical may be, what exposures may occur to a chemical, and the issues and uncertainties associated with a calculated risk. In fiscal year 2017, the EPA evaluated more than 120 pesticides using the risk assessment process.

The EPA's Office of Pesticides Programs is a science driven organization, employing more than 300 scientists. To evaluate the hazard of pesticides effects, we employ toxicologists, epidemiologists, botanists, and biologists. To evaluate the exposure of pesticides, the office employs industrial hygienists, chemists, physical scientists, agronomists, geologists, hydrologists, and environmental engineers. The office has entomologists and microbiologists who ensure the products we register are efficacious. The EPA also has statisticians, mathematicians, computer scientists, and experts in the Geographic Information System to support predictive modeling approaches. Our scientists work together in interdisciplinary teams

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[1] See https://www.epa.gov/pesticide-reevaluation/registration-review-process
[2] National Research Council. 1983. *Risk Assessment in the Federal Government: Managing the Process*. Washington, DC: The National Academies Press. Available at https://doi.org/10.17226/366.

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to evaluate the complex science associated with pesticide risk assessment. Our scientists also routinely work with risk managers and attorneys to support science based decision making in accordance with the relevant statutes. Within the limits defined by federal statutes, we also consider the benefits of pesticides to users, growers, and to society.

Scientists in the EPA's Office of Pesticides Programs work collaboratively with other program offices and regions within the EPA such as the Office of Water, the Office of Air, and the Office of Children's Health Protection. We engage with and depend upon input from the agency's Office of Research and Development to help solve some our most challenging science issues. In addition, the EPA's scientists are involved in projects with states and other federal agencies such as the U.S. Department of Agriculture, the Food and Drug Administration, the National Institute for Environmental Health Sciences, the U.S. Geological Survey, and the Centers for Disease Control and Prevention on numerous topics. The agency is involved internationally with at the Organisation for Economic Co-operation and Development (OECD) and the World Health Organization (WHO) to support harmonization and advancing risk assessment science. The EPA's methods are broadly accepted on an international basis. Many countries have adopted the methods developed and used by the EPA.

Under FIFRA, the EPA requires substantial amounts of toxicology and exposure data to be collected and submitted for pesticide registration. For example, numerous studies involving laboratory animals are conducted on a variety of pesticidal effects such as cancer and systemic toxicity.. The FQPA requires specific consideration of the potential for infants and children to be sensitive to pesticides. Accordingly, the EPA requires testing on developmental toxicity and

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reproductive toxicity and often specific evaluations on neurotoxicity and brain development. Multiple species are tested, namely rats, mice, dogs, rabbits, birds, fish, plants, bees and other insects. These tests range in their duration of exposure from a single day up to the entire lifetime of the laboratory animal and are conducted in different routes of exposure such as oral, dermal, inhalation.

Risk is not only a function of the toxicity of a chemical, it is also related to exposure that can occur due to its use. The EPA quantifies exposure to all facets of the U.S. population by considering diet and drinking water, as well as from other possible contact with pesticides both in the general population and as part of their job. The EPA also considers exposure in the environment to various plant and animal species. Many types of diverse data are required to evaluate such exposure patterns. These include monitoring of pesticide users (e.g., occupational exposure), behavioral information (e.g., dietary intake patterns), data intended to quantify how pesticides behave in the environment (e.g., chemical fate, transport, and persistence), as well as data to quantify what pesticides could end up in food (e.g., residue from crops where a pesticide is applied). These data requirements are found in 40 CFR Part 158.

To ensure data quality and consistency, the EPA has standard guidelines for how testing is to be conducted. The EPA's test guidelines are largely harmonized with those established internationally by the OECD. Harmonized test guidelines reduce the burden on chemical producers and conserve scientific resources, including reducing use of laboratory test animals while maintaining a thorough evaluation of the toxicity profile of pesticides.

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The EPA strives for transparency in our scientific analysis. Our science policies, guidance documents, and guidelines have been through peer review and public comments, and are publicly available. The agency's scientists develop independent, objective evaluations of studies sponsored by pesticide registrants and those available in the open scientific literature. The EPA's science reviews are publicly available in the federal docket and the agency's scientists routinely give presentations to the public and to other scientific experts. The EPA frequently meets with stakeholders, including industry, growers, non-governmental organizations, and states, on numerous issues pertaining to pesticides.

The EPA uses a tiered approach to conduct risk assessment in order to focus its efforts on areas where additional refinement is needed. This is practical from both a regulatory and resource perspective, as it allows the EPA and the regulated community to focus on critical issues and refine as needed, and conserves resources. In this approach, the EPA starts with highly conservative risk assessment then adds refinement as appropriate. For example, when dietary intake is evaluated, the EPA might assume the entirety of a particular crop is treated using the maximum allowable amount of pesticide when crops are not actually produced this way. As a refinement, information related to how much of a particular crop is treated could be considered. Amounts in food close to the point of consumption, such as sampled from a grocery store, is another refinement.

Glyphosate (commonly known as Roundup®) was initially registered by the EPA in 1974. Glyphosate acid and several related glyphosate salt compounds are also registered pesticides. Glyphosate is one of the most widely used agricultural pesticides in the United States,

with approximately 270 million pounds of active ingredient applied annually (2011-2015). Glyphosate is used on a large number of agricultural crops, primarily glyphosate-resistant corn and glyphosate-resistant soybeans. Glyphosate also makes up 40 percent of the total pounds of herbicides sold in the U.S. residential consumer market for use on lawns and turf. Other important uses are direct uses in aquatic systems and rights-of-way for total vegetation control.

Registration review for glyphosate was initiated in 2009. As mentioned above, the EPA has a statutory registration review process that is being applied to all registered pesticides, including glyphosate, involving evaluation of significant amounts of scientific information. As part of this process, several types of assessments have been initiated including evaluations of human health, ecological risk, carcinogenicity, endocrine disruption, and risk to pollinators and endangered species. The assessments are subject to extensive technical review and public comment at several time points throughout the review process.

The EPA released the draft human health and ecological risk assessments on December 18, 2017.[3] The EPA's human health review evaluated dietary, residential/non-occupational, aggregate, and occupational exposures. Glyphosate is considered to have little to no hazard when exposure is to the skin and when it is inhaled. Effects in laboratory animals were only seen through ingestion at high doses. In the case of glyphosate, the human health risk assessment was developed with high end assumptions known to be overestimates of exposure. However, even with these assumptions, no risk to humans, including infants and children, were identified. This conclusion about showing no risk to humans is consistent with risk assessment findings in other

[3] See https://www.epa.gov/ingredients-used-pesticide-products/draft-human-health-and-ecological-risk-assessments-glyphosate.

countries and international organizations such as Canada, Australia, and the European Food Safety Authority.

As required under the FFDCA, glyphosate was subject to endocrine screening as part of the EPA's Endocrine Disruptor Screening Program (EDSP). The EPA received and reviewed all the required Tier 1 assay data. Based on weight of evidence considerations, there is no convincing evidence of potential interaction with the estrogen, androgen or thyroid pathways, and no additional EDSP related studies are considered necessary.

In 2015, the International Agency on the Research for Cancer (IARC) released its final conclusions that glyphosate is "probably carcinogenic to humans (Group 2A)."[4] In 2016, the EPA conducted a comprehensive analysis of all the available laboratory animal carcinogenicity, mutagenicity, and epidemiology data to inform the human carcinogenic potential of glyphosate. In December 2016, the EPA presented its evaluation to the FIFRA Scientific Advisory Panel (SAP). The EPA received the SAP's recommendations in March 2017. The agency's cancer issue paper was updated to incorporate revisions based on the SAP's report. Based on the comprehensive analysis of all available data and reviews, the EPA concludes that glyphosate is "not likely to be carcinogenic to humans." The EPA's cancer classification for glyphosate is based on a weight of evidence evaluation in accordance with the agency's 2005 Guideline for Carcinogen Risk Assessment.[5] The dataset considered by the EPA included studies submitted for registration of glyphosate, as well as studies identified in the open literature as part of a systematic review.

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[4] See http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-10.pdf.
[5] See https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment.

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There are some fundamental differences between the IARC review and the EPA's review of glyphosate. For instance:

- IARC only considers data that has been published or accepted for publication in the openly available scientific literature. As a result, IARC only considered 10 laboratory animal cancer studies whereas the EPA includes 14 laboratory animal cancer studies in its evaluation;
- IARC does not consider exposure and only bases its decision on the hazard of a chemical where the EPA considers exposure as a critical component of the cancer evaluation;
- IARC's conclusion is inconsistent with the international community, where the EPA's conclusion that glyphosate is "not likely to be carcinogenic to humans," is consistent with other countries and international organizations including: Australia (2013), Canada (2015), Japan (2016), New Zealand (2016), the European Food Safety Authority (EFSA) (2015), Germany (2014), the European Chemicals Agency (ECHA) (2017) and the Joint Food and Agriculture Organization of the United Nations (FAO)/WHO Meeting on Pesticide Residues (JMPR) (2016).

On November 9, 2017, the National Cancer Institute, which is part of the National Institutes of Health (NIH), published a new epidemiology study entitled "Glyphosate Use and Cancer Incidence in the Agricultural Health Study".[6] The Agricultural Health Study (AHS) is a prospective cohort of more than 57,000 licensed pesticide applicators in Iowa and North Carolina. The results of this new study, which has a longer follow up period than previously

[6] J Natl Cancer Inst. 2017 Nov 15. doi: 10.1093/jnci/djx247, available at https://www.ncbi.nlm.nih.gov/pubmed/29155945.

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available evaluations of the AHS cohort, provide additional strong support for the agency's conclusion that glyphosate is "not likely to be carcinogenic to humans."

In an ecological risk assessment, the EPA evaluates the potential that exposure to pesticides may cause harmful effects to non-target organisms. The effects can be direct, such as fish deaths from a pesticide entering waterways, or birds do not reproduce normally after ingesting contaminated fish, or indirect, such as a bird that can't reproduce because the plant it requires for nesting has been stunted by pesticide exposure. Specific to glyphosate, the ecological risk assessment indicates that there is potential for effects on birds (surrogates for reptiles and terrestrial-phase amphibians), mammals, and terrestrial and aquatic plants but not fish (surrogates for aquatic-phase amphibians) or aquatic invertebrates. Available data show low toxicity for honeybees and other terrestrial invertebrates.

While the draft human health and ecological risk assessments are already publicly available on the EPA website[7], the official public comment period for the registration review of the draft glyphosate risk assessments and supporting science evaluations will soon be announced in the Federal Register. Once announced, this will begin the official public comment period which is anticipated to last for 60 days. After public comments are received on the risk assessment, if needed, the EPA will revise its risk assessments and issue a Proposed Interim Decision for public comment. If necessary, the Proposed Interim Decision will include proposed labeling changes and other risk mitigation measures. After public comments on the Proposed Interim Decision are received and evaluated, the EPA will issue an Interim Decision. The EPA

[7] See https://www.epa.gov/pesticides/epa-releases-draft-risk-assessments-glyphosate.

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plans to complete a Final Decision after an evaluation of risks to pollinators and an endangered species assessment is complete. In addition, the EPA plans to initiate endangered species consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service by 2020. As mentioned earlier, registration review must be completed by 2022.

In sum, the EPA has a statutory registration review process that is being systematically and transparently applied to glyphosate and all other pesticides reviewed by EPA. The EPA's pesticide risk assessments are based upon science and are subject to extensive science technical review and public comment. Draft risk assessments on glyphosate for human health and ecological effects are publically available at this time.

Thank you for the opportunity to testify today. I will be happy to answer any questions you and the other members may have.

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