Comments by the Center for Regulatory Effectiveness ("CRE") to the
Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) meeting on Carcinogenic Potential of Glyphosate ("Cancer Assessment")

I am Scott Slaughter, and I am commenting today on behalf of the Center for Regulatory effectiveness.

CRE's comments focus on the Federal Government quality standards that apply to EPA's Cancer Assessment. These quality standards also apply to this SAP's review of that Assessment.

In summary, EPA's Glyphosate Cancer Assessment cannot use or rely on any SAP report--or on any other report, study, assessment, review or any other information--that does not meet these Federal government quality standards.

For example, the IARC Glyphosate Review is subject to these quality standards, and it does not meet them. Consequently, EPA cannot use or rely on the IARC Review.

The overwhelming weight of evidence is that glyphosate does not cause cancer. Any contrary conclusion would be inaccurate and misleading, and would violate mandatory Federal government quality standards.

I'll now discuss these points in more detail.

This SAP is a Peer Review Panel subject to Federal Government Quality standards, including the Information Quality Act, or IQA.

The IQA is a federal statute that imposes quality standards on all information disseminated by EPA and by most federal agencies. Information and dissemination are broadly defined.[1] EPA and other Agencies cannot use or rely on information that does not meet these mandatory quality standards, which are designed to help ensure that the Government acts on sound science.

Pursuant to its authority under the IQA, the U.S. Office of Management and Budget, or OMB, published an Information Quality Bulletin for Peer Review. This SAP is a "peer review panel" subject to the OMB Peer Review Bulletin's requirements.[2]

CRE's written comments explain why the EPA Cancer Assessment, and this SAP's peer review of it, are subject to the most rigorous quality standards under the OMB Peer Review Bulletin. In the interests of brevity, I will not repeat that explanation in my oral comments.

The OMB Peer Review Bulletin requires that EPA inform the SAP reviewers

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[1] See Office of Management and Budget ("OMB") Government-wide IQA Guidelines at https://www.gpo.gov/fdsys/pkg/FR-2002-02-22/pdf/R2-59.pdf ; EPA IQA Guidelines at https://www.epa.gov/quality/epa-information-quality-guidelines.

[2] See https://www.epa.gov/pesticides/scientific-advisory-panel-meet-cancer-potential-glyphosate .

"of applicable access, objectivity, reproducibility and other quality standards under federal information quality laws."[3]

EPA has not informed this SAP of all these federal quality standards, so I will try to fill in the blanks,

In general, OMB and EPA IQA Guidelines require that EPA insure the "objectivity, utility and integrity" of all information that EPA disseminates, uses or relies on. The OMB and EPA IQA guidelines explain that

"Objectivity' focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased."[4]

Influential information like EPA's Cancer Assessment is subject to especially rigorous standards of transparency and reproducibility. EPA's IQA Guidelines explains that :

"A higher degree of transparency about data and methods will facilitate the reproducibility of such information by qualified third parties, to an acceptable degree of imprecision. For disseminated influential original and supporting data, EPA intends to ensure

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[3] OMB Peer Review Bulletin, pages 25 and 37 at http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf .

[4] EPA IQA Guidelines, page 15, at https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf .

reproducibility according to commonly accepted scientific, financial, or statistical standards." [5]

These IQA quality standards apply to all sources of information that EPA is considering for possible use in a risk assessment like EPA's Cancer Assessment.[6] This applicability includes information *"that EPA obtains for use in developing a policy, regulatory, or other decision*," like SAP reports or the IARC Glyphosate Review.[7]

This means that both the SAP Report and the IARC Glyphosate Review must meet IQA standards before EPA can use or rely on them in the Cancer Assessment, which must itself meet these quality standards. Therefore, if this SAP discusses the IARC review in the SAP's peer review report, then the SAP must determine whether the IARC Review meets IQA standards.

I'll try to explain why the IARC review does not meet IQA standards.

First, however, I'd like to provide some examples of federal agencies rejecting similar studies or reports because they do not meet IQA standards.

***As a First example*: EPA was preparing an ecological risk assessment for the herbicide atrazine. The available**

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[5] EPA IQA Guidelines, pages 20-21, at https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf .

[6] EPA IQA Guidelines, page 28, at https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf .

[7] See *Id.*

external (*i.e.*, non-EPA) studies disagreed as to whether atrazine causes adverse endocrine effects in amphibians. CRE submitted a Request for Correction ("RFC") under the IQA, which provides a statutory right to *"seek and obtain correction of information maintained and disseminated by the agency that does not comply with" I*QA standards.[8] CRE's RFC claimed that none of the available amphibian effects studies could be used for the atrazine risk assessment because none of the studies used test methods that have been demonstrated to be accurate and reliable. EPA agreed with CRE; did not use any of the studies; and supervised development of properly validated studies. Another SAP helped EPA formulate the procedures for developing an accurate and reliable amphibian effects test.[9]

As a *Second example*: CRE argued to the National Oceanic and Atmospheric Administration that reports by the International Whaling Commission's Scientific Committee had to meet IQA requirements. If the reports do not meet these requirements, then NOAA cannot use them to regulate various industries under the Marine Mammal Protection Act. NOAA wrote back agreeing with CRE. NOAA's letter stated:

> **"*Prior to releasing or relying on third party information, such as IWC Scientific Committee reports, [NOAA's National Marine Fisheries Service] must conduct a pre-dissemination review to determine that***

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[8] OMB's Government-wide IQA Guidelines, page 8452 at https://www.gpo.gov/fdsys/pkg/FR-2002-02-22/pdf/R2-59.pdf .

[9] See the CRE website at http://www.thecre.com/quality/20030224_epa.html for links to relevant documents and a more detailed discussion.

it is of known quality and consistent with NOAA's IQA Guidelines."[10]

As a *Third example:* the U.S. Department of Health and Human Services informed the World Health Organization that HHS could not use a WHO report entitled "Diet, Nutrition and the prevention of Chronic Disease" because the report does not Meet IQA requirements. [11]

Closer to home, the IARC Glyphosate Review is information that doesn't meet IQA standards; therefore, it cannot be used or relied on by EPA.[12]

In reaching this conclusion, we rely on several documents that are identified with links in CRE's written comments. I won't repeat this long list of documents in my oral comments. I do, however, suggest that this Panel pay particular attention to public comment during the last couple of days, and to the following documents, which are all in EPA's administrative record for this SAP:

1) Comments by CropLife America on EPA's Glyphosate Cancer Evaluation; [13]

2) Monsanto's Critique of the IARC review;[14]

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[10] See the CRE website at http://www.thecre.com/pdf/NOAA-IWC_Letter.pdf for this NOAA letter.
[11] See the CRE website at http://thecre.com/pdf/20041101_hhs.pdf for HHS' letter to WHO.
[12] The IARC Monograph for glyphosate is available at http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf .
[13] https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0005 .
[14] http://oehha.ca.gov/media/downloads/crnr/comments/monsantoevaliarcglyphosate.pdf .

3) Comment submitted by Intertek Scientific & Regulatory Consultancy; [15]

4) Comment submitted by Dow Agrosciences; [16] and

5) Comment submitted by Joseph K. Haseman, J. K. Haseman Consulting. [17]

Based on these documents, on other documents in the SAP record, and on comment during the last couple of days, the IARC Glyphosate Review is not accurate, is not reliable, does not meet IQA standards, and cannot be used by EPA because, *for example:*

1) IARC relied on study results that are not statistically significant.

2) IARC relied on studies where there was no dose response curve.

3) IARC relied on studies where there was no consistent association between glyphosate exposure and cancer.

4) There is no mode of action for glyphosate and cancer.

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[15] https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0338 .
[16] https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0357 .
[17] https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0461 .

5) IARC relied on studies that use non-standardized and unvalidated test methods and procedures.

6) IARC was biased in its exclusion of tests.

7) IARC used tests that are not reproducible.

8) IARC's conclusions are not biologically plausible.

Many other expert panels have reviewed glyphosate and cancer. None of them concluded that glyphosate causes cancer.[18] There is no reason to believe that they are all wrong, and that IARC is right.

The overwhelming weight of evidence is that glyphosate does not cause cancer. Any different EPA conclusion would be inaccurate and unreliable. It would violate the Government's quality standards.

EPA got it right this time.

CRE appreciates this opportunity to comment. I also emphasize CRE's great respect for SAPs. We believe they are essential to ensuring that EPA's pesticide assessments and regulation are based on fact and science and not bias or political agendas.

Thank you for this opportunity to comment, and I'll try to answer any questions you might have.

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[18] *E.g.,* CropLife America Comments to this SAP, pages 2-3, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0005 .