

**CENTER FOR REGULATORY EFFECTIVENESS' ("CRE")
COMMENTS ON ENVIRONMENTAL PROTECTION
AGENCY'S ("EPA") PROPOSED PESTICIDE WORKER
PROTECTION STANDARDS ("WPS"),**

<http://www.epa.gov/oppfead1/safety/workers/proposed/index.html>

**COMMENTS FILED July 28, 2014, at
WWW.REGULATIONS.GOV , EPA-HQ-OPP-2011-0184**

I. EXECUTIVE SUMMARY

EPA repeatedly states that reduction of human chronic disease from pesticide exposure is one of the primary WPS benefits. Yet even EPA admits there is no record showing that pesticide exposure as currently regulated causes chronic disease.

EPA also repeatedly states that there is an association between chronic human disease and "generalized" pesticide exposure. The WPS' blanket indictment of all pesticide exposure is irreconcilable with EPA's conclusions during FIFRA registrations that individual pesticides do not pose any significant risk of human chronic disease.

EPA's WPS statements about pesticides and chronic disease are inaccurate, misleading, unreliable, biased, and not based on reproducible studies. They violate EPA's Information Quality Act ("IQA") Guidelines and EPA's other data requirements for pesticides. EPA should revise these statements to clearly and unequivocally state that there is no scientifically supportable correlation between worker pesticide exposure, as currently regulated, and chronic disease. Any chronic disease concerns are adequately addressed during pesticide registrations. Consequently, there is no rational basis for counting reduction of chronic disease as a benefit of the WPS, and there is no rational basis for the Agency's Cost-Benefit analysis.

EPA needs a new Information Collection Request ("ICR") under the Paperwork Reduction Act ("PRA") for the WPS. This new ICR is not enforceable unless and until it is approved by the Office of Management and Budget ("OMB"). OMB is withholding approval of this new ICR until OMB has reviewed EPA's response to comments on the WPS. CRE's comments demonstrate that OMB should not approve this new ICR because the ICR and WPS do not meet IQA Guidelines; they do not meet EPA's other data requirements for pesticides; and they lack practical utility.

EPA's cost benefit analysis for the WPS cannot support these rules because the analysis does not meet IQA Guidelines, and does not comply with OMB Guidance. There is no valid cost benefit analysis supporting the WPS, and the WPS should not be promulgated as final rules.

II. THE WPS VIOLATE IQA GUIDELINES AND EPA'S OTHER DATA REQUIREMENTS FOR PESTICIDES

A) EPA's WPS Statements About Pesticides and Chronic Human Disease Violate the IQA Guidelines' Objectivity and other Requirements for Influential Information

EPA's WPS Federal Register notice doesn't mention IQA Guidelines. We have found no reference to IQA Guidelines anywhere in the WPS record. This omission violates OMB's requirement that EPA demonstrate that all its rules comply with IQA Guidelines. OMB states:

"[Y]ou [EPA] should assure compliance with the Information Quality Guidelines for your agency and OMB's 'Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies' ('data quality guidelines')...."

"Information Quality Guidelines

Under the Information Quality Law, agency guidelines, in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002), have established basic quality performance goals for all information disseminated by agencies, including information disseminated in support of proposed and final rules. The data and analysis that you use to support your rule must meet these agency and OMB quality standards."¹

In April 30, 2013, the National Academy of Sciences' National Research Council ("NAS/NRC") released its report *Assessing Risks to Endangered and Threatened Species from Pesticides*. The NAS/NRC prepared this report at the request of EPA, the U.S. National Oceanic and Atmospheric Administration's National Marine Fisheries Service ("NOAA/NMFS"), the U.S. Fish and Wildlife Service ("FWS"), and the U.S. Department of Agriculture ("Ag").²

The NAS/NRC report acknowledges the importance of IQA Guidelines. The report explains that

"all federal agencies are expected to comply with the Office of Management and Budget (OMB) guidelines on objectivity, utility, and integrity of disseminated information. OMB (67 Fed. Reg. 8452 [2002]) describes those attributes as follows:

¹ OMB Circular A-4, at http://www.whitehouse.gov/omb/circulars_a004_a-4.

² The NRC report is available online at http://thecre.com/pdf/NAS--Assessing_Risks.pdf.

‘Objectivity’ focuses on the extent to which information is presented in an accurate, clear, complete and unbiased manner; and, as a matter of substance, the extent to which the information is accurate, reliable and unbiased. ‘Utility’ refers to the usefulness of the information to the intended users. ‘Integrity’ refers to security, such as the protection of information from unauthorized access or revision, to ensure the information is not compromised through corruption or falsification.”³

EPA repeatedly states in its Cost-Benefit Analysis that the WPS will cause reductions in chronic diseases. These alleged disease reductions are a crucial component of EPA’s Cost-Benefit Analysis for the WPS. EPA’s chronic-disease reduction statements do not meet IQA Guidelines requirements because they are inaccurate, misleading, unreliable, and not based on reproduced studies.⁴

EPA itself admits that the record does not show that pesticide exposure, as currently regulated, causes chronic diseases:

“It is important to note that EPA is not stating that there is a causal link between certain health outcomes and exposure to specific pesticides. It would be premature at this stage to suggest a causal link between these exposures and the health outcomes.”⁵

Without proof of causation, prevention of chronic human disease cannot be a benefit of the WPS.

EPA also repeatedly states that there is an association between all pesticide exposure and chronic human disease: *e.g.*, “associations between pesticide exposure and certain cancer and non-cancer chronic health effects are well documented in the peer-reviewed Literature...”⁶ These WPS statements do not meet IQA Guidelines requirements because they are inaccurate, misleading, unreliable, and not based on reproduced studies.⁷

³ *Id.*, page 31.

⁴ See, *e.g.*, EPA IQA Guidelines, pages 15-18, at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

⁵ *Economic Analysis of the Proposed Agricultural Worker Protection Standard Revisions*, page 199, <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0184-0102>.

⁶ 79 FR 15447, 1st column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf>.

⁷ See, *e.g.*, EPA IQA Guidelines, pages 15-18, at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

The WPS' blanket indictment of all pesticide exposure does not distinguish the many individual pesticides that EPA has already correctly concluded are **NOT** chronic disease risks. The WPS arbitrarily lump all pesticides together for purposes of estimating risks and benefits. Not all pesticides are the same in this regard, and it is wrong to consider and treat them the same.

Attached as Appendix A to CRE's comments is a list of some pesticides that do not cause chronic human disease. Included are links to EPA's FIFRA registration conclusions that these pesticides do not cause chronic human disease. This list is not complete or exhaustive.

EPA's FIFRA pesticide registrations, such as the ones on Appendix A, are based on extensive individual and cumulative risk assessments.⁸ The WPS analysis and decisions are not based on any risk assessments at all.

EPA admits that there is no cause-effect relation between specific pesticide exposure and chronic disease. EPA also admits that the record does not show a cause-effect relation between generalized exposure to multiple pesticides and chronic disease. However, EPA hopes there may be one "at some point in the future":

"EPA is not stating that there is a causal link between certain health outcomes and exposure to specific pesticides. It would be premature at this stage to suggest a causal link between these exposures and the health outcomes. However, information linking pesticide exposure and illness is compelling enough to suggest some of the statistical associations may at some point in future be determined to be causal in nature. Therefore, overall pesticide exposure reduction through WPS may have substantial benefits that cannot be quantified at this time."

"6.6.3. Summary of Chronic Exposure and Risks

Overall, epidemiological or human study data do not suggest a clear cause-effect relation between specific pesticide exposure and certain chronic health outcomes. However, the totality of national and international research efforts and initial research results in conjunction with plausible hypotheses, taken together, suggest

⁸ EPA's cumulative risk assessments for pesticides are discussed at <http://www.epa.gov/oppsrrd1/cumulative/>.

that pesticide exposure may result in chronic adverse health effects beyond those mitigated as a result of chemical-specific label requirements and standards.”⁹

Highly equivocal words like “suggest” and “may at some point in the future” do not denote a record capable of meeting the IQA Guidelines requirements for the WPS. EPA’s unsupported assertion of chronic disease benefits does not meet IQA Guidelines requirements. This assertion is also arbitrary, capricious, an abuse of discretion, and without rational basis.

EPA states in the WPS that preventing human chronic diseases is necessary to justify the costs and other burdens of the WPS:

“It also provides an estimate of the number of chronic illnesses with a plausible association with pesticide exposure that would have to be prevented by the proposed changes in order for the total estimated benefits to meet the estimated cost of the proposal.”¹⁰

There is no such “plausible association.” We suspect that EPA invented this nonexistent link to chronic disease solely in order to justify the costs of the WPS. This reflects a bias that also violates IQA Guidelines.

B) No Reproduced Studies Support the WPS Information Disseminations about Pesticides and Chronic Disease.

“Non-reproducible single occurrences are of no significance to science.”

—Karl Popper

EPA states that the WPS are a “significant regulatory action” under Executive Order 12866.¹¹ Consequently, the WPS should be considered “influential information” under EPA’s IQA Guidelines.¹²

⁹ *Economic Analysis of the Proposed Agricultural Worker Protection Standard Revisions*, pages 199 and 206, <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0184-0102> .

¹⁰ 79 FR at 15446, 3rd column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf> .

¹¹ 79 FR 15445, 3rd column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf> .

EPA's IQA Guidelines require:

“For disseminated influential original and supporting data, EPA intends to ensure reproducibility according to commonly accepted scientific, financial, or statistical standards. It is important that analytic results for influential information have a higher degree of transparency regarding (1) the source of the data used, (2) the various assumptions employed, (3) the analytic methods applied, and (4) the statistical procedures employed. It is also important that the degree of rigor with which each of these factors is presented and discussed be scaled as appropriate, and that all factors be presented and discussed....”¹³

The importance of reproducibility is also emphasized by other federal agencies and by scientific journals. For example, CRE recently posted a Nature article on one of its websites, which explains that reproducibility problems have led the National Institutes of Health (“NIH”) to consider verification rules for some experiments:

“The growing [reproducibility] problem is threatening the reputation of the US National Institutes of Health (NIH) based in Bethesda, Maryland, which funds many of the studies in question. Senior NIH officials are now considering adding requirements to grant applications to make experimental validations routine for certain types of science, such as the foundational work that leads to costly clinical trials. As the NIH pursues such top-down changes, one company is taking a bottom-up approach, targeting scientists directly to see if they are willing to verify their experiments.”¹⁴

This Nature article explains some of the causes for concern:

“In biomedical science, at least one thing is apparently reproducible: a steady stream of studies that show the irreproducibility of many important experiments. In a 2011 internal survey, pharmaceutical firm Bayer HealthCare of Leverkusen, Germany, was unable to validate the relevant preclinical research for almost two-thirds of 67 in-house projects. Then, in 2012, scientists at Amgen, a drug company based in Thousand Oaks, California, reported their failure to replicate 89% of the findings from 53 landmark cancer papers. And in a study published in May, more than half of the respondents to a survey at the MD Anderson Cancer Center in Houston, Texas, reported failing at least once in

¹² EPA IQA Guidelines, pages 19-20, at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

¹³ EPA IQA Guidelines, page 21, at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

¹⁴ <http://www.thecre.com/insurance/?p=1117> (reprinting article originally published in Nature Magazine).

attempts at reproducing published data....”¹⁵

Nature also recognizes reproducibility problems with articles it publishes. Nature is taking steps to try to ensure reproducibility in the data it publishes.¹⁶

The NAS/NRC recently released a report reviewing EPA’s work on assessing Non-Monotonic Dose Responses in pesticides. This NAS/NRC report emphasized the importance of “replicability” in the NMDR studies used by EPA:

“The methodologic features that would be necessary for a study to be able to detect an NMDR relationship should be identified. Ideally, multiple dose groups would be spaced across a defined exposure domain, including doses below those typically tested. Statistical design, biologic plausibility, and replicability should be factored into interpreting and weighing the evidence from such studies.”¹⁷

In the WPS, EPA cites studies that EPA claims support an “association” between pesticide exposure and chronic disease. There is no record showing that these studies have been replicated, or that they meet any of the other IQA Guidelines requirements. In fact, EPA admits some of the flaws in these studies.

For example, EPA explains:

“Blair and Beane-Freeman (2009) provides a review of epidemiologic studies of cancer among agricultural populations. They report that meta-analyses of mortality surveys of farmers find excesses of several cancers, including those of the connective tissue, NHL and multiple myeloma and cancers of the skin, stomach and brain and deficits for total mortality, heart disease, total cancer, and cancers of the esophagus, colon, lung and bladder. . . . ***It should also be noted, however, that these authors conclude factors other than pesticide exposures may partially explain the observed increased risk of cancer among those engaged in agriculture (Blair and Beane-Freeman 2009).***

¹⁵ <http://www.thecre.com/insurance/?p=1117> (reprinting article originally published in Nature Magazine).

¹⁶ See, e.g., Announcement: Reducing our irreproducibility, at <http://www.nature.com/news/announcement-reducing-our-irreproducibility-1.12852> ; Challenges in Irreproducible Research, at <http://www.nature.com/nature/focus/reproducibility/> ; and If a Job is worth doing, It is worth doing twice, at <http://www.nature.com/news/if-a-job-is-worth-doing-it-is-worth-doing-twice-1.12727> .

¹⁷ <http://thecre.com/pdf/pestnasmdr.pdf> .

“(Bassil *et al.*, 2007). *These authors note several limitations of each of the studies included in this systematic review, and note they were not able to assess whether population bias was a factor in the results of this review.*”

“Wigle *et al.* (2008) conducted a review of studies investigating links between occupational exposure to pesticides and leukemia in workers’ children. *They found no evidence of a direct link between children’s leukemia and all parents’ occupational exposure....*”

“The association of prostate cancer with certain pesticide exposure varies by family history of prostate cancer, and molecular epidemiology studies are underway that may shed light as to the potential role of genetic variation in the association. This work is not yet complete. However, initial investigations recently released indicate that a genetic variation in genetic region *8q24* may partially explain the association between pesticide exposure and prostate cancer (Koutros *et al.*, 2010b). Although these genetic variations do not fully explain the cancer relationships within a family, so other shared environmental exposures may play an important role. *Overall, however, across studies published, results are not consistent, possibly due to differing study designs used.*”

“There have been studies on the link between pesticide exposure and lung cancer. Alavanja *et al.* (2004), reported a positive association between four pesticides and pesticide exposure among the AHS cohort. In this study, exposure to these pesticides was associated with lung cancer risk in the cohort, *despite the fact that, in general the lung cancer risk for the cohort is lower than the population as a whole.*”

“*Neurological Function*

The authors acknowledge uncertainties present in the data at this time which limit causal inference including a clear biologically plausible mechanism of action, among other study characteristics.”¹⁸

These studies would not support an individual pesticide registration. They also don’t

¹⁸ *Economic Analysis of the Proposed Agricultural Worker Protection Standard Revisions*, pages 201-205 (emphasis added), at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0184-0102>

support the WPS.

C) The WPS Do Not Meet EPA’s Other Data Requirements for Pesticides

EPA has promulgated extensive regulations establishing other data requirements for the regulation of pesticides under FIFRA.¹⁹ Subpart K of these regulations govern “Human exposure,” including “Applicator exposure” and “post-application exposure.”²⁰ Consequently, these EPA data requirement regulations apply to the WPS.²¹

The WPS and their statements about chronic disease do not meet these regulatory data requirements for all pesticides. The WPS record does not even mention these regulatory data requirements for all pesticides, just like it doesn’t mention the IQA Guidelines requirements.

D) EPA Should Correct the WPS Information Disseminations About Pesticides and Chronic Disease

EPA’s Federal Register notice of the proposed WPS, and EPA’s economic analysis of the WPS, disseminates the following statements. For the reasons stated above and below, these and other EPA WPS statements violate IQA Guidelines and EPA’s other data requirements. Therefore, these statements should be corrected:

1) “However, associations between pesticide exposure and certain cancer and non-cancer chronic health effects are well documented in the peer-reviewed literature, and reducing these chronic health effects is an important FIFRA goal.”²²

This is inaccurate and misleading and violates IQA Guidelines because i) EPA admits there is no record showing that pesticide exposure, as currently regulated, causes or is associated with “certain cancer and non-cancer chronic health effects”; and ii) EPA does not distinguish those pesticides that EPA has found not to cause chronic disease.

¹⁹ 40 CFR Parts 158 and 160, at <http://www.gpo.gov/fdsys/pkg/CFR-2011-title40-vol24/pdf/CFR-2011-title40-vol24-part158.pdf>

²⁰ 40 CFR Part 158, at <http://www.gpo.gov/fdsys/pkg/CFR-2011-title40-vol24/pdf/CFR-2011-title40-vol24-part158.pdf>.

²¹ See, e.g., 79 FR 15452, col. 1 (March 19, 2014), at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf>, where EPA explains that the scope of the WPS includes applicators.

²² 79 FR 15447, 1st column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf>.

2) “Qualitative Benefits...Reduced chronic effects from lower chronic pesticide exposure to workers, handlers, and farmworker families, including a range of illnesses such as Non-Hodgkins lymphoma, prostate cancer, Parkinson’s disease, lung cancer, chronic bronchitis, and asthma.”²³

This is inaccurate and misleading and violates IQA Guidelines because i) EPA admits there is no record showing that pesticide exposure, as currently regulated, causes “a range of illnesses such as Non-Hodgkins lymphoma, prostate cancer, Parkinson’s disease, lung cancer, chronic bronchitis, and asthma; and ii) EPA does not distinguish those pesticides that EPA has found not to cause these diseases.”

3) “It also provides an estimate of the number of chronic illnesses with a plausible association with pesticide exposure that would have to be prevented by the proposed changes in order for the total estimated benefits to meet the estimated cost of the proposal.”²⁴

This is inaccurate and misleading and violates IQA Guidelines because i) EPA admits there is no record showing that pesticide exposure, as currently regulated, causes a “number of chronic illnesses”; and ii) EPA does not distinguish those pesticides that EPA has found not to cause chronic illnesses.

4) “It is difficult to quantify a specific level of risk and project the risk reduction that would result from this proposal because workers and handlers are potentially exposed to a wide range of pesticides with varying toxicities and risks. However, there is strong evidence that workers and handlers may be exposed to pesticides at levels that can cause adverse effects and that both the exposures and the risks can be substantially reduced.”²⁵

This is inaccurate and misleading and violates IQA Guidelines because i) EPA admits that there is no record showing that pesticide exposure, as currently regulated, may expose “workers and handlers...to pesticides at levels that can cause adverse effects

²³ 79 FR 15445, table, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf> .

²⁴ 79 FR 15446, 3rd column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf> .

²⁵ 79 FR 15446, 3rd column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf> .

and that both the exposures and the risks can be substantially reduced”; and ii) EPA does not distinguish those pesticides that EPA has found not to cause adverse effects.

5) “Even if the lack of quantitative data impairs the reliability of estimates of the total number of chronic illnesses avoided, it is reasonable to expect that the proposed changes to the WPS will reduce the incidence of chronic disease resulting from pesticide exposure. Therefore, EPA conducted a ‘break even’ analysis to consider the plausibility of the proposed changes to the WPS reducing the incidence of chronic disease enough to cause the net benefits of the proposed rule to exceed its anticipated costs. Under this analysis, EPA looked at the costs associated with non-Hodgkin’s lymphoma, prostate cancer, Parkinson’s disease, lung cancer, bronchitis, and asthma and their frequency among agricultural workers, and found that reducing the incidence of lung cancer by 0.08% and the incidence of the other chronic diseases by 0.8% per year (about 53 total cases per year among the population of workers and handlers protected under the WPS) would produce quantified benefits sufficient to bridge the gap between the quantified benefits from reducing acute incidents and the \$62.1 million to \$72.9 million cost of the proposed rule. Overall, the weight of evidence suggests that the proposed requirements would result in long-term health benefits to agricultural workers and pesticide handlers in excess of the less than 1% reduction in just six diseases that corresponds with the break-even point for the proposed rule, not only by reducing their daily risk of pesticide exposures, but also by improving quality of life throughout their lives, resulting in a lower cost of health care and a healthier society.”²⁶

This is inaccurate and misleading and violates IQA Guidelines because i) EPA admits that there is no record showing that pesticide exposure, as currently regulated, causes “non-Hodgkin’s lymphoma, prostate cancer, Parkinson’s disease, lung cancer, bronchitis, and asthma and their frequency among agricultural workers, and...lung cancer...and other chronic diseases” ; and ii) EPA does not distinguish those pesticides that EPA has found not to cause chronic disease.

6) “Well-documented associations between pesticide exposure and certain cancer and non-cancer chronic health effects exist in peer-reviewed literature; however, the wide range of employment histories and pesticide exposures characteristic of the agricultural workforce generally prevents reliable estimates of the full impact of chronic pesticide exposure. In order to account for the reduction in chronic diseases expected as a result of the proposed WPS changes, OPP used a ‘break-even’ analysis. Based on a literature review, EPA evaluated the costs associated with six chronic illnesses that have well-documented association with agricultural pesticide exposure: non- Hodgkin’s lymphoma, prostate cancer, Parkinson’s disease, lung cancer, bronchitis, and asthma. Owing to the high costs associated with these chronic illnesses, improvements to the WPS that could

²⁶ 79 FR 15447, 1st column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf>.

reduce the frequency of these illnesses among workers and handlers by less than 1% (53 total cases per year) would result in sufficient benefits to bridge the gap between the estimated costs of the revisions and the anticipated benefits associated with reducing acute pesticide exposures. For the reasons identified below, it is reasonable to expect that the proposed changes to the WPS will reduce chronic pesticide exposures enough to reduce the frequency of chronic illnesses by at least 0.08% for lung cancer and at least 0.8% for the other illnesses.”²⁷

This is inaccurate and misleading and violates IQA Guidelines because i) EPA admits that there is no record showing that pesticide exposure, as currently regulated, causes “non-Hodgkin’s lymphoma, prostate cancer, Parkinson’s disease, lung cancer, bronchitis, and asthma”; and ii) EPA does not distinguish those pesticides that EPA has found not to cause these diseases.

7) “The revised rule is expected to substantially mitigate the potential for adverse health effects (both acute and chronic) for these workers and handlers from occupational exposures to pesticides. It is difficult to quantify a specific level of risk and project the risk reduction that will result from this rulemaking, because workers and handlers are potentially exposed to a wide range of pesticides with different toxicities and risks; however, the proposed changes to the WPS are designed to reduce occupational exposure to all pesticides. EPA believes there is sufficient evidence in the peer-reviewed literature to suggest reducing pesticide exposure would result in a benefit to public health through reduced acute and chronic illness. Overall, the weight of evidence suggests that the proposed requirements would result in long-term health benefits to agricultural workers and pesticide handlers. EPA is not able to estimate the dollar value of the benefits that accrue from reducing chronic exposure to pesticides but there are well-documented associations between pesticide exposure and certain cancer and non-cancer chronic health effects in the peer-reviewed literature.”²⁸

This is inaccurate and misleading and violates IQA Guidelines because i) EPA admits that there is no record showing that pesticide exposure, as currently regulated, causes “certain cancer and non-cancer chronic health effects” ; and ii) EPA does not distinguish those pesticides that EPA has found not to cause these health effects.

²⁷ 79 FR 15450, 1st column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf>

²⁸ 79 FR 15511, 3rd column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf> .

8) “Because the proposed changes to the requirements for protection of workers and handlers apply to many different pesticides in many different situations, EPA is not able to quantify the benefits expected to accrue from reducing chronic exposure to pesticides; however, well-documented associations between pesticide exposure and certain cancer and non-cancer chronic health effects exist in peer-reviewed literature. EPA conducted a ‘break even’ analysis to demonstrate the potential benefits that would result from reducing a very small number of chronic illnesses that have well-documented associations with pesticide exposure. Under this analysis, avoiding only 53 total cases of non-Hodgkin’s lymphoma, prostate cancer, Parkinson’s disease, lung cancer, bronchitis, and asthma (under 0.8% of total cases among workers) would bridge the gap between the estimated benefits from reducing acute incidents and the cost of the rule, about \$63.7 million. Overall, the weight of evidence suggests that the proposed requirements would result in long term health benefits to agricultural workers and pesticide handlers, not only by reducing their daily risk of pesticide exposures, but also by improving quality of life throughout their lives, resulting in a lower cost of health care and a healthier society.”²⁹

This is inaccurate and misleading and violates IQA Guidelines because i) EPA admits that there is no record showing that pesticide exposure, as currently regulated, causes “non-Hodgkin’s lymphoma, prostate cancer, Parkinson’s disease, lung cancer, bronchitis, and asthma” ; and ii) EPA does not distinguish those pesticides that EPA has found not to cause these diseases.

9) “Even such minor errors are likely to lead to lead to chronic exposure to pesticides, which are associated with long-term health issues such as Parkinson’s and several forms of cancer.”³⁰

This is inaccurate and misleading and violates IQA Guidelines because i) EPA admits that there is no record showing that pesticide exposure, as currently regulated, causes “Parkinson’s and several forms of cancer”; and ii) EPA does not distinguish those pesticides that EPA has found not to cause chronic disease.

E) Requested Corrections

EPA should revise the above-quoted statements and other statements to state clearly and unequivocally that there is no scientifically supportable correlation between pesticide exposure, as currently regulated, and chronic human disease. Consequently, there is no

²⁹ 79 FR 15512, 1st column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf>.

³⁰ *Economic Analysis of the Proposed Agricultural Worker Protection Standard Revisions*, page 1, at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0184-0102>.

IQA-compliant record that supports using reduction of human chronic diseases as a benefit of the WPS; and there is no association between pesticide exposure, in general, and chronic human disease. Any chronic disease concerns are adequately addressed during pesticide registrations.

III. OMB SHOULD NOT APPROVE THE WPS ICR BECAUSE THE ICR DOES NOT MEET IQA GUIDELINES AND LACKS PRACTICAL UTILITY

A) OMB Is Withholding Approval of the WPS ICR

EPA needs a new ICR under the PRA in order to implement the WPS. This new ICR is not enforceable until and unless it is approved by OMB. EPA's Federal Register notice for the WPS explains:

“B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 et seq. EPA has prepared an Information Collection Request (ICR) document to replace the existing approved ICR. The new ICR document, which is titled ‘Agricultural Worker Protection Standard Training and Notification (Proposed Rule)’ and is identified by EPA ICR No. 2491.01 and OMB Control No. 2070–NEW, has been placed in the docket for this proposed rule (Ref. 105).”

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.”³¹

OMB is withholding approval of this new ICR until OMB has reviewed EPA's response to comments on the WPS:

“OMB files this comment in accordance with 5 CFR 1320.11(c) of the Paperwork Reduction Act and is withholding approval of this collection at this time. This OMB action is not an approval to conduct or sponsor an information collection under the Paperwork Reduction Act of 1995. The agency shall examine public comment in response to the Notice of Proposed Rulemaking and will include in the supporting

³¹ 79 FR 15512, 2nd column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf>.

statement of the next ICR, to be submitted to OMB at the final rule stage, a description of how the agency has responded to any public comments on the ICR. This action has no effect on any current approvals.”³²

CRE’s comments demonstrate above and below that OMB should not approve an ICR for the WPS because the WPS do not meet IQA guidelines, and because the WPS ICR lacks practical utility.

B) ICRs Must Meet IQA Guidelines and Must Have Practical Utility

In order for OMB to approve a WPS ICR, EPA must demonstrate that the WPS will generate information that meets the IQA quality standards of accuracy, reliability, reproducibility and utility. OMB’s IQA guidance is unambiguous and unequivocal on this requirement:

“...we note that each agency is already required to demonstrate the 'practical utility' of a proposed collection of information in its PRA submission, i.e., for draft information collections designed to gather information that the agency plans to disseminate. Thus, we think it important that each agency should declare in its guidelines that it will demonstrate in its PRA clearance packages that each such draft information collection will result in information that will be collected, maintained, and used in a way consistent with the OMB and agency information quality standards. It is important that we make use of the PRA clearance process to help improve the quality of information that agencies collect and disseminate. Thus, OMB will approve only those information collections that are likely to obtain data that will comply with the OMB and agency information quality guidelines.”³³

EPA’s own IQA Guidelines emphasize that EPA will demonstrate IQA Guidelines compliance for every ICR that EPA submits to OMB:

“For all proposed collections of information that will be disseminated to the public, EPA intends to demonstrate in our Paperwork Reduction Act clearance submissions that the proposed collection of information will result in information that will be collected, maintained and used in ways consistent with the OMB guidelines and these EPA Guidelines. These Guidelines apply to all information EPA disseminates to the public; accordingly, if EPA later identifies a new use for the information that was collected, such use would not be precluded and the

³² http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201403-2070-001 .

³³ Page 12 of OMB IQA Guidance at http://www.whitehouse.gov/sites/default/files/omb/inforeg/iqg_comments.pdf .

Guidelines would apply to the dissemination of the information to the public.”³⁴

EPA’s WPS violate this requirement because EPA’s Supporting Statement for the new WPS ICR does not even mention the IQA, much less demonstrate compliance with the IQA.

Independent of EPA’s IQA compliance failure, OMB’s ICR rules also require that EPA demonstrate that the WPS information collections have “practical utility.” OMB’s ICR rules define the term practical utility as “the actual, not merely the theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability....”³⁵

With regard to EPA’s duties, the ICR rules state that “[t]o obtain OMB approval of a collection of information, an agency shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information...has practical utility.”³⁶

The PRA itself states:

“Before approving a proposed collection of information, the Director shall determine whether the collection of information by the agency is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility.”³⁷

With regard to OMB’s duties, the ICR rules require that

“OMB shall determine whether the collection of information, as submitted by the agency, is necessary for the proper performance of the agency's functions. In making this determination, OMB will take into account the criteria set forth in paragraph (d) of this section, and will consider whether the burden of the collection of information is justified by its practical utility.”³⁸

³⁴ EPA IQA Guidelines, page 28, at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf (footnotes omitted).

³⁵ 5 CFR §1320.3(l), at <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=ee3022a406e4b99581354a4cd083f29e&rgn=div8&view=text&node=5:3.0.2.3.9.0.48.3&idno=5> .

³⁶ 5 CFR 1320.5(d)(1)(iii), at <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=ee3022a406e4b99581354a4cd083f29e&rgn=div8&view=text&node=5:3.0.2.3.9.0.48.3&idno=5> .

³⁷ 44 U.S.C. 3508, at <http://www.law.cornell.edu/uscode/text/44/3508> .

³⁸ 5 CFR § 1320.5(e), at <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=ee3022a406e4b99581354a4cd083f29e&rgn=div8&view=text&node=5:3.0.2.3.9.0.48.3&idno=5> .

In other words, OMB has an independent, mandatory duty under its own PRA/ICR rules to determine whether EPA has produced a public record demonstrating that the WPS information collections covered by this ICR will generate valid, accurate, useful, and reproducible information.

C) OMB Should Not Approve the WPS ICR Because EPA Has Not Demonstrated IQA Guidelines Compliance and Practical Utility

The WPS and ICR record does not demonstrate IQA Guideline compliance. EPA does not even mention the IQA.

As demonstrated above and below, the WPS statements about chronic disease lack objectivity. They are inaccurate, unreliable and misleading. They are based on studies and assumptions that have not been reproduced, and which do not meet EPA's Other Data Requirements for Pesticides. Consequently, the WPS ICR does not meet IQA Guidelines, and it lacks practical utility.

Therefore, OMB should not approve it.

These IQA violations are evidenced by EPA's Supporting Statement for the WPS ICR, where EPA states:

“The employer must inform the handler that pesticide application equipment may be contaminated with pesticides, the potential harmful effects of pesticide exposure....”

“The pesticide handler employer must inform any person who cleans or launders personal protective equipment (PPE) that such equipment may be contaminated with pesticides, the potentially harmful effects of exposure to pesticides....”

“The handler employer must also provide information to persons not employed directly by the establishment before they clean, repair or adjust pesticide application equipment. The handler employer must inform the person that the equipment may be contaminated with pesticides, the potential harmful effects of pesticide exposure....”³⁹

According to the WPS, “the potential harmful effects of pesticide exposure” include several serious chronic human diseases. Does the employer have to explain these chronic

³⁹ WPS ICR Supporting Statement A, pages 6, 13 and 26, at http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201403-2070-001 .

disease risks to employees, even though there is no record showing that the pesticide being used causes them?

IV. EPA’S WPS COST BENEFIT ANALYSIS CANNOT BE USED BECAUSE IT DOES NOT MEET IQA GUIDELINES AND DOES NOT COMPLY WITH OMB GUIDANCE

A) The WPS Cost Benefit Analysis Does Not Meet IQA Guidelines Because EPA Uses Non-Existent Chronic Disease Risk to Calculate Benefits

The Cost Benefit analysis required for the WPS must meet IQA Guidelines. OMB clearly explains:

“Information Quality Guidelines

Under the Information Quality Law, agency guidelines, in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002), have established basic quality performance goals for all information disseminated by agencies, including information disseminated in support of proposed and final rules. ***The data and analysis that you use to support your rule must meet these agency and OMB quality standards.***⁴⁰

Preceding sections of CRE’s comments demonstrate that the WPS statements regarding chronic disease benefits do not meet IQA Guidelines.

EPA admits that its cost benefit analysis depends on the WPS preventing chronic human diseases:

“It also provides an estimate of the number of chronic illnesses with a plausible association with pesticide exposure that would have to be prevented by the proposed changes in order for the total estimated benefits to meet the estimated cost of the proposal.”⁴¹

An essential part of the WPS Cost Benefit analysis does not meet IQA Guidelines and should not be used to support these rules.

⁴⁰ OMB Circular A-4, at http://www.whitehouse.gov/omb/circulars_a004_a-4 (emphasis added).

⁴¹ 79 FR at 15446, 3rd column, at <http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-04761.pdf>.

B) The WPS Cost Benefit Analysis Does Not Comply with OMB Guidance

OMB's Circular A-94 Revised states that agencies should take certain actions to deal with uncertainty during their cost benefit analyses. EPA has not taken these steps during its WPS Cost Benefit analysis, which is plagued with uncertainty, especially regarding WPS benefits.

Circular A-94 states:

“9. **Treatment of Uncertainty.** Estimates of benefits and costs are typically uncertain because of imprecision in both underlying data and modeling assumptions. Because such uncertainty is basic to many analyses, its effects should be analyzed and reported. Useful information in such a report would include the key sources of uncertainty; expected value estimates of outcomes; the sensitivity of results to important sources of uncertainty; and where possible, the probability distributions of benefits, costs, and net benefits.

a. **Characterizing Uncertainty.** Analyses should attempt to characterize the sources and nature of uncertainty. Ideally, probability distributions of potential benefits, costs, and net benefits should be presented. It should be recognized that many phenomena that are treated as deterministic or certain are, in fact, uncertain. In analyzing uncertain data, objective estimates of probabilities should be used whenever possible. Market data, such as private insurance payments or interest rate differentials, may be useful in identifying and estimating relevant risks. Stochastic simulation methods can be useful for analyzing such phenomena and developing insights into the relevant probability distributions. In any case, the basis for the probability distribution assumptions should be reported. Any limitations of the analysis because of uncertainty or biases surrounding data or assumptions should be discussed.”

“c. **Sensitivity Analysis.** Major assumptions should be varied and net present value and other outcomes recomputed to determine how sensitive outcomes are to changes in the assumptions. The assumptions that deserve the most attention will depend on the dominant benefit and cost elements and the areas of greatest uncertainty of the program being analyzed. For example, in analyzing a retirement program, one would consider changes in the number of beneficiaries, future wage growth, inflation, and the discount rate. In general, sensitivity analysis should be considered for estimates of: (i) benefits and costs; (ii) the discount rate; (iii) the general inflation rate; and (iv) distributional assumptions. Models used in the analysis should be well documented and, where possible, available to facilitate independent review.”⁴²

⁴² http://www.whitehouse.gov/omb/circulars_a094.

CRE agrees with the Department of Agriculture’s recommendation that additional necessary Cost-Benefit steps include EPA’s performing a sensitivity analysis of the WPS.⁴³

The WPS Cost Benefit Analysis is also inconsistent with OMB guidance because it does not include a Monte Carlo Analysis of Uncertainty. OMB’s 2012 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, states:

“ APPENDIX G: RESPONSE TO PEER REVIEWERS AND PUBLIC COMMENTS”

“Stavins also suggests the use of improved ways to deal with uncertainty, including formal assessment through Monte Carlo analysis. We agree with the suggestion and note that it is endorsed by OMB Circular A-4: “Apply a formal probabilistic analysis of the relevant uncertainties – possibly using simulation models and/or expert judgment...” In the past, several agencies have engaged in such analysis. While acknowledging that such analysis can be time-consuming, we agree that it can also be extremely valuable, and we will work with agencies to promote it.”

“265 OMB Circular A-4, p. 41. For rules that exceed the \$1 billion annual benefits or costs, a formal quantitative analysis of uncertainty is required. For rules with annual benefits or costs in the range from \$100 million to \$1 billion, agencies should seek to match the more rigor of their approach with the magnitude of a rule’s consequences.”⁴⁴

⁴³ Page 15, at <http://www.noticeandcomment.com/U-S-Department-of-Agriculture-USDA-FIFRA-Review-Formal-Comments-to-EPA-on-WPS-Proposed-Revisions-fn-127514.aspx> .

⁴⁴ Page 152 (footnote omitted), at http://www.whitehouse.gov/sites/default/files/omb/inforeg/2012_cb/2012_cost_benefit_report.pdf .

V. THE WPS COST BENEFIT ANALYSIS VIOLATES EXECUTIVE ORDER 13563

Executive Order 13563 requires EPA to base the WPS Cost Benefit Analysis “on the best available science.”⁴⁵ The WPS Cost Benefit Analysis violates this requirement because it ignores and contradicts EPA’s own records and determinations in pesticide registrations. EPA’s pesticide registration records and findings are “the best available science.”

Executive order 13563 also requires EPA to “ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions.”⁴⁶

EPA’s IQA Guidelines state that “[o]bjectivity” 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.”⁴⁷

The WPS Cost Benefit Analysis violates the objectivity requirement of Executive Order 13563 because there is no record demonstrating that it is “accurate, clear, complete, and unbiased.”

In fact, it is not accurate, clear, complete, and unbiased because it ignores and contradicts the best available science, which is EPA’s own record and determinations in pesticide registrations.

VI. CONCLUSION

EPA’s WPS cost benefit analysis cannot support these rules because the analysis does not meet IQA Guidelines, and because the analysis does not comply with OMB Guidance. Consequently, there is no valid cost benefit analysis supporting the WPS, and the WPS should not be promulgated as final rules.

OMB should not approve EPA’s ICR because the ICR and WPS do not meet IQA Guidelines; because they do not meet EPA’s other data requirements for pesticides; and because they lack practical utility.

⁴⁵ Executive Order 13563, Section 1 at <http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order> .

⁴⁶ Executive order 13563, section 5 at <http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order> .

⁴⁷ EPA’s Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA, Section 5.1, at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf .

EPA's statements about the WPS reducing chronic diseases, and about pesticide exposure being associated with chronic disease, are inaccurate, misleading, unreliable, biased, and not based on reproducible studies. They violate EPA's IQA Guidelines and EPA's other data requirements for pesticides. EPA should revise these statements to clearly and unequivocally state that there is no scientifically supportable correlation between worker pesticide exposure, as currently regulated, and chronic disease. Any chronic disease concerns are adequately addressed during pesticide registrations.

The WPS Cost Benefit Analysis violates Executive Order 13563 because it ignores and contradicts the best available science, which is EPA's own record and determinations in pesticide registrations.

There is no rational basis for including reduction of chronic disease as a benefit of the WPS.

Thank you for the opportunity to submit these comments. We look forward to EPA's and OMB's responses to our comments.

The Center for Regulatory Effectiveness
www.TheCRE.com

APPENDIX A TO CRE'S COMMENTS ON THE WPS

THE FOLLOWING LINKS ARE TO EPA'S CONCLUSIONS THAT THESE FIFRA REGISTERED PESTICIDES POSE NO SIGNIFICANT RISKS OF CHRONIC HUMAN HEALTH EFFECTS

THESE ARE ONLY EXAMPLES. THIS IS NOT A COMPREHENSIVE LIST OF SUCH PESTICIDES.

Sulfur

<http://www.epa.gov/oppsrrd1/REDs/factsheets/0031fact.pdf>

Streptomycin

<http://www.epa.gov/oppsrrd1/REDs/factsheets/0169fact.pdf>

Soap Salts

<http://www.epa.gov/oppsrrd1/REDs/factsheets/4083fact.pdf>

Pyrazon

http://www.epa.gov/oppsrrd1/REDs/factsheets/pyrazon_factsheet.pdf

Primisulfuron-methyl

http://www.epa.gov/oppsrrd1/REDs/factsheets/primisulfuron_tred_fs.htm

Nuranone

<http://www.epa.gov/oppsrrd1/REDS/factsheets/4113fact.pdf>

Nosema Locustae

<http://www.epa.gov/oppsrrd1/REDS/factsheets/4104fact.pdf>

Metalaxyl

<http://www.epa.gov/oppsrrd1/REDS/factsheets/0081fact.pdf>

Mepiquat Chloride

<http://www.epa.gov/oppsrrd1/REDS/factsheets/2375fact.pdf>

Maleic Hydrazide

<http://www.epa.gov/oppsrrd1/REDS/factsheets/0381fact.pdf>

Indole-3-Butyric Acid

<http://www.epa.gov/oppsrrd1/REDS/factsheets/2330fact.pdf>

Hexadecadienol Acetates

<http://www.epa.gov/oppsrrd1/REDS/factsheets/4111fact.pdf>

Heliothis Zea NPV

<http://www.epa.gov/oppsrrd1/REDs/factsheets/0151fact.pdf>

Flower and Vegetable Oils

<http://www.epa.gov/oppsrrd1/REDs/factsheets/4097fact.pdf>

Ethylene

<http://www.epa.gov/oppsrrd1/REDs/factsheets/3071fact.pdf>

Desmedipham

<http://www.epa.gov/oppsrrd1/REDs/factsheets/2150fact.pdf>

Cytokinin

<http://www.epa.gov/oppsrrd1/REDs/factsheets/4107fact.pdf>

Cryolite

<http://www.epa.gov/oppsrrd1/REDs/factsheets/0087fact.pdf>

Chloropicrn

<http://www.epa.gov/oppsrrd1/REDs/factsheets/chloropicrn-fs.pdf>

**Colletotrichum gloeosporioides f.sp. aeshynomene (C.g.a.)
ATCCstrain 20358 i**

<http://www.epa.gov/oppsrrd1/REDs/factsheets/4103fact.pdf>

Copper Salts

http://www.epa.gov/oppsrrd1/REDs/factsheets/copper_red_fs.pdf

Carboxin

http://www.epa.gov/oppsrrd1/REDs/factsheets/0012fact_carboxin.pdf

Bacillus Thuringiensis

<http://www.epa.gov/oppsrrd1/REDs/factsheets/0247fact.pdf>

Acephate

<http://www.epa.gov/oppsrrd1/REDs/factsheets/4101fact.pdf>