From: Mancini, Dominic J.
Sent: Thursday, March 11, 2010 2:58 PM
To: Higgins, Cortney
Subject: RE: BIA Request for OMB Review

That's a good question, they are correct that the number in the ICR can be less than 9 if it impacts a particular industry sector, so perhaps if you talk to EPA you can bring this up. (b) (5) [redacted]

From: Higgins, Cortney
Sent: Thursday, March 11, 2010 2:46 PM
To: Mancini, Dominic J.
Subject: FW: BIA Request for OMB Review

Hi Dom,
I'm going to give EPA a call and ask what information they are trying to collect from the Brick Industry, but do you know how we handle a request to review a data collection under 5 CFR 1320.14(c)?

Regards,
Cortney

From: Susan Miller [mailto:SMiller@bia.org]
Sent: Thursday, March 11, 2010 11:57 AM
To: Higgins, Cortney
Cc: Gregg Borchelt; Evans, David C.; Terry Schimmel (Bricks Phenix City)
Subject: BIA Request for OMB Review

Dear Ms. Higgins,

Please see the attached letter as a follow-up to the message I left for you on February 12, 2010. Please feel free to contact me should you have any questions or concerns.

Susan J. Miller
Vice President, Environment, Health & Safety
The Brick Industry Association
302 Davis Grove Circle, Suite 6001
Cary, NC 27519
smiller@bia.org
(703) 674-1545 (o)
(703) 624-3652 (c)

Make it a great day!

From: Higgins, Cortney
Sent: Thursday, March 11, 2010 2:46 PM
To: Mancini, Dominic J.
Subject: FW: BIA Request for OMB Review
Attachments: OMB Review Request.pdf

Hi Dom,
I'm going to give EPA a call and ask what information they are trying to collect from the Brick Industry, but do you know how we handle a request to review a data collection under 5 CFR 1320.14(c)?

Regards,
Cortney

From (b) (6)
Sent: Thursday, March 11, 2010 11:57 AM
To: Higgins, Cortney
Cc: Gregg Borchelt; Evans, David C.; Terry Schimmel (Bricks Phenix City)
Subject: BIA Request for OMB Review

Dear Ms. Higgins,

Please see the attached letter as a fo llow-up to the message I left for you on February 12, 2010. Please feel free to contact me should you have any questions or concerns.

(b) (6)
The Brick Industry Association
(b) (6)

Make it a great day!

THE BRICK INDUSTRY ASSOCIATION

March 11, 2010

Cortney Higgins
Office of Information and Regulatory Affairs
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Ms. Higgins,

The Brick Industry Association (BIA) is the national trade association representing brick manufacturers, distributors and suppliers of related products and services in the United States. The Association is involved in a broad range of technical, research, marketing, government relations, and communications activities. It is the recognized national authority on brick construction and our members account for 90% of the total brick production in the United States. We have welcomed non-member brick manufacturers and manufacturers of other heavy clay products to join us in working with the U.S. Environmental Protection Agency (EPA) to develop maximum achievable control technology (MACT) standards for our industry.

We are hereby requesting that the Office of Management and Budget (OMB) conduct a review of the anticipated data collection activity for our industry. While we understand that EPA contends that review by OMB is unnecessary since the survey is only going to nine entities within the brick industry, we request your review for the following reasons:

1. We believe that we are allowed to request such a review under 5 CFR 1320.14(c).
2. We believe that EPA should not be requesting stack tests from facilities that will not be subject to regulation under the final standards being considered. Almost half of the sources requiring testing under the draft information collection request (ICR) that we have seen are not major sources of HAP and would not be subject to the final Brick MACT.
3. We question whether the ability to bypass OMB review should apply to cases where EPA is requiring extensive and expensive stack testing and data collection, regardless of the number of individual ICRs being used. We estimate approximately $2.5 to 3.0 million in costs if we were required to, and able to, fully respond to this survey (i.e, stack tests at over 100 sources). This is a huge cost on our small industry, which had approximately $700 million in total revenues in 2009, with little to no profit.

13000 Commonwealth Park Drive, Suite 301 | Reston, Virginia 20191-1645 | Phone: 703.620.0010 | Fax: 703.620.3928 | www.gobrick.com

THE BRICK INDUSTRY ASSOCIATION

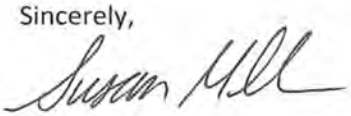
4. We question the validity of the approach being contemplated by EPA in the scope of the pollutants to be tested, the plants selected for testing, and the lack of pre-control tests. We have outlined these and other issues in a letter to EPA sent on February 12, 2010.
5. We question whether the "less than 10 rule" is accurately being applied when EPA is undergoing similar requests in a number of industries. From what we understand, EPA is staying below ten letters in each of these requests, but is requiring multiple facilities to test multiple sources in each request.

We are continuing to work out scope and technical issues related to these tests with the EPA's Office of Air Quality Planning and Standards, with a meeting planned for March 22, 2010. However, we are concurrently requesting this review because we are concerned that the timing of EPA's request will not allow for sequential review, due to internal deadlines (but not court orders) established by EPA.

Please feel free to contact me, Susan Miller, BIA's Vice President for Environment, Health and Safety if you have any additional questions or would like any background information. I can be reached at (703) 624-3652 or smiller@bia.org. If you need a request to come directly from the proposed recipients of this ICR, please let us know.

Thank you for your time and thoughtful consideration of our concerns.

Sincerely,



Susan Miller
Vice President
Environment, Health and Safety
Brick Industry Association

From: Ahmed, Shagufta
Sent: Tuesday, March 20, 2012 3:17 PM
To: Hunt, Alex
Subject: PRA Q

(b) (5) [redacted]

c) Any person may request OMB to review any collection of information conducted by or for an agency to determine, if, under this Act and this part, a person shall maintain, provide, or disclose the information to or for the agency. Unless the request is frivo lous, OMB shall, in coordination with the agency responsible for the collection of information:
(1) Respond to the request within 60 days after receiving the request, unless such period is extended by OMB to a specified date and the person making the requ est is given notice of such extension; and
(2) Take appropriate remedial action, if necessary.

From: Susan Ferenc <sferenc@cpda.com>
Sent: Friday, March 30, 2012 10:12 AM
To: kneyland@omb.eop.gov; Dominic Mancini (Dominic J. Mancini@omb.eop.gov)
Subject: FW: Request for Review Under PRA Section 3517
Attachments: image001.png; image002.png; image003.png; image004.png; Request For Review Under PRA Section 3517 (2).pdf

Kevin and Dom,

For your information.

Regards,
Sue

Susan Ferenc, DVM, Ph.D.
President

Chemical Producers & Distributors Association

1730 Rhode Island Ave., NW | Suite 812 | Washington, DC 20036
Phone: 202-386-7407 | Cell: 202-403-4367 | Email: sferenc@cpda.com | Web: www.cpda.com

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From: Diane Schute
Sent: Thursday, March 29, 2012 4:57 PM
To: Cass R. Sunstein@omb.eop.gov
Cc: Susan Ferenc; JessicaS@peta.org; fgraul@mindspring.com
Subject: Request for Review Under PRA Section 3517

The Honorable Cass Sunstein
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, D.C. 20503

Dear Administrator Sunstein:

Please find attached a request from the Chemical Producers & Distributors Association, the Halogenated Solvents Industry Alliance, Inc., and People for the Ethical Treatment of Animals for a review of ICR 2070-0176 under Section 3517[b] of the Paperwork Reduction Act. Thank you.

Diane Schute
Director of Communications and Programs

Chemical Producers & Distributors Association

1730 Rhode Island Ave., NW | Suite 812 | Washington, DC 20036
Phone: 202-386-7407 | Email: diane@cpda.com | Web: www.cpda.com

VIA EMAIL March 29, 2012

The Honorable Cass Sunstein
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

Dear Administrator Sunstein:

The Chemical Producers & Distributors Association, the Halogenated Solvents Industry Alliance, Inc., and People for the Ethical Treatment of Animals submit this Joint Request for Review to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act (44 U.S.C. § 3517(b)) (PRA).

Section 3517(b) reads as follows:

> (b) Any person may request the Director to review any collection of information conducted by or for an agency to determine, if, under this subchapter, a person shall maintain, provide, or disclose the information to or for the agency. Unless the request is frivolous, the Director shall, in coordination with the agency responsible for the collection of information--
>
> > (1) respond to the request within 60 days after receiving the request, unless such period is extended by the Director to a specified date and the person making the request is given notice of such extension; and
> >
> > (2) take appropriate remedial action, if necessary.

THE SUBJECT OF OUR JOINT REQUEST FOR REVIEW: ICR 2070-0176

On October 2, 2009, OMB approved the Environmental Protection Agency's (EPA) Information Collection Request (ICR) 2070-0176 (Tier I Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)). This ICR was and remains highly controversial. The information EPA needs for the proper performance of its statutory functions may well be available without Tier I screening, rendering some or all of the collection of information duplicative. In addition, EPA's Supporting Statement did not identify any actual practical utility for the statutory purpose for which EPA made the collection mandatory.

EPA's Authorities

Congress delegated to EPA the authority to devise a screening program to "determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other effects as [EPA] may designate."[1] EPA's authority was limited to obtaining data from "appropriate and validated test systems and other scientifically relevant information" (OSRI). EPA has subjected components of the battery to validation "processes" of varying quality and some results have been publicly disputed. Therefore, the Tier I test battery does not consist of "validated test systems" as Congress clearly intended.

[1] 21 U.S.C. § 346(p)(3).

OMB's Authorities

Congress delegated to OMB the authority to review information collection requests to ensure that they minimize Federal information collection burdens and maximize the practical utility of and public benefit from information collected by or for the Federal government.[2] To meet these statutory criteria, a collection of information must serve an agency purpose,[3] meet a specific need,[4] have practical utility,[5] and not be unnecessarily duplicate available information.[6] In addition, a collection of information must minimize the burden on respondents[7] and the cost of the collection to the Federal government.[8] Agencies are required to certify compliance with each of these criteria and support these certifications with "a record supporting such certification."[9]

EPA's Problematic Adherence to Applicable Law

In its Supporting Statement, EPA did not demonstrate that this collection of information complies with the PRA's minimum statutory requirements. The Supporting Statement makes clear that the Tier I test battery had not actually been scientifically validated.[10] Further, by the absence of any burden estimate for it, EPA also makes clear

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[2] 44 U.S.C. § 3504(c)(3)-(4).

[3] Historically, OMB has interpreted "purpose" as an administrative equivalent to the reference to "functions of the agency" as used in 44 U.S.C. § 3508 because "purpose" is the way an agency tends to describe an activity that serves to advance a "function of the agency."

[4] Historically, OMB has interpreted "need" as the administrative equivalent to stating that the collection of information "is necessary for the proper performance" of the functions of the agency. See 44 U.S.C. § 3508. The legislative history of the Paperwork Reduction Act confirms this interpretation: "If the [OMB] Director determines that a collection is not necessary, he should not approve it." H. Rpt. 96-835, 96th Cong., 2d Sess. (March 19, 1980) at 29. "Necessity is thus the test under this section." S. Rpt. 96-930, 96th Cong., 2d Sess. (September 8, 1980) at 49.

[5] See 5 C.F.R. § 1320.3(l): "*Practical utility* means 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, and the agency's ability to process the information it collects … in a useful and timely fashion."

[6] An agency is to include as part of its clearance package submitted for OMB review a certification stating, e.g., that the "collection of information submitted to [OMB] for review ... is not unnecessarily duplicative of information otherwise reasonably accessible to the agency." See 44 U.S.C. 3506(c)(3)(B). The Information Collection Rule succinctly reiterates this requirement: "To 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 (i) is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives; (ii) is not duplicative of information otherwise accessible to the agency; and (iii) has practical utility." See 5 C.F.R. § 1320.5(d)(1).

[7] 44 U.S.C. § 3501(1).

[8] 44 U.S.C. § 3501(5). The Information Collection Rule prohibits an agency from minimizing its own costs by shifting them to the public. See 5 C.F.R. § 1320. 5(d)(iii).

[9] 44 U.S.C. § 3506(c)(3).

[10] U.S. Environmental Protection Agency. 2009. *Supporting Statement for an Information Request [EPA ICR No. 2249.01, OMB Control No. 2070–new]; Docket No. EPA-HQ-2007-1081-0017 [Docket ID EPA-HQ-OPPT-2007-1081-0017, April 15, 2009]*., p. 7: "EPA scientists will continue to use such experience, together with insights from the validation process for Tier 1 assays, to address the potential of chemicals to cause adverse effects as a consequence of interaction with the endocrine system" (emphasis added). § 2(b). Available at: http://www.reginfo.gov/public/do/DownloadDocument?documentID=112492&version=1.

that it has little genuine interest in receiving "other scientifically relevant information (OSRI)".[11]

In stakeholder comments it was shown that the Tier I test battery lacked practical utility[12] and was unreasonably duplicative of information already in EPA's possession. [13] A host of errors in EPA's burden estimate in the Information Collection Request were also identified, including the use of multiple and incompatible units of analysis upon which EPA performed impermissible arithmetic operations; the omission of numerous known and large burdens, such as the burden of establishing, operating, and managing testing consortia and submitting OSRI; and the inexplicable counting of only a fraction of the actual burden of generating test data.[14]

Moreover, EPA did not make any effort to minimize burden to respondents beyond what the Federal Food, Drug, and Cosmetic Act (FFDCA) required it to do. [15] Practical utility was so lacking that the Supporting Statement did not even make a practical utility claim. "Purpose" and "need" consisted of the mere recitation of FFDCA § 408(p) and an allegedly "growing awareness of the possible adverse effects in humans and wildlife from exposure to chemicals that can interfere with the endocrine system." [16] While the ICR included each of the PRA's required certifications, [17] the Supporting Statement did not include "a record supporting such certification[s]" as required by law and OMB regulations.

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[11] Ibid. The Supporting Statement does not address OSRI, instead referring readers to EPA's simultaneously published Policies and Procedures Document (74 Fed. Reg. 17560). This document also does not address OSRI, referring readers to a third document, "EPA's Approach for Considering Other Scientifically Relevant Information (OSRI) under the Endocrine Disruptor Screening Program," March 26, 2009. This document erects substantial barriers to OSRI and does not address in any way the matter of duplication as it is defined by the Paperwork Reduction Act.

[12] Joint Comments to the Office of Management and Budget of the Chemical Producers and Distributors Association, the Consumer Specialty Products Association, CropLife America, and the American Chemistry Council on ICR 2070-new [-0176], May 22, 2008, pp. 16-21. Available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2007-1081-0020 .

[13] Ibid, pp. 13-16.

[14] Ibid, pp. 21-48.

[15] The Supporting Statement identifies no efforts to minimize burden except for what the FFDCA requires.; op. cit. footnote 10, p. 3 (FFDCA section 408(p)(5)(B) requires that, "to the extent practicable, the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information. . . .") and p. 33 ("[T]he procedures are intended to minimize potential duplicative testing, and emphasize collaborative efforts to generate the requested data. If there is a small business that does happen to manufacture one of the chemicals and therefore receives a Tier 1 Order, the small business may minimize potential burden by joining a consortium or task force, which may relieve the small business of direct responsibility for generating or submitting the data.").

[16] Supporting Statement, p. 6.

[17] Office of Management and Budget, *Data Record: ICR Reference No 200904-2070-001*, certifications (a) through (j) dated April 15, 2009. Available at http://www.reginfo.gov/public/do/PRAViewICR?ref nbr=200904-2070-001#section0 anchor.

OMB's Terms of Clearance

OMB recognized the merit of stakeholder comments concerning the lack of actual (not mere theoretical or potential) practical utility, and EPA's gross underestimate of burden.[18] Nonetheless, OMB approved the ICR but made it subject to terms of clearance that permit EPA to collect Tier I assay data only in cases where it is not duplicative of OSRI:

> "This information collection is approved for the 67 chemicals published by EPA at 74 Fed. Reg. 17579 (April 15, 2009). OMB appreciates the continuing dialog with respect to the practical utility of the Tier I battery of EDSP assays and the role that the results from these first 67 chemicals will play in ensuring practical utility for subsequent groups of chemicals. Nonetheless, under the principles of the PRA, EPA should promote and encourage test order recipients to submit Other Scientifically Relevant Information (OSRI) in lieu of performing all or some of the Tier I assays, and EPA should accept OSRI as sufficient to satisfy the test orders to the greatest extent possible."[19]

OMB also directed EPA to provide a report documenting its performance with respect to OSRI and prepare a valid burden estimate:

> "For this reason, and to further validate EPA's burden estimates, OMB requests that EPA provide a report re-estimating the burden of this information collection based on responses to the Tier I test orders, including the use of cost-sharing and data compensation, the submission and acceptance of existing data and OSRI, and description of any instances in which submission of OSRI was deemed insufficient to satisfy the testing order." [20]

OMB made preparation of this report and demonstration that practical utility had been maximized prerequisites for any EPA proposal to extend the ICR to additional chemicals:

> "OMB requests this report prior to or at the time of submission of revision of this information collection to cover additional chemicals." [21]

Finally, OMB directed EPA to actually comply, however belatedly, with the PRA's statutory requirement for practical utility. Compliance would be demonstrated in part through public comment and peer review of the guidance documents used to "actually, not merely theoretically or potentially, utilize" the information to determine whether any of the 67 chemicals must proceed to Tier II:

> "In addition, in order to ensure that EPA has maximized the practical utility of the Tier I assays as the program moves forward, EPA should ensure sufficient opportunity prior to submission of any revision to this collection for public

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[18] The definition of practical utility excludes the theoretical or potential usefulness of the information. See footnote 5.

[19] Office of Management and Budget, *Notice of Action: ICR Reference Number 200904-2070-001*. Available at: http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200904-2070-001 .

[20] Id.

[21] Id.

comment and peer review of the EPA tools to be developed to guide agency decisions on whether a chemical must proceed to Tier II, including the Weight of the Evidence Approach and Standard Evaluation Procedures." [22]

OUR PETITION TO EPA SEEKS COMPLIANCE WITH THE PRA AND OMB'S TERMS OF CLEARANCE

In our Joint Petition to EPA dated December 7, 2011, a copy of which is attached, we seek the Agency's affirmative compliance with the plain language of the PRA and good-faith adherence to the terms of clearance that are integral elements of OMB's approval. [23, 24] Our petition makes the following well-documented assertions:

- This information collection is unreasonably duplicative of information previously submitted to EPA or another Federal agency. There is no public evidence that EPA has examined the extensive data previously provided to the Agency. In the approved ICR, EPA even demands Tier I test data in cases where duplication is beyond rational debate, such as for chemicals already known to interact with the endocrine system sufficient to trigger Tier II testing.
- The Tier I battery assays have no actual, as opposed to merely theoretical or potential, practical utility for determining whether a chemical "may" or "may not" have the potential to interact with the human endocrine system sufficient to trigger Tier II testing. Several of the Tier I assays are expected to lack sufficient selectivity to inform these judgments unless the standard for advancement to Tier II is so inclusive that Tier I test data are superfluous.

The Non-duplication Provisions of the Terms of Clearance

This portion of the terms of clearance directs EPA to "promote and encourage test order recipients to submit Other Scientifically Relevant Information (OSRI) in lieu of performing all or some of the Tier I assays, and EPA should accept OSRI as sufficient to satisfy the test orders to the greatest extent possible." EPA has already violated these terms of clearance.

First, EPA has refused to publish any useful guidance that test order recipients could have used to inform their decisions whether to submit OSRI. EPA's 2007 OSRI guidance did not provide enough insight to have much practical value. It listed "[f]actors that EPA may consider" without explaining how this would be done. It said "[j]udgments will be made considering all factors" without explaining the criteria EPA would use to make these

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[22] Id.

[23] U.S. Environmental Protection Agency. 2012. *Petition To Demonstrate Paperwork Reduction Act Compliance of the Endocrine Disruptor Screening Program*; *Docket No. EPA-HQ-OPP-2012-0061.* EPA is currently seeking public comment on the petition. Comments must be received on or before May 29, 2012. *Federal Register* 77(40): 12297-12299.

[24] The Chemical Producers & Distributors Association, the Halogenated Solvents Industry Alliance, Inc., and People for the Ethical Treatment of Animals, to the U.S. Environmental Protection Agency, Petition to Demonstrate Paperwork Reduction Act Compliance of the Endocrine Disruptor Screening Program, December 7, 2011.

judgments. As to the weight EPA would give to specific studies submitted as OSRI, the Agency said this "may depend on whether the protocol meets information quality and scientific standards," a standard much higher than what the Tier I assays themselves can meet.[25] By directing EPA to "promote and encourage" the submission of OSRI, OMB's terms of clearance implicitly require EPA to revise its OSRI guidance to make them useful. So far, EPA has provided no hint that it intends to do so.[26]

Second, EPA's weight-of-evidence guidance also lacks enough clarity to have any practical value to test order recipients. Like the OSRI guidance, it is not transparent, nor does it explain how EPA will actually use Tier I test data and OSRI to determine whether a chemical "may" or "may not" have the potential to interact with the endocrine system. Because this guidance is not transparent, it is highly susceptible to arbitrary and capricious application. One aspect of the weight-of-evidence guidance is distressingly clear, however: EPA has erected a strong presumption that the Agency will decide that OSRI is technically insufficient, thus actively penalizing and discouraging its submission rather than "promot[ing] and encourag[ing]" its submission.[27]

The Practical Utility Provisions of the Terms of Clearance

This portion of the terms of clearance directs EPA to provide a report detailing "the submission and acceptance of existing data and OSRI, and [a] description of any instances in which submission of OSRI was deemed insufficient to satisfy the testing order." This report is an essential bulwark protecting the public from the imposition of highly burdensome information collections that have no actual practical utility.

To our knowledge, EPA has prepared no such report documenting its actions with respect to OSRI.

The Burden Estimation Provisions of the Terms of Clearance

After OMB approved ICR 2070-0176 on October 2, 2009, EPA proposed in November 2010 to amend the list of chemicals subject to Tier I screening.[28] EPA did not adopt any of the recommendations made by stakeholders to obtain reliable burden estimates; indeed, the Agency used the same erroneous methodology as if no comments had ever been submitted.[29] Meanwhile, EPA had on its own sought and obtained more

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[25] U.S. Environmental Protection Agency. 2009. *EPA's Approach for Considering Other Scientifically Relevant Information (OSRI) under the Endocrine Disruptor Screening Program; Docket No. EPA-HQ-OPPT-2007-1080-0032*. Washington, D.C.: U.S. Environmental Protection Agency. Stakeholder comments show that the Tier I assays do not adhere to applicable information quality standards. See footnote 23, pp. 4-6.

[26] U.S. Environmental Protection Agency. 2009. *EPA Response to the Comments In the CropLife America Petition of July 11, 2008*.

[27] Any Tier I test order recipient that submitted OSRI in lieu of performing Tier I tests thus risked being unable to meet the deadline for data submission, and thus subject to potentially ruinous penalties.

[28] U.S. Environmental Protection Agency. 2010a. Agency Information Collection Activities; Proposed Collection; Comment Request; Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP); EPA ICR No. 2249.02, OMB Control No. 2070–0176. *Federal Register* 75(221): 70568-70570.

[29] In a revision to the Supporting Statement for ICR 2070-0176 that EPA made before clearance but withheld from the public, the number of pesticide active ingredient (PAI) test order recipients inexplicably

reliable data but did not incorporate them into the burden estimates for the proposed addendum, presumably because the new burden figures were much greater and confirmed the views of stakeholders. [30]

In short, EPA has displayed a persistent pattern of grossly understating burden, ignoring stakeholder comments that clearly identify these errors, and even failing to incorporate its own best data. Inasmuch as OMB has been aware from the outset that EPA's burden estimate had no merit, and it is now aware that EPA has had at least one opportunity to correct them but failed to do so, the importance of this element of OMB's terms of clearance cannot be denied.

EPA's Response to Our Petition Requires Coordinated Determinations by OMB

The Joint Petition seeks EPA's affirmative commitment to comply with OMB's terms of clearance. This requires clarity about how the terms of clearance are to be interpreted, as well as clarity about how certain provisions of the PRA and the Information Collection Rule are to be interpreted and applied. By law, only OMB's interpretation of the terms of clearance is valid and only OMB has the authority to define and interpret the statute and applicable regulations. Therefore, EPA requires certain determinations from OMB in order for it to provide an informed response to our Joint Petition.

QUESTIONS RELATED TO THE APPLICABILITY OF ICR 2070-0176 SUBMITTED TO OMB FOR RESOLUTION PURSUANT TO PRA § 3517(b)

Section 3517(b) of the PRA provides a mechanism for the public to seek and obtain, with respect to "any collection of information conducted by or for an agency," a clear and authoritative opinion from OMB concerning whether "a person shall maintain, provide, or

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increased from 207 to 219, and the number of inert ingredient manufactures/importers increased from 163 to 530. These changes increased total burden by at least a factor of two. EPA also revised, though not transparently, the number of respondents expected to collaborate in a consortium. In the original ICR Supporting Statement, EPA claimed (without providing any documentation) that the average consortium would have "less than five" Tier I test order recipients, and the maximum would be 56 recipients. The 2009 amendment to the Supporting Statement yields an average of 3.78 recipients per chemical, and a maximum of 310 recipients. See Chemical Producers and Distributors Association comments on Addendum for the Second List of Chemicals, EPA ICR No. 2249.02, OMB Control No. 2070-0176. *Docket No. EPA-HQ-OPPT-2007-1081-0046*.

[30] EPA developed a report in 2009 titled " *Laboratory testing of chemicals for endocrine disrupting potential – analysis of market factors*" which includes comprehensive test cost data collected by the Agency from 15 laboratories. The EPA data were submitted to the Organization of Economic Cooperation and Development and the results appear in an annex of a January 2010 draft document. See Organization for Economic Cooperation and Development. 2010. *Guidance Document on the Assessment of Chemicals for Endocrine Disruption" Version 9.* The annex provides summary tables of the EPA data from which it can be determined that the Agency has known for at least two years that the median cost for conducting the Tier I battery is $544,397 - 35% greater than the estimates used in ICR 2070-0176 and the subsequent proposed addendum.

disclose the information to or for the agency." OMB cannot delegate this authority to a sponsoring agency even if it has delegated primary clearance authority. [31]

This mechanism has obvious application in cases where an agency has not obtained OMB approval for an information collection or allowed a clearance to expire. This ICR belongs to a different category - information collections that were presumptively valid at the time they were approved, but which have been materially altered by the way in which the sponsoring agency implemented the collection. Supporting Statements and research protocols are integral parts of a collection of information, so every OMB approval must be conditional on an agency's adherence to them. The same should be true for terms of clearance: agencies must not be permitted to substantially fail to comply with them and expect OMB approvals to remain intact. If they did, then terms of clearance, Supporting Statements, and research protocols all would be superfluous. An agency could make any manner of commitments to OMB in order to secure an approval then choose not to fulfill them without penalty.

Therefore, because OMB has the exclusive statutory authority to make PRA compliance determinations, there is no body other than OMB through which we can obtain relief. We respectfully seek clear and authoritative answers to the following questions:

1. If OMB uses terms of clearance to limit the applicability of a collection of information, are these limits binding on the agency that conducts or sponsors the collection?
2. If OSRI exists that is sufficient to enable EPA to determine whether a substance "may" or "may not" have the potential to interact with the endocrine system sufficient to warrant Tier II testing, but EPA requires test order recipients to develop and submit Tier I assay data anyway, are these data "duplicative of information otherwise accessible to the agency," as defined by 5 C.F.R. § 1320.5(d)(1)(ii), and thus covered by the limitation in the terms of clearance?
3. In its ICR, EPA provided certifications of compliance with each of the requirements listed in 5 C.F.R. § 1320.9, but as far as we can tell the Agency provided no "record supporting such certification[s]."
    a. Does OMB agree that EPA did not provide a record supporting these certifications?
    b. If OMB does not agree, where is this record located and what does it say specifically with respect to each certification?
4. Has EPA submitted to OMB the report required by the terms of clearance, in draft or final form, or has EPA submitted to OMB any of the information that such a report must include?

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[31] OMB has limited authority to delegate approval authority to the Senior Official of an agency. See 44 U.S.C. § 3507(i)(1). EPA is not among the agencies listed in Appendix A to 5 C.F.R. Part 1320 as having been delegated review and approval authority. More importantly, OMB's authority to delegate can be withdrawn at any time (44 U.S.C. § 3507(i)(2)), and nothing in § 3517(b) suggests that this particular authority can be ever delegated.

5. For each of the following elements in the terms of clearance, has EPA complied, not complied, or not yet complied (perhaps because it is too early for OMB to make this determination):

    a. "[P]romote and encourage test order recipients to submit Other Scientifically Relevant Information (OSRI) in lieu of performing all or some of the Tier I assays"

    b. "[A]ccept OSRI as sufficient to satisfy the test orders to the greatest extent possible"

    c. "[P]rovide a report re-estimating the burden of this information collection based on responses to the Tier I test orders, including the use of cost-sharing and data compensation, the submission and acceptance of existing data and OSRI, and description of any instances in which submission of OSRI was deemed insufficient to satisfy the testing order."

6. If OMB determines that EPA did not comply with the terms of clearance cited in Question 5.a, are respondents still required to provide the information contained in the collection of information even though the information collection would be unreasonably duplicative? If respondents are so required, what is the legal rationale under the PRA?

7. If EPA is determined to have not complied with the terms of clearance cited in Question 5.b, are respondents still required to provide the information contained in the collection of information even though the collection of information would be unreasonably duplicative? If respondents are so required, what is the legal rationale under the PRA?

8. If EPA is determined to have not complied with the terms of clearance cited in Question 5.c, are all future expansions of the ESDP screening and testing programs presumptively disapproved unless and until EPA complies?

Section 3517(b) requires OMB to respond to this request within 60 days and take appropriate remedial action, if necessary. We believe that by issuing clear opinions on these questions OMB can provide constructive assistance to EPA, thus removing uncertainties concerning the proper understanding and application of the PRA. We respectfully request that OMB complete its response in a timely manner so that EPA can respond to our petition without undue delay.

REMEDIAL ACTION

In this § 3517(b) request, we seek clarity from OMB about the proper interpretation of critical elements of the terms of clearance for this ICR. We believe that EPA also needs clarity from OMB in order to properly respond to our Petition, which seeks an affirmative commitment to adhere to the terms of clearance. Without OMB providing this clear understanding, EPA's response to our petition may not be reliable or authoritative.

To the extent that OMB determines that EPA has not adhered to the terms of clearance, we ask OMB to take the following remedial actions:

1. Formally remind EPA that OMB's approval of ICR 2070-0176 was conditioned on the Agency's adherence to the terms of clearance, and that less than full compliance may make this collection of information susceptible to challenge under the public protection provisions in 44 U.S.C. § 3512.
2. Publicly state that OMB will not approve any amendment to ICR 2070-0176 until such time as:
    a. EPA complies with all regularly applicable requirements of the PRA;
    b. The report required by the terms of clearance is submitted to OMB and disseminated for no less than 60 days' public comment; and
    c. EPA fully responds to all significant public comments received.
3. As provided for in 5 C.FR. § 1320.18(b), initiate a rulemaking proceeding to determine whether ICR 2070-0176, as actually implemented by EPA, is consistent with the requirements of the PRA.

We appreciate the opportunity provided by the PRA to seek and obtain OMB's review of ICR 2070-0176 to obtain authoritative opinions concerning the proper interpretation and applicability of OMB's terms of clearance. If you have any questions concerning this request, please contact Susan Ferenc by calling (202) 386-7407or at sferenc@cpda.com. Thank you.

Sincerely,

Susan A. Ferenc, DVM, Ph.D.
President
Chemical Producers & Distributors Association

Faye Graul
Executive Director
Halogenated Solvents Industry Alliance, Inc.

Jessica Sandler
Senior Director, Regulatory Testing Division
People for the Ethical Treatment of Animals

Petition to Demonstrate Paperwork Reduction Act Compliance of the Endocrine Disruptor Screening Program

SUBMITTED TO

U.S. Environmental Protection Agency

SUBMITTED BY

Chemical Producers & Distributors Association
Halogenated Solvents Industry Alliance, Inc.
People for the Ethical Treatment of Animals

December 7, 2011

Dr. Steven Bradbury, Director
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U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
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Washington, D.C. 20460

Ms. Wendy Cleland-Hamnett
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Mr. Frank Sanders, Director
Office of Science Coordination and Policy
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1200 Pennsylvania Ave., NW
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Cc: Louise Wise, Acting Deputy Assistant Administrator, OCSPP, EPA

Dear Dr. Bradbury, Ms. Cleland-Hamnett and Mr. Sanders:

The Chemical Producers & Distributors Association, the Halogenated Solvents Industry Alliance, Inc. and People for the Ethical Treatment of Animals ("the Petitioners") submit this petition to ask the Environmental Protection Agency (EPA or Agency) to fully comply with the Paperwork Reduction Act

(PRA)[1] as specified in the Office of Management and Budget's (OMB) Terms of Clearance (TOC) [2] for the Information Collection Request (ICR) associated with 67 pesticide chemicals under the Endocrine Disruptor Screening Program (EDSP) before issuing test orders for Tier 1 screening of additional chemicals.

I) Introduction

In October 2009, EPA began issuing test orders for Tier 1 screening of 67 pesticide chemicals (List 1) under the Federal Food, Drug and Cosmetic Act (FFDCA).[3] EPA indicated that all screening results must be submitted within two years from the date a test order was issued or, for the List 1 chemicals, by February 2012. Under the PRA information collection regulations ("Information Collection Rule"), EPA is required to demonstrate that any proposed collection of information "is not duplicative of information otherwise accessible to the agency" and that it "has practical utility." [4] In approving the ICR for Tier 1 screening of List 1 chemicals, the OMB, under authority of the PRA, attached a notice of TOC directing the Agency to demonstrate the maximum practical utility of the information collection and evaluate the sufficiency of other scientifically relevant information (OSRI) on these chemicals prior to requiring the public to screen additional chemicals.

The Agency has not complied with these requirements and, by extension, cannot meet its FFDCA obligation to rely on science.

Assertions:

EPA has failed to comply with the PRA under Tier 1 screening of the EDSP:

- The Agency has not demonstrated that the information collection is non-duplicative of information to which it may already have access.
- The Agency has not demonstrated that the Tier 1 assays have practical utility by providing the scientific support on which to make the necessary distinction that a chemical "may" or "may not" have the potential to interact with the endocrine system.[5]

Resolution:

To ensure compliance with the mandates of the PRA, EPA must demonstrate that any proposed collection of information is not duplicative of information otherwise accessible to the agency, and demonstrate the practical utility of EDSP Tier 1 screening by reviewing and revising the Tier 1 Battery before requiring screening of additional chemicals.

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[1] 44 U.S.C. §§ 3501 *et seq.*
[2] Office of Management and Budget. 2009. *Notice of Office of Management and Budget Action, ICR Reference Number 200904 2070 001; New ICR 2070 0176*.
[3] 21 U.S.C. § 346(p)(3); FDCA § 408(p)(3).
[4] 5 C.F.R. § 1320.5(d)(ii) and (iii).
[5] Comments submitted by the Chemical Producers & Distributors Association *et al*., available in Docket ID Number EPA HQ OPP 2007 1081 0020.

II) EPA must demonstrate that the information collected during Tier 1 screening of the EDSP is not duplicative of already existing information.

To obtain OMB approval, EPA must "demonstrate that it has taken every reasonable step to ensure that the proposed collection of information … [i]s not duplicative of information otherwise accessible to the agency."[6] EPA incorrectly interprets the prohibition on duplication in FFDCA as being the same "duplicative" prohibition in the PRA. The FFDCA provision restricts EPA from collecting newly duplicative information,[7,8] whereas the PRA requires EPA to avoid duplication of existing data. The latter prohibition is considerably broader.

Under the PRA, duplication exists if the need for the proposed collection can be served by information "otherwise reasonably accessible to the agency."[9] At a minimum, this includes vast quantities of test data that EPA already possesses, much of which has been provided by chemical manufacturers under the Toxic Substances Control Act [10] and pesticide registrants under the Federal Insecticide, Fungicide and Rodenticide Act. [11] However, it appears that EPA did not thoroughly evaluate the feasibility of using existing information, whether held by the Agency or by other federal agencies, prior to sending Tier 1 test orders to List 1 chemical recipients.

OMB directed consideration of OSRI under the ICR Terms of Clearance .

1) EPA should accept OSRI as sufficient to satisfy the test orders to the greatest extent possible.

The OMB Information Collection Rule states 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…" [12] and that OMB has the sole authority to determine "whether the burden of the collection of information is justified by its practical utility."[13] Therefore, OMB has oversight authority for interpreting the adequacy of federal agencies' compliance with the PRA's provisions and the ICRs they submit.

OMB attempted to address the PRA compliance issues via conditional TOC on the 2009 EDSP List 1 ICR approval.[14] The text implicitly and undeniably recognizes that EPA did not adequately demonstrate the information to be collected in Tier 1 screening of List 1 chemicals would not be duplicative of existing information or demonstrate that it would have practical utility, and directed EPA to use the information collected and evaluated on

[6] 5 C.F.R. § 1320.5. The responsible agency official must certify this "and provide a record supporting such certification " (21 C.F.R. § 1320.9).
[7] 21 U.S.C. § 346a(p)(5)(B).
[8] Similarly, the Agency improperly uses a narrow definition of duplicative testing for the screening of List 1 chemicals: "the term 'duplicative testing' applies when more than one company conducts the exact same assay on the exact same substance." EPA Response to CropLife Petition available in Docket ID Number EPA HQ OPP 2007 1080.
[9] 44 U.S.C. § 3506(c)(3)(B).
[10] 15 U.S.C. §§ 2601 *et seq*.; TSCA §§ 2 *et seq*.
[11] 7 U.S.C. §§ 136 *et seq*.; FIFRA §§ 2 *et seq*.
[12] 5 CFR § 1320.5(e).
[13] *Id.*
[14] *Supra* note 2.

the List 1 chemicals before expanding the program to include screening of additional chemicals. The TOC specifically states that:

> "OMB appreciates the continuing dialog with respect to the practical utility of the Tier 1 battery of EDSP assays and the role that the results from the se first 67 chemicals will play in ensuring practical utility for subsequent groups of chemicals. Nonetheless, ***under the principles of the PRA, EPA should promote and encourage test order recipients to submit Other Scientifically Relevant Information (OSR I) in lieu of performing all or some of the Tier 1 assays, and EPA should accept OSRI as sufficient to satisfy the test orders to the greatest extent possible.***
>
> For this reason, and to further validate EPA's burden estimates, OMB requests that EPA provide a report re-estimating the burden of this information collection based on the responses to the Tier 1 test orders, including the use of cost -sharing and data compensation, ***the submission and acceptance of existing data and OSRI, and description of any instances in which submission of OSRI was deemed insufficient to satisfy the testing order***. OMB requests this report prior to or at the same time of submission of revision of this information collection to cover additional chemicals. " [emphasis added]

2) EPA rejected the majority of the OSRI submitted on List 1 chemicals.

Although EPA provided List 1 test order recipients with the required opportunity to submit existing data or OSRI in lieu of conducting some or all of Tier 1 Battery screening assays,[15] the Agency did not clearly articulate its basis for evaluating OSRI submissions for the List 1 chemicals and did not clearly outline its policy goals concerning OSRI. In November 2010, EPA stated that it would review submitted existing data or OSRI "to determin e whether a submission provides sufficient information to allow EPA to identify substances that have the potential to interact with the estrogen, androgen, or thyroid systems. In making this judgment, EPA compares the ability of OSRI to answer the questi on with the types of information we would get from the assays in the Tier 1 battery."[16] The Agency also noted that it would use a "weight-of-the-evidence approach in review of OSRI."

The Agency published its final Weight-of-Evidence (WoE) Guidance ("Guidance") in September 2011. The Guidance does not set forth, in a transparent, reproducible, and consistent way, how EPA plans to determine whether existing data or OSRI satisfy EPA's stated purpose for the information : to enable it to discriminate scientifically between substances that "may" or "may not" have the potential to interact with the endocrine system. Contrary to the OMB TOC, EPA discourages the submission of valid scientific data in the Guidance and categorically dismisses such information by asserting that "to comply with the test orders, recipients must submit the results of EDSP Tier 1 screening ."

[15] OMB stated in the Terms of Clearance: "EPA should promote and encourage test order recipients to submit Other Scientifically Relevant Information (OSRI) in lieu of performing all or some of the Tier I assays, and EPA should accept OSRI as sufficient to satisfy the test orders to the greatest extent possible."

[16] EPA Response to CropLife A merica *et al.,* Nov 17, 2010 available in Docket Number EPA HQ OPP 2009 0634 0233.

All initial List 1 chemical test order responses, including OSRI, were due to the Agency by spring of 2010, well before the Guidance was published. The OSRI submitted with responses to these test orders was apparently accepted or rejected without the benefit of review under the Agency's Guidance and as of August 2011, the Agency had rejected 323 of the 412 (78%) OSRI submissions reviewed.[17] Without having published the Guidance prior to its review of OSRI submitted in response to List 1 chemical test orders, the Agency cannot justify the OSRI determinations it made at that time. It is obvious from EPA's dismissive treatment of OSRI for List 1 chemicals that the body of knowledge for a particular chemical had not been fully considered in a WoE approach, nor had a consistent weighting scheme been applied to assess the quality of the studies and results submitted.

3) Non-duplication must be demonstrated in order to justify animal testing in EDSP screening.

EPA, as a charter member of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), is committed to "eliminate unnecessary duplicative efforts" and "reduce, refine, or replace the use of animals in testing, where feasible." [18,19] Consistent with Congress' directive in the PRA to avoid collecting duplicative information, [20] the OMB directive to promote and encourage the use of OSRI, the statutory mandates to reduce animal testing, [21] and the requirements of the PRA, EPA must ensure through transparent and reproducible review of existing data that the information collection is not duplicative of information "otherwise reasonably accessible to the agency." The refore, the Agency must demonstrate that its "may" and "may not" administrative decisions on the Tier 1 information: (1) cannot be made without the use of animal testing , and (2) cannot be made based on OSRI.

III) EPA must demonstrate the practical utility of the information collected in Tier 1 screening of the EDSP.

The Information Collection Rule defines 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, and the agency's ability to process the information it collects …." [22] FFDCA § 408(p) directs EPA to establish the EDSP relying on science (*i.e.,* based on "appropriate and validated test systems") to discern substances t hat "may" have the potential to interact with one or more components of the endocrine syste m from substances that "may not " have this potential. Each transparent and reproducible "may" and "may not" administrative decision made by EPA must be based on a solid scientific foundation to have practical utility.

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[17] Willett CE, Bishop PL, Sullivan KM. 2011. A Strategy for Reducing Animal Use in the U.S. EPA's Endocrine Disruption Screening Program. 8th World Congress on Alternatives & Animal Use in the Life Sciences, August 21 – 25, Montreal, Canada.
[18] 42 U.S.C. § 285l *et seq.;* ICCVAM Authorization Act of 2000.
[19] *Id.* at § 285l 4(b). According to the Act, as a Federal Agency, EPA "shall promote and encourage the development and use of alternatives to animal test methods (including batteries of tests and test screens), where appropriate, for the purpose of complying with Federal statutes, regulations, guidelines, or recommendations (in each instance, and for each chemical class) if such test methods are found to be effective for generating data, in an amount and of a scientific value that is at least equivalent to the data generated from existing tests, for hazard identification, dose response assessment, or risk assessment purposes."
[20] 21 U.S.C. § 3506(c)(3)(B).
[21] 42 U.S.C § 285l 4(e); NIH Revitalization Act of 1993 (P.L. 103 43).
[22] 5 C.F.R. § 1320.3(1).

To demonstrate practical utility under the PRA, the information collected through the EDSP Tier 1 Battery assays must provide a sufficient scientific basis on which to make administrative decisions.

During the development and implementation process for Tier 1 screening under the EDSP, serious scientific concerns were raised regarding the appropriateness, suitability and validation status of the assays included in the EDSP Tier 1 Battery[23] and the practical utility of the information provided by the collection.[24] In addition, Congress and EPA's own Office of the Inspector General (OIG) have instructed EPA to improve the EDSP by reviewing and revising the Tier 1 assays to ensure maximal practical utility of the information derived from EDSP -mandated testing. For instance, the OIG specifically recommended in its May 2011 review report[25] that EPA: (1) develop and publish a standardized methodology for prioritizing the universe of chemicals for screening and testing , (2) finalize specific Tier 1 and Tier 2 criteria to evaluate testing data, (3) develop performance measures, (4) develop a comprehensive management plan, and (5) hold annual program reviews.

Congress has also expressed its concern regarding the adequacy of the Tier 1 screening battery by providing guidance to EPA in both 2010 and 2011 House Appropriations Committee Reports. The report language for Fiscal Year (FY) 2010[26] instructed EPA to re-evaluate and revise, as needed, the Tier 1 battery. Additionally, the report language for FY 2012[27] recognized that technical advances have occurred since the Tier 1 Battery was developed and need to be considered. The report instructed EPA to: (1) take steps to ensure EDSP testing minimizes the use of animals and considers existing knowledge and targeted testing, and justifies use with appropriate statistical considerations; (2) evaluate the Tier 1 test chemicals in ToxCast assays and determine their performance in endocrine relevant estrogenic, androgenic, and thyroid assays to refine toxicological prediction models; and (3) utilize high throughput *in vitro* screening assay results to prioritize Tier 1 chemical testing and to inform future endocrine disruptor investigations. These instructions are consistent with a general policy shift at EPA toward predictive human health and environmental protection.[28]

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[23] Comments submitted by People for the Ethical Treatment of Animals *et al.,* Crop Life America, the American Chemistry Council, the Center for Regulatory Effectiveness , available in Docket ID no. EPA HQ OPP 2008 0012.

[24] Comments submitted by the Chemical Producers & Distributors Association *et al*., available in Docket ID Number EPA HQ OPP 2007 1081 0020.

[25] OIG Report, available at http ://www.epa.gov/oig/reports/2011/20110503 11 P 0215.pdf.

[26] H.R. Report No. 111 180 at 105 (2009), directing EPA to "engage in a timely re evaluation of the battery of screening, replacing outdated ones with updated, more efficient screens that have been val idated (for example, a recombinant receptor assay to replace the cytosolic receptor assay for estrogen receptor binding)" and "develop and publish criteria for evaluatin g the results of Tier I screening and determining whether a chemical should undergo Tie r II analysis within one year of enactment."

[27] H.R. Report No. 112 151 (2011), "Recognizing ToxCast has great promise to streamline and significantly increase the throughput of the Endocrine Disruptor Screening Program (EDSP), the Committee directs EPA to accelerate the evaluation, validation and implementation of the endocrine relevant ToxCast assays. The Agency shall (1) in future EDSP Test Orders, use a targeted approach and adjust individual Test Orders in response to scientifically credible requests by taking existing data i nto account, and using information from valid in vitro assays or computer models, including ToxCast, as appropriate; and (2) use a peer consultation process to revise the EDSP weight of the evidence guidance to assure a systematic and consistent approach for evaluating other scientifically relevant information and EDSP results. These two activities shall include public comment and publication of Agency responses."

[28] This approach has been articulated in a 2007 report from the National Research Council (Toxicity Testing in the 21st Century: a Vision and a Strategy. National Academies Press, Washington, DC.) , has been adopted by EPA in their 2009 Strategic Plan for Evaluating the Toxicity of Chemicals, and is in a large part the impetus for a recent departmental reorganization of EP A's Office

1) ***EPA has not demonstrated the scientific reliability and appropriateness of the current Tier 1 Battery assays.***

It has been repeatedly pointed out to EPA that the Tier 1 assays are not reproducible or sufficiently specific to adequately identify chemicals that are capable of interacting with estrogen, androgen or thyroid hormone receptors or systems.[29,30,31] EPA has responded to some of these concerns;[32] however, several of the responses highlight, rather than mitigate, many of the concerns. For example, in response to concerns about inter-laboratory variability (reproducibility) of the amphibian metamorphosis assay and the male and female pubertal assays, EPA acknowledged that, while different labs did indeed obtain different results, "the overall trend was consistent among laboratories." This admission is disconcerting since a single chemical will be screened in Tier 1 assays in a single lab and there will be no "overall trends" available for comparison.

Likewise, in response to concerns about specificity (*i.e.,* the ability to distinguish true negatives from true positives) of several of the assays, EPA argued that, "[b]ecause the Tier 1 assays will operate in a battery and will only identify a chemical's potential to interact with the endocrine system, rather than to predict actual effects, the rate of false positives and negatives for individual assays in the battery is not an essential part of validation." This reasoning is deeply flawed. Logically, if a battery consists of multiple assays of low specificity, the combined results will be heavily skewed toward false positives. For several of the assays, all chemicals tested in the validation studies gave some positive response, including some of the negative controls. This calls into question the ability of this testing battery to distinguish positives from negatives, and thus the overall practical utility of the battery.

2) ***Practical utility of the List 1 information cannot be demonstrated without the use of a scientifically sound weight of evidence approach that is applied to all information collected.***

OMB, OIG and Congress collectively instructed EPA to provide decision criteria and guidance for Tier 1 testing and decision-making. On September 28, 2011, EPA published the Guidance that contractors and Agency reviewers are to use to consider all screening information collected on the List 1 chemicals. While this 47-page document is certainly an improvement over the 8-page draft issued for public comment in November 2010,[33] it remains a self-described "general" guidance document that lacks the rigor and specificity required to provide a transparent, consistent review of data. The Guidance addresses assays and

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of Research and Development (http://www.epa.gov/ord/priorities/chemicalsafety.htm) as well as a collaboration between EPA, the National Institutes of Health, and the Food and Drug Administration to address the technical aspects of this shift in policy (Collins *et al.* 2008. Science 319:906; M.A. Hamburg. 2011. Science 331: 987).

[29] *Supra* note 25.

[30] Comment document entitled: EPA Response to the Center for Regulatory Effectiveness (CRE) Information Quality Act Request for Correction Regarding the Amphibian Metamorphosis Assay, available in Docket ID no. EPA HQ OPPT 2007 1080.

[31] Physicians Committee for Responsible Medicine (PCRM) Comments to OMB on the Endocrine Disruptor Screening Program (EDSP), available in Docket ID Number EPA HQ OPPT 2007 1080.

[32] Draft Response to Comment document entitled: "Physicians Committee for Responsible Medicine's Comments to OMB and EPA's Responses," available in Docket ID Number EPA HQ OPPT 2007 1080.

[33] Endocrine Disruptor Screening Program (EDSP); Announcing the Availability of a Draft for Weight of Evidence Guidance Document: Evaluating Results of EDSP Tier 1 Screening To Identify Candidate Chemicals for Tier 2 Testing, 75 Fed. Reg. 67,963 (Nov. 4, 2010); EPA HQ OPPT 2010 0877 0002.

endpoints applicable to each endocrine pathway and does not lend clarity to WoE evaluations of several or all assay results combined. The Guidance also provides only a general overview of how data might be used to decide whether any Tier 2 testing is indicated.

The Guidance includes general considerations in evaluating the quality of scientific information and lists general factors to consider when evaluating data (*e.g.*, soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review), but does not describe how data from the Tier 1 assays will be evaluated according to these criteria. Although the Guidance correctly points out that specificity, sensitivity, and rigor of validation are important considerations in evaluating assay results, it then ignores these critical considerations by giving only one general illustration of a simple, straightforward hypothesis-driven evaluation description of how data might be tabulated without any explanation of how such data would be evaluated according to a WoE approach.

For the EDSP Tier 1 assays, many of the elements necessary for a transparent and reproducible WoE approach could be informed by the validation studies. Moreover, the wealth of existing information for the List 1 chemicals could be used to revise and improve the comprehensiveness and utility of the Guidance.[34] In addition, there are several alternative WoE approaches to evaluating endocrine testing data in the published literature, including guidance for evaluating EDSP data that is more appropriate in terms of rigor and completeness.[35,36,37,38]

IV) Conclusions:

We acknowledge EPA's obligation to screen chemicals for endocrine effects pursuant to the FFDCA and recognize the Agency's significant efforts to implement the program at this time. Nevertheless, it appears that EPA has abandoned its initial intention to implement the phased approach to the EDSP recommended by its Scientific Advisory Board (SAB).[39] The SAB recommended that EPA initially screen 50 to 100 substances and that once the Agency collects data from those substances, it should review all endocrine screening battery data and test methods to revise the program "with an eye towards revising the process and eliminating those methods that don't work."[40] However, EPA has instead initiated actions to issue a second round of test orders for an additional group of chemicals.[41] These actions

[34] This is especially important for several of the assays for which validation studies indicated insufficient specificity or reproducibility (*i.e.,* the pubertal assays, the amphibian metamorphosis and fish short term assays).
[35] Willett CE, Bishop PL, Sullivan KM. 2011. Application of an integrated testing strategy to the U.S. EPA Endocrine Disruptor Screening Program. Toxicol. Sci. 123(1):15 25.
[36] Bars R, Broeckaert F, Fegert I, *et al*. 2011. Science based guidance for the assessment of endocrine disrupting properties of chemicals. Regul. Toxicol. Pharmacol. 59(1):37 46.
[37] Borgert CJ, Mihaich EM, Quill TF, *et al*. 2011. Evaluation of EPA's Tier 1 Endocrine Screening Battery and recommendations for improving the interpretation of screening results. Regul. Toxicol. Pharmacol. 59: 397 411.
[38] Borgert CJ, Mihaich EM, Ortego LS, *et al*. 2011. Hypothesis driven weight of evidence framework for evaluating data within the US EPA's Endocrine Disruptor Screening Program. Regul. Toxicol. Pharmacol. In press: doi:10.1016/j.yrtph.2011.07.007.
[39] Consistent with the SAB recommendation, EPA confirmed in the EDSP List 1 policies and procedures document, that the Agency intended use the results from the first phase of EDSP screening to review and revise as necessary its Tier 1 battery prior to issuing new testing orders.
[40] *Review of the EPA's Proposed Environmental Disruptor Screening Program; Review of the Endocrine Disruptor Screening Program by a Joint Subcommittee of the Science Advisory Board and Scientific Advisory Panel* . EPA SAB EC 99 013, July 1999.
[41] Draft documents and comments submitted available in Docket ID Numbers EPA HQ OPPT 2007 1080 9, EPA HQ OPPT 2009 0477, and EPA HQ OPPT 2007 1081.

clearly are not in accordance with OMB's TOC admonition to not order additional endocrine screening until the EDSP Tier 1 screening of List 1 chemicals was completed; until EPA had assessed the performance of its screening assays and battery and made necessary changes to the assays and battery; and until EPA had evaluated the sufficiency of other scientifically relevant information to satisfy test orders and avoid unnecessary testing. We believe the Agency has the obligation and opportunity to consider recommendations by the SAB, OMB, OIG, Congress and stakeholders to demonstrate non-duplicativeness and practical utility of the EDSP through careful review of Tier 1 information on List 1 chemicals before requiring the screening of additional chemicals.

V) Recommendations:

EPA should not require the screening of additional chemicals until it has demonstrated the practical utility of the information collected through Tier 1 screening.

- *EPA should review and revise the Tier 1 Battery, including promoting use of OSRI, before requiring the screening of additional chemicals.*

- *EPA should re-evaluate all OSRI submitted on the List 1 chemicals after all assay results have been evaluated, to demonstrate where OSRI would have been sufficient for the "may" or "may not" administrative decision on whether a chemical has the potential to interact with the endocrine system.*

- *EPA should review and revise, as needed, the Tier 1 Battery assays with alternative validated testing methodologies.*

EPA should evaluate the sufficiency of the Guidance to reproducibly and transparently characterize screening assay results across reviewers, chemicals and laboratories for the List 1 chemicals and revise the Guidance appropriately.

From: Susan Ferenc <sferenc@cpda.com>
Sent: Tuesday, May 24, 2016 3:48 PM
To: Shelanski, Howard
Cc: Mancini, Dominic
Subject: Council of Producers & Distributors Petition to OIRA
Attachments: CPDA Petition to OIRA.pdf; CPDA Petition to OIRA Cover Letter.pdf

Importance: High

Please find attached a cover letter and petition seeking certain determinations and actions by the Office of Management and Budget.

Susan Ferenc, DVM, Ph.D.
President

Council of Producers &
Distributors of Agrotechnology

1730 Rhode Island Ave., NW | Suite 812 | Washington, DC 20036
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COUNCIL OF PRODUCERS &
DISTRIBUTORS OF AGROTECHNOLOGY

May 24, 2016

The Honorable Dr. Howard Shelanski
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

Dear Dr. Shelanski:

The Council of Producers & Distributors of Agrotechnology (CPDA) provided comments to the Office of Management and Budget (OMB) in July and December of 2015 concerning OMB Control No. 1218-0072 (80 FR 36856; June 26, 2015), the Information Collection Request for the Occupational Safety and Health Administration's 2012 Hazard Communication Standard (HCS). We are now submitting the attached petition, which further describes the real-world worker safety risks and the economic impacts on the agricultural chemical industry associated with compliance to HCS 2012.

As we noted in our 2015 comments, CPDA is the preeminent U.S. based trade association representing the interests of the agrotechnology products industry, including manufacturers, suppliers, formulators and distributors of myriad agricultural production inputs. With a value of more than $7 billion annually, in excess of 10 million agrotechnology end-use product containers such as tank-mix adjuvants and bags of fertilizers and plant nutritionals are manufactured and distributed in the U.S. annually. This represents more than 10% of the 949 million shipped containers of hazardous chemicals identified by OSHA.

We are also requesting a meeting with OMB to discuss the industry-based information we have gathered since submission of our supplemental comments in December 2015, as per our offer in those comments. We are available to meet with OMB officials to discuss the new information, and the issues and possible solutions presented in the petition at OMB's convenience. Please contact Dr. Susan Ferenc at 202-386-7407 or sferenc@cpda.com to arrange a meeting as soon as possible.

Thank you for your kind consideration.

Sincerely,

Susan Ferenc, DVM, Ph.D.
President
Council of Producers & Distributors of Agrotechnology

CC: Dominic Mancini, Deputy Administrator

COUNCIL OF PRODUCERS &
DISTRIBUTORS OF AGROTECHNOLOGY

May 24, 2016

The Honorable Dr. Howard Shelanski
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

SUBJECT: Petition Seeking Certain Determinations and Actions by the Office of Management and Budget Pursuant to its Author ities under 44 U.S.C. § 3517(b), 5 C.F.R. § 1320.18(a), and 5 C.F.R. § 1320.18(b)

Dear Dr. Shelanski:

The Council of Producers & Distributors of Agrotechnology (CPDA) respectfully submits this petition to the Office of Information and Regulatory Affairs (OIRA) pursuant to authorities delegated to the Administrator by the Director as set forth in the Paperwork Reduction Act of 1995 (PRA)(44 U.S.C. § 3503(b)).[1] Through this petition we seek to offer a constructive path forward to resolve certain issues posed by a pending Information Collection Request (ICR) submitted by the Occupational Safety and Health Administration .[2]

I. BACKGROUND

This ICR seeks a 3-year renewal of OMB approval for OMB Control No. 1218-0072,[3] which exhibits a checkered past. For starters, it was the focal point for an existential test of the PRA and OMB's statutory authorities thereunder. Although the U.S.

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[1] Paperwork Reduction Act of 1995 (Pub. L. 104-3), 109 Stat. 163 (Government Printing Office, 1995).

[2] "Hazard Communication Standard," ICR Reference No. 201506-1218-003; submitted June 30, 2015.

[3] Office of Information and Regulatory Affairs, *ICR Reference No. 201506-1218-003; Hazard Communication (29 CFR 1910.1200, 1915.1200, 1917.28, 1918.90, 1926.59, and 1928.21)* , OIRA/GSA(2015), *available at* http://www.reginfo.gov/public/do/PRAViewICR?ref nbr=201506 - 1218-003.

Supreme Court held that the original 1980 Act did not apply to information contained in disclosure rules such as the Hazard Communication Standard (HCS),[4] Congress eliminated any confusion in the 1995 PRA amendments.

Since 1983, OSHA has submitted 31 separate ICRs for the Hazard Communication Standard, seven of them requests for so-called "emergency extensions."[5] The ICR corresponding to this OMB Control Number lapsed on June 30, 2015 the same day that OSHA submitted its most recent ICR[6] and OMB has yet to act on this submission. This lapse is not unprecedented, however. OMB records show that this Control Number also lapsed from March 1, 2002 through June 10, 2002 (101 days), August 1, 2006 through October 10, 2006 (70 days), and from November 1, 2009 through January 7, 2010 (67 days).

In the absence of a valid OMB Control Number, paperwork requirements in the HCS are legally unenforceable.[7] Nonetheless, we are unaware of any evidence suggesting that regulated entities have taken advantage of these lapse periods to evade or forego compliance. In particular, CPDA members are committed to complying with HCS 2012 to the best of their ability. The problem they face is that it is impossible for them to comply with certain provisions without violating others. We have explained these problems to OSHA and to OMB in a pair of public comments.[8]

We have also chronicled in our comments how OSHA has defied the PRA's procedural and substantive requirements. This is manifest in OSHA's Supporting Statement,[9] which contains numerous errors of commission and omission, including:

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[4] *Dole v. United Steelworkers of America*, 494 U.S. 26 (February 21, 1990).

[5] See Office of Information and Regulatory Affairs, *OMB Control Number History; OMB Control Number: 1218-0072*, OMB/GSA(2016), available at http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=1218-0072. Emergency processing of ICRs is provided by OMB's 5 C.F.R. § 1320.13. Such requests must be accompanied by a certification of several facts, none of which appear to have been in evidence at the time and which, in any case, OMB need not confirm are correct.

[6] Supra, note 2.

[7] 44 U.S.C. § 3512.

[8] Our most recent comment, dated December 23, 2015, includes as an attachment our comments dated July 30, 2015, and is attached to this petition as Appendix A. *See also* Council of Producers & Distributors of Agrotechnology, Additional Comment - Agency Information Collection Activities; Submission for OMB Review; Comment Request; Hazard Communication Standard; Notice (OMB Control No. 1218-0072; 80 FR 36856 (June 26, 2015).

[9] Occupational Safety and Health Administration, *Supporting Statement for the Revised Hazard Communication Standard* (29 CFR 1910.1200, 1915.1200, 1917.28, 1918.90, 1926.59, and 1928.21)

- No evidence of actual practical utility, as required by 5 C.F.R. § 1320.4(l). [10]

- Burden estimates that are fatally flawed with respect to the burdens OSHA deigned to estimate. For example:

  - OSHA assumed without substantiation that initial classification and labeling requirements in HCS 2012 apply to only a small fraction of covered substances. This assumption is false, and if it were corrected the actual burden of classification and labeling would be a large multiple of OSHA's estimate, exceeding $500 million over the 3-year approval term. These paperwork burdens of this clearly major rule are greater if they are spread out over the 3-year ICR approval period instead of a 4-year regulatory implementation period.

  - OSHA provides no evidence that any of its burden estimates has an objective basis, as required by 5 C.F.R. § 1230.8(a)(4).

- Missing estimates for those burdens OSHA deemed to be incremental, as though baseline burdens are not cognizable under the PRA. This violates law, regulation and 35 years of federal agency practice. No permissible distinction may be made between the baseline and incremental burdens of a federal information collection. Both require OMB approval, and both must be estimated and included.

- OSHA does not acknowledge the existence of a significant paperwork burden related to HCS 2012 regulatory requirements even though the requirement is unambiguously incremental, and thus would be counted even under OSHA's incorrect reading of the law. The purposes of the PRA are undermined if agencies are permitted to strategically and willfully fail to acknowledge and account for significant paperwork burdens.

  - A minor text revision to the Standard in HCS 2012 results in the "dynamic" requirement to relabel hazardous chemical product containers within six months of becoming aware of new information. Millions of already compliantly labeled containers residing in warehouses may need to be relabeled, at extreme expense, at any time over the future of the HCS as

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Incorporating Globally Harmonized System of Classification and Labelling of Chemicals (OMB Control No. 1218-0072; February 2012).

[10] The Supporting Statement could have recycled benefit estimates from OSHA's Regulatory Impact Analysis, but these unsupported estimates are charitably described as fanciful. *See* Occupational Safety and Health Administration, *Hazard Communication; Final Rule*, 77 Fed. Reg. 17574, 17605-17606 (March 26, 2012).

written. The Agency did not consider the technical or economic feasibility of relabeling product containers.[11]

These errors also are clear violations of the Information Quality Act (IQA, codified at 44 U.S.C. 3516 note) and applicable OMB and OSHA guidance.[12] Because OMB is the statutorily designated agency responsible for ensuring OSHA's compliance with the IQA, and OMB is by now aware of these errors, the public interest is not served by filing a separate request for correction to OSHA.

With respect to these technical matters, OMB must deny OSHA an ICR approval unless and until the public has been provided a meaningful opportunity to comment on corrected estimates to ensure a reasonable degree of PRA compliance. Approving this ICR without effective error correction would tacitly justify OSHA's willful noncompliance with core statutory and regulatory requirements.

The public never had a meaningful opportunity to comment on the actual relabeling burdens in HCS 2012. In the preamble to the final rule, OSHA responded to public comments on the cost of relabeling by denying that it would ever occur. The Supporting Statement for OSHA's June 2015 ICR also did not provide updated burden estimates for relabeling from the ICR that OMB most recently approved.[13] OSHA instead denies that there is a burden to affixing labels because manufacturers presumably do it at no cost. Thus, OSHA ignored relabeling burdens in two ways: (1) denying that HCS 2012 imposed any such burdens on employers other than manufacturers, and (2) assuming relabeling burdens borne by manufacturers are costless. OMB must deny OSHA's request for an approval for the imposition of paperwork burdens that the agency says do not exist, or which exist but OSHA incorrectly deems to be exempt under the PRA.

II. RECENT DEVELOPMENTS

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[11] Over 95% of "manufacturing" sector firms writing SDSs and 97.5% of firms associated with warehousing and transportation ("non-manufacturing" sector), are small firms as defined by OSHA. Information provided by CPDA hazardous chemical manufacturing and distribution members reveals that the cost of relabeling an individual container represents from 10%-200% of the value of the container residing in a warehouse and awaiting shipment.

[12] Office of Management and Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication* (67 Fed. Reg. 8452; February 22, 2002); Occupational Safety and Health Administration, OSHA Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor (October 1, 2002).

[13] Office of Information and Regulatory Affairs, *ICR Reference No: 201506-1218-001; Hazard Communication (29 CFR 1910.1200, 1915.1200, 1917.28, 1918.90, 1926.59, and 1928.21)*, OIRA/GSA(2012), *available at* http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201203-1218-001.

Since OSHA submitted the June 2015 ICR, several important events have occurred. Each of these developments indicates that OSHA has no intention of correcting the errors that CPDA and others have identified. Indeed, it appears that these errors were features rather than bugs in OSHA's regulatory design for HCS 2012.

A. <u>OSHA's July 2015 Enforcement Directive added new burdensome regulatory requirements containing significant new paperwork burdens, all without notice and comment under the Administrative Procedure Act or the Paperwork Reduction Act.</u>

In July 2015, OSHA published an instruction directive for OSHA inspectors enforcing HCS 2012 (hereinafter "Enforcement Directive").[14] This document is troubling for several reasons, which we summarized in our December 2015 supplemental public comment to OMB. It includes several major new regulatory requirements that were not subjected to notice-and-comment rulemaking as required by the Administrative Procedure Act (APA). These new regulatory requirements also have no substantive merit because they do not provide employees any additional protection from hazardous substances in the workplace. According to longstanding OMB policy, agencies may not use guidance to impose regulatory requirements that adversely affect the public.[15]

These new regulatory requirements impose substantial new paperwork burdens beyond those contained in HCS 2012. Independent of APA compliance, these paperwork burdens could have been included in OSHA's June 2015 ICR. After all, they were under development at least since the beginning of 2015 and are partially included in interim enforcement guidance published in February [16] and May.[17] Nonetheless, OSHA did not include these paperwork burdens in its June 2015 ICR and the reason why is publicly unknown.

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[14] Occupational Safety and Health Administration, *OSHA Instruction Directive Number CPL 02-02-079: Inspection Procedures for the Hazard Communication Standard (HCS 2012)*; Effective Date July 9, 2015.

[15] Office of Management and Budget, *Final Bulletin for Agency Good Guidance Practices*, 72 Fed. Reg. 3432 (January 25, 2007). OSHA's resort to guidance in this instance also is contrary to the Administrative Procedure Act and applicable case law. See, e.g., *Chamber of Commerce* v. *Dep't of Labor,* 174 F.3d 206 (D.C. Cir. 1999) (striking down an OSHA Directive as legislative rule requiring notice and comment).

[16] Occupational Safety and Health Administration, *Enforcement Guidance for the Hazard Communication Standard's (HCS)* (February 9, 2015; June 1, 2015 Effective Date), available at https://www.osha.gov/dep/enforcement/hazcom_enforcement-memo.html.

[17] Occupational Safety and Health Administration, *Interim Enforcement Guidance for Hazard Communication 2012* (May 29, 2015; Effective Date June 1, 2015), available at https://www.osha.gov/dep/enforcement/hcs_guide_052015.html.

Our petition seeks a formal OMB opinion as to whether OMB Control No. 1218-0072, if OMB were to renew it, covers burdens related to new regulatory requirements contained in the July 2015 Enforcement Directive even though they are not mentioned in the ICR. The PRA requires agencies to clearly identify, and seek public comment on, exactly what is to be covered by an ICR. Allowing agencies to infer coverage for paperwork burdens nowhere mentioned in an ICR, much less estimated, would undermine the purposes of the PRA.

B. OSHA denied CPDA's request for a common-sense letter of interpretation adapting the container relabeling rule the Environmental Protection Agency applies to pesticides.

On December 11, 2014, CPDA submitted to OSHA a formal request for a letter of interpretation that would allow distributors to comply with HCS 2012 in the same manner they are legally permitted by the U.S. Environmental Protection Agency (EPA) to comply with respect to pesticides.[18] Under this approach, distributors handling sealed containers of hazardous chemicals, labeled in compliance with the HCS when manufactured, would remain exempt from HCS 2012 relabeling requirements. Because substances covered by the HCS are predominantly less hazardous than pesticides, allowing compliance in the same manner would impose no new occupational safety and health risks, or user risks, while significantly reducing the paperwork burden.

In September 2015, OSHA denied our request, stating *inter alia* that it rejected CPDA's proposal because the agency believes that HCS 2012 was designed to protect the safety of "downstream consumers" as well as distributors' employees.[19,20] This is deeply troubling for at least three reasons.

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[18] Susan Ferenc, Letter to Maureen Ruskin "Re: Request for a Letter of Interpretation that Clarifies the Container Label for a Category of Non-Pesticide Agrichemical Products, Labeled in Accordance with the HCS When Initially Shipped From the Manufacturer/Importer, as Compliant with HCS 2012 for the Life of the Product."

[19] September 2015 letter of Thomas Galassi, Director, Directorate of Enforcement Programs, OSHA, responding to an industry "Request for a Letter of Interpretation that Clarifies the Container Label for a Category of Non-Pesticide Agrichemical Products, Labeled in Accordance with the HCS When Initially Shipped From the Manufacturer/Importer, as Compliant with HCS 2012 for the Life of the Product." A copy is attached as Appendix B.

[20] Similarly, OSHA denied the August 12, 2014 industry-submitted "Petition to Reopen Rulemaking On The Hazard Communication Standard, 29 C.F.R. § 1910.1200, To Extend Time For Implementation." In the undated response letter from Dr. David Michaels, Assistant Secretary of Labor, OSHA, the nine chemical industry trade organization signatories were separately told: "The Agency understands the complexity and scale of the changes required of manufacturers during this transition period. However, the Agency continues to believe that the Hazard Communication

First, OSHA provided neither a logical explanation nor evidence that "downstream consumers" would bear any incremental risk if OSHA adopted EPA's regulatory approach. Because EPA's regulation has no adverse effect on "downstream consumers" of pesticides, OSHA's stated reason for denying our request is without merit.

Second, nothing in HCS 2012 offers any potential benefit to "downstream consumers." It includes no regulatory provisions that require manufacturers, importers, distributors or retailers - or anyone else - to provide consumers the training they presumably would need to understand HCS 2012 labels, much less act on this information. If OSHA believes that "downstream consumers" benefit without training, then the extensive and burdensome training requirements in HCS 2012 that apply to manufacturers, importers and distributors are superfluous and OSHA could rescind them without adverse effect on employees.[21]

Third, OSHA lacks any statutory authority to promulgate regulations for the purpose of protecting "downstream consumers." Of course, no one would object if downstream consumers benefited coincidentally, but as noted above, there is neither logic nor evidence suggesting that such benefits are even feasible. It would be unconscionable for OSHA to effectively impose significant occupational safety and health risks on warehouse employees in pursuit of imaginary benefits to persons outside the ambit of the Occupational Safety and Health Act.

CPDA's petition seeks a formal OMB opinion concerning whether the potential for new occupational safety and health risks on warehouse employees, particularly for the purpose of protecting "downstream consumers," is consistent with 44 U.S.C. §§ 3501 and 3508 in the absence of statutory authority and clear and convincing evidence of substantial actual practical utility.[22]

Standard as currently designed *is necessary for the long-term safety of downstream consumers*." (emphasis added)

[21] OSHA's logic also implies that the burdens imposed by training requirements have no actual practical utility, and thus cannot be approved by OMB because the demonstration of actual practical utility is a mandatory provision in OMB's Information Collection Rule.

[22] As set forth in section 3501, the primary purposes of the PRA are to (1) " minimize the paperwork burden for individuals, small businesses, educational and nonprofit institutions, Federal contractors, State, local and tribal governments, and other persons resulting from the collection of information by or for the Federal Government," and (2) to "ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government." The gratuitous creation of occupational safety and health risks to consumers is inherently inconsistent with these purposes. Section 3508 further directs OMB to "determine whether the collection of information by the agency is necessary for the proper performance of the functions of the agency …"

CDPA is no longer interested in a letter of interpretation because we are now convinced that any regulatory relief that might be provided would be uncertain and unstable. Our position has changed because of OSHA's recent revocation of a longstanding letter of interpretation on which other regulated parties have reasonably relied for almost two decades. In a notice published on July 22, 2015,[23] OSHA revoked a letter of interpretation issued in 1994[24] concerning its 1992 Process Safety Management Rule.[25] We are understandably concerned that if OSHA could take this action, without notice and comment and arguably without merit, it could just as easily revoke, at any time and for any reason, any letter of interpretation the agency might provide to our members and others similarly situated.[26]

Moreover, it is now abundantly clear that OSHA will not budge until and unless affected parties bear the expense of filing suit in federal district court, or some other administrative action is taken. By filing this petition we have chosen at this time to first take the administrative route. The PRA is the best available venue for securing administrative relief, and the PRA grants OMB all the necessary statutory authority to secure it.

We are now convinced that only a revision of the text in HCS 2012 can provide certain and appropriate relief. Therefore, concurrently with this petition to OMB we have identified specific regulatory changes needed in a separate joint petition submitted to OSHA ("Joint Petition") to restore a common-sense understanding of

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[23] Thomas Galassi, Director, Directorate of Enforcement Programs, OSHA; Process Safety Management of Highly Hazardous Chemicals and Application of the Retail Exemption (29 CFR 1910.119(a)(2)(i)) (July 22, 2015).

[24] Occupational Safety and Health Administration, OSHA Instruction CPL 2-2.45A CH-1; Subject: 29 CFR 1910.119, Process Safety Management [PSM] of Highly Hazardous Chemicals and Application of the Retail Exemption - Compliance Guidelines and Enforcement Procedures (September 13, 1994).

[25] Occupational Safety and Health Administration, *Process Safety Management of Highly Hazardous Chemicals; Explosives and Blasting Agents*; 57 Fed. Reg. 6356 (February 24, 1992).

[26] OSHA's revocation of its 1992 letter of interpretation illustrates why letters of interpretation no longer offer a reliable remedy for the type of problems described herein. In a press release issued by the Agricultural Retailers Association after Congress included a rider in the FY 2016 appropriation bill temporarily prohibiting OSHA from moving forward, ARA Chairman and CEO of Premier Ag Cooperative Harold Cooper states, "OSHA intentionally exempted ag[ricultural products] retailers from PSM since the rule's inception in 1992. Forcing us to comply with regulations aimed at manufacturers would cost my business at least $60,000, and not provide any improvement in worker safety - just more bureaucratic red tape" (emphasis added). *See* Agricultural Retailers Association, *Congress Stalls OSHA Overreach*, ARA, (2015), available at http://www.aradc.org/blogs/brian-reuwee/2015/12/22/congress-stalls-osha-overreach. A similar conclusion is appropriate in the case of distributors forced to act as if they are manufacturers under HCS 2012, as OSHA's enforcement guidance requires.

HCS 2012 with respect to the relabeling of sealed containers .[27] These proposed changes are summarized below in Section III.

III. SUMMARY OF THE JOINT PETITION TO OSHA SEEKING COMMON-SENSE RELIEF FROM THE DANGEROUS RELABELING REQUIREMENTS IN HCS 2012 AND THE JULY 2015 ENFORCEMENT DIRECTIVE

The Joint Petition submitted to OSHA explains clearly why the agency's relabeling requirements offer no occupational safety and health benefits to employees and are unduly burdensome and inappropriate for warehouse owners and employers. The Joint Petition also explains why compliance is technically and economically infeasible unless warehouse owners and employers forego a longstanding exemption for the relabeling of sealed containers in warehouses.[28] This exemption has been part of the HCS regulatory framework for decades, and OSHA's July 2015 Enforcement Directive surreptitiously takes it away.

The Joint Petition asks OSHA to initiate a rulemaking to revise HCS 2012 in a common-sense way that prevents unintended noncompliance and protects warehouse employees from the avoidable and significant new occupational safety and health risks caused by the very regulation that is supposed to prevent such risks. For OMB's convenience, we summarize below key points from the Joint Petition in subsections A-D and, to illustrate the important issues addressed , Subsection E describes our recommended revision of paragraph (f)(11) of HCS 2012[29] that provides a simple solution.

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[27] Petition to Revise HCS 2012 to Clarify Application of the Sealed Container Exception. This petition for rulemaking emphasizes a somewhat different set of issues than those raised by other petitioners. We hope that OSHA will be more receptive to our petition than it has been to others. A copy is attached as Appendix C.

[28] 29 C.F.R. §1910.1200(b)(4). Paragraph (b)(4) and subparagraph (b)(4)(i) state: "[i]n work operations where employees only handle chemicals in sealed containers which are not opened under normal conditions of use (such as are found in marine cargo handling, warehousing, or retail sales), this section applies to these operations only as follows: (b)(4)(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or def aced."

[29] 29 C.F.R. §1910.1200(f)(11). "Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again. "

A. HCS 1994-compliant products only temporarily escape HCS 2012 relabeling requirements.

HCS 2012 permitted distributors to ship containers of hazardous chemicals with HCS 1994-compliant labels until December 1, 2015. The Enforcement Directive extended this grace period an additional two years. However, many products containing hazardous substances are manufactured occasionally or periodically in batches, are manufactured more than a year before sale, and have shelf lives measured in *many* years. The Enforcement Directive requires any of these products remaining under the control of a distributor after December 1, 2017 be relabeled in accordance with paragraph (f)(11).

B. Temporary enforcement forbearance for HCS 1994-compliant labeled product comes at a high cost.

The Enforcement Directive further states that distributors must provide an HCS 2012-compliant label "for *each and every individual container"* of HCS 1994-compliant labeled product shipped after December 1, 2015. This entails the printing of potentially millions of labels and somehow transmitting them with each shipment. Additionally, there is nothing in HCS 2012 or the Enforcement Directive that describes what recipients must do with the labels, since they cannot apply them to the containers.

The Supporting Statement for OSHA's June 2015 ICR does not even acknowledge that these burdens exist.

C. HCS 2012-compliant products *never* escape HCS 2012 relabeling requirements.

On December 1, 2015, compliance requirements also changed for all product labeled after June 1, 2015. As interpreted by OSHA in the Enforcement Directive, HCS 2012 prohibits the shipment of product after six months of becoming aware of significant new information (e.g., receiving a new safety data sheet) unless all individual containers have been relabeled. The problem is OSHA's switch from a "hazard determination" approach to "hazard classification" approach results in a vast change in scope of paragraph (f)(11). It now applies to an untold and unpredictable number of products manufactured and labeled in compliance with HCS 1994 or HCS 2012, and to virtually every firm in the supply chain prior to retail .[30]

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[30] In fact, products now residing in warehouses, manufactured only with inputs bearing HCS 2012 - compliant labels produced on or before June 1, 2015 are already out of compliance with paragraph (f)(11) due to receipt of significant new information from upstream suppliers.

There are no provisions in the final rule that address *how* relabeling is to be to be accomplished; the Enforcement Directive offers no insight; and t he Supporting Statement for OSHA's June 2015 ICR denies that these burdens exist.[31]

D. OSHA's July 2015 Enforcement Directive clarifies these requirements by making them worse.

The Enforcement Directive further states that containers bearing an HCS 1994-compliant label in the control of a distributor after December 1, 2017 must be labeled in compliance with HCS 2012 prior to shipping. Thus, it appears that distributors must remove HCS 1994 compliant labels, *in violation of paragraph (b)(4)(i)*, then affix new labels to each and every individual sealed container.[32] The Enforcement Directive clearly states that after December 1, 2015, "[d]istributors must ship containers that are compliant with HCS 2012." [33]

This relabeling of each and every individual container effectively requires employers to forego the sealed container exemption in paragraph (b)(4)(i). This exemption, which has been in place for decades, ensures labeling requirements that are relevant only for employees engaged in manufacturing do not apply to non-manufacturing employees, whose employment does not contemplate these tasks . Moreover, the Supporting Statement for OSHA's June 2015 ICR also does not acknowledge that the Enforcement Directive implicitly establishes a new, restrictive and burdensome definition of "label."

E. A simple, effective, and worker-protective proposed revision to HCS 2012 .

The Joint Petition proposes the following common -sense amendment to HCS 2012. The first paragraph would alter only one word. By changing the locus of applicability from products *shipped* to products *manufactured*, this revised text would ensure that products correctly labeled when manufactured do not have to be later relabeled at extraordinary expense to firms and occupational risks to their employees. The second paragraph would establish a safe harbor for operations handling sealed containers that were properly labeled when manufactured , and which do not pose manufacturing -like risks to employees who handle them.

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[31] Supporting Statement For The Hazard Communication Standard (29 CFR 1910.1200, 1915.1200, 1917.28, 1918.90, and 1928.21)(Office of Management and Budget Control No. 1218 -0072 (April 2015)). Exhibit A -1, Item 9: "Labeling Shipping Containers (§ 1910.1200(f)) . There is no burden for affixing labels to off -site containers because it is usual and customary practice for manufacturers to affix labels to containers being shipped. "

[32] Supra, note 14 at 21.

[33] Id. at 82.

Revision to 29 C.F.R. § 1900.1200(f)(11)

> Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals ~~shipped~~ manufactured after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.
>
> For work operations where employees handle chemicals only in sealed containers that are not opened under normal conditions of handling (such as found in marine cargo handling, warehousing, or retail sales), the manufacturer, importer, distributor, or employer may comply with this section by ensuring that an updated label is provided at the time those containers are shipped.

This text would ensure that warehouse employees remain fully protected from occupational safety and health risks resulting from activities outside the normal scope of their employment. Timely transmission of updated label information to downstream employers would be achieved by providing one label with each shipment. This approach to informing employees of new health and safety information is no different than the long-established approach retained by OSHA in paragraphs (g)(6), (7) and (8) of HCS 2012 for providing access to and transmitting safety data sheet information, including updates, throughout the chemical supply chain to employers and users.

The history of deliberations on this ICR has been extensive and content-rich. However, there is no public evidence of meaningful progress toward an acceptable solution. The Joint Petition seeks constructively to break the impasse. The signatories are united in their willingness to abide by reasonable hazard communication rules but not when it comes to putting their members' employees at risk. We are hopeful that OSHA this time will be convinced of the need to revise HCS 2012.

IV. ELEMENTS OF OUR PETITION TO OMB SEEKING ADMINISTRATIVE RELIEF AS AUTHORIZED BY THE PAPERWORK REDUCTION ACT

That hope is not unbounded, however, and for that reason CPDA also seeks administrative relief that only OMB can provide.

HCS 2012 is a high-profile member of the narrow class of regulations for which paperwork burden comprises a large fraction of regulatory costs. Therefore, the PRA provides a uniquely appropriate administrative venue. Indeed, when Congress enacted the PRA it expected OMB to resolve paperwork controversies without injured parties having to bear the expense of appealing to Article III courts for relief. Congress delegated administrative authority to OMB to monitor and enforce agency compliance with the PRA, and it provided an explicit statutory route by which the public could seek formal action by OMB in 44 U.S.C. § 3517(b).

A. <u>Congress has delegated to OMB all the authority necessary to correct the nonsensical relabeling provisions in HCS 2012 and the July 2015 Enforcement Directive.</u>

The PRA grants the following authorities to OMB, which are unlike those held by any other federal agency. These authorities are found in statute and the Information Collection Rule promulgated by OMB in 1995. Specifically:

- OMB has statutory authority to "determine whether the collection of information by [an] agency is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility." See 44 U.S.C. § 3508.

- OMB has regulatory authority to determine whether an information collection is "the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives." See 5 C.F.R. § 1320.5(d)(1)(i).

- OMB has regulatory authority to determine "whether any collection of information or other matter is within the scope of the Act." See 5 C.F.R. § 1320.18(a).

- OMB has regulatory authority to "initiate a rulemaking proceeding to determine whether an agency's collection of information is consistent with statutory standards" and "in accordance with the informal rulemaking procedures of the Administrative Procedure Act." See 5 C.F.R. § 1320.18(b).

We ask OMB to exercise each of these authorities in the case of OMB Control No. 1218-0072 and the ICR under review. We also ask OMB to ensure that OSHA submits to OIRA the required draft status reports on its retrospective review of the HCS, as required for "existing significant regulations" by section 4 of Executive Order 13610 and related review plans developed under section 6 of Executive Order

13563.[34] According to an August 2014 Department of Labor summary of retrospective review plan reports of its agencies and sub-agencies, the HCS is not among the listed retrospective reviews.

B. The imposition of regulatory requirements and paperwork burdens that put employees at risk without actual practical utility is contrary to the statutory purposes of the Paperwork Reduction Act.

Under 44 U.S.C. § 3708 and 5 C.F.R. § 1320.5(d)(1)(i), OMB should determine that the imposition of paperwork burdens that have no actual practical utility and unambiguously create new occupational safety and health risks is not necessary for the proper performance of OSHA's functions and is inconsistent with the purposes of the PRA, as set forth in 44 U.S.C. § 3501, and thus is not approvable by OMB. This could be accomplished by direct disapproval or by terms of clearance that explicitly exclude from OMB approval paperwork burdens and non-burden hour costs that create new occupational safety and health risks without any benefit to affected employees.

C. OMB should deny clearance for paperwork burdens contained in HCS 2012, but neither acknowledged by OSHA nor included in its ICR.

Under 5 C.F.R. § 1320.18(a), OMB should determine that certain paperwork burdens imposed by HCS 2012 are cognizable under the PRA but not approvable as part of OSHA's June 2015 ICR because they are missing from OSHA's submission. To implement this determination, OMB should use terms of clearance to explicitly state that only the information collection requirements clearly identified in the Supporting Statement are approvable. In particular, OMB should note that paperwork burdens contained in the relabeling provision (29 C.F.R. §1910.1200(f)(11)) are not approved unless and until OSHA submits a revised ICR.

OMB should sustain this exclusion in each subsequent ICR submitted for OMB Control No. 1218-0072 unless and until OSHA complies with all material procedural and substantive requirements of the PRA with respect to the excluded information. This includes a new and complete 60-day notice containing an objective basis for each burden estimate, an opportunity for meaningful public comment, and a good-faith response to public comments received.

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[34] Executive Order 13610, *Identifying and Reducing Regulatory Burdens*, 77 Fed. Reg. 28469 (May 14, 2012); Executive Order 13563, *Improving Regulation and Regulatory Review*, 76 Fed. Reg. 3821 (January 21, 2011).

D. OMB should deny clearance for paperwork burdens contained in OSHA's July 2015 Enforcement Directive.

Under 5 C.F.R. § 1320.18(a), OMB should determine that paperwork burdens imposed by OSHA's July 2015 Enforcement Directive are cognizable under the PRA but not approvable as part of OSHA's June 2015 ICR because they are missing from OSHA's submission. Further, OMB should clearly state that these burdens are not approvable unless and until OSHA submits an ICR that includes them, with such ICR fully complying with all material requirements of the PRA. Specific paperwork burdens contained in the Enforcement Directive but not in HCS 2012 should be mentioned as examples, such as the reasonable diligence requirement, relabeling of HCS-compliant containers, and the burden-exacerbating requirement to accompany shipments with paper labels for *each and every* container in a shipment.

Because the Enforcement Directive imposes substantial new regulatory requirements without notice and comment, as required by the Administrative Procedure Act, OMB also should consider whether information collection requirements resulting from regulatory requirements contained in guidance are even eligible for approval under the PRA.

E. OMB should initiate rulemaking proceedings to determine whether the paperwork burdens manifest in the relabeling requirements of HCS 2012 and the July 2015 Enforcement Directive are consistent with statutory standards.

Under 5 C.F.R. § 1320.18(b), OMB should initiate a rulemaking to determine whether certain provisions of HCS 2012, in combination with the July 2015 Enforcement Directive, are consistent with statutory standards to protect employees from significant occupational safety and health risks. Sections 1320.5(d)(1) and (2) state that an agency shall not conduct or sponsor a collection of information unless, in advance of its adoption or revision, the agency has "demonstrate[d] that it has taken every reasonable step to ensure that" the "collection of information is necessary to satisfy statutory requirements or other substantial need." As noted above, OMB has explicit statutory authority under 44 U.S.C. § 3508 to direct OSHA not to engage in the collection of information that is not necessary for the proper performance of its statutory functions.

Under Section 5(a) of the Occupational Safety and Health Act (OSH Act), employers are required to furnish "place[s] of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm." However, the relabeling provisions in HCS 2012, combined with the surreptitious revocation of the HCS sealed container exemption in the July 2015 Enforcement Directive, requires that warehouse owners and employers impose on their

employees precisely the kind of unsafe work environment that Section 5(a) prohibits.

Denying approval to OSHA, as OMB has done to date, would prevent the agency from legally imposing penalties against employers who refuse to put their employees in harm's way.

V. CONCLUSION

CPDA appreciates OMB's sustained interest in this ICR and its evident willingness to expect OSHA's full compliance with the PRA. CPDA looks forward to a favorable response by OMB to this petition.

APPENDIX A: Additional Comment - Agency Information Collection Activities; Submission for OMB Review; Comment Request; Hazard Communication Standard; Notice. (OMB Control No. 1218-0072); 80 FR 36856 (June 26, 2015).

COUNCIL OF PRODUCERS & DISTRIBUTORS OF AGROTECHNOLOGY

December 23, 2015

VIA E-MAIL (OIRA_submission@omb.eop.gov)

Office of Information and Regulatory Affairs
ATTN: OMB Desk Officer for DOL-OSHA
Office of Management and Budget
725 17th Street, NW
Room 10235
Washington, DC 20503

Additional Comment - Agency Information Collection Activities; Submission for OMB Review; Comment Request; Hazard Communication Standard; Notice. (OMB Control No. 1218-0072); 80 FR 36856 (June 26, 2015).

The Council of Producers & Distributors of Agrotechnology (CPDA) provided comments to the Office of Management and Budget in July 2015 concerning the above-referenced ICR Reference Number ("Hazard Communication Standard").[1] We are writing to improve the administrative record by supplementing this public comment based on information we have gathered since then.

As we noted previously, CPDA is the preeminent U.S. based trade association representing the interests of the agrotechnology products industry, including manufacturers, suppliers, formulators and distributors. More than 10 million agrotechnology end-use product containers such as tank-mix adjuvants and bags of fertilizer are manufactured and distributed annually. This represents more than 10% of the 94 9 million shipped containers of hazardous chemicals identified by the Occupational Safety and Health Administration (OSHA).[2] Small, medium and large businesses involved in this distribution system are directly affected by HCS 2012.

In a recently published HCS 2012 Enforcement Directive (Directive),[3] OSHA acknowledges the significant changes HCS 2012 made to decades-long practices in occupational hazard communication:

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[1] Council of Producers & Distributors of Agrotechnology. 2015. *Letter to Office of Information and Regulatory Affairs Re: Agency Information Collection Activities; Submission for OMB Review; Comment Request; Hazard Communication Standard; Notice. (OMB Control No. 1218 0072); 80 FR 36856 (June 26, 2015),* July 30, 2015 (not posted by OMB on www.reginfo,gov; copy included as Attachment A).

[2] OSHA. 2015. *Supporting Statement for the Hazard Communication Standard (29 CFR 1910.1200, 1915.1200, 1917.28, 1918.90, 1926.59, and 1928.21) (June 2015)* (hereinafter "2015 ICR Supporting Statement").

[3] Occupational Safety and Health Administration. 2015. *OSHA Instruction Directive Number CPL 02 02 079: Inspection Procedures for the Hazard Communication Standard (HCS 2012); Effective Date July 9, 2015* (hereinafter, "Directive").

> The revised standard changes "hazard determination" to the specific requirements for hazard classification of chemicals, standardizes label elements for containers of hazardous chemicals, and specifies the format and required content for [safety data sheets, or SDSs]...Chemicals must be evaluated in accordance with specific guidance outlined in Appendices A and B of the standard. The hazard classification will result in the specification of pictograms, signal word, hazard statements, and precautionary statements which [*sic*] must be included on the labels. Specifications for these label elements are provided in Appendix C of the standard. The SDSs will have a standardized 16-section format (see Appendix D of the standard) and includes the information from the hazard classification (e.g., hazard class, pictogram).

Thus, OSHA acknowledges that HCS 2012 was not merely an exercise in harmonizing U.S. and international occupational hazard communication. Rather, it is a fundamental policy realignment in which OSHA implies that it no longer believes that HCS 1994 was effective. [4]

I. AMENDMENT OF CPDA'S JULY 2015 COMMENTS ON THE ICR

CPDA's initial comments emphasized that OSHA's demonstration of practical utility and burden estimation methodology for the HCS 2012 ICR, referenced in the 2015 extension request, are fundamentally flawed and biased in several ways. Since submission of those comments we have identified new regulatory requirements and significant paperwork burdens that the Agency imposed prior to submission of the HCS 2012 ICR extension request in June 2015. However, these burdens were not included in OSHA's request. For example:

1. Re-labeling of manufactured product in inventory is required [5] if a distributor (a) becomes aware of significant new information from upstream sources that affects labels on HCS 2012-compliant labeled product or (b) has HCS 1994-compliant labeled product in distribution after December 2017.[6] OSHA denied that there is any burden associated with the HCS 2012 requirement to affix revised labels to products that were properly labeled when manufactured.[7]

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[4] See, e.g., the HCS 2012 Regulatory Impact Analysis ("RIA"): "[T]he performance oriented requirements of [HCS 1994] that do not specify how the information should be presented in SDSs have led manufacturers to provide widely varying and confusing information about identical chemicals." Policy Planning & Evaluation Inc., "Data and Analysis in Support of an Economic Analysis of Proposed Changes to the OSHA Hazard Communication Standard; Revised Final Report," Herndon VA: Policy Planning & Evaluation, Inc., p. 2.

[5] HCS 2012 §(f)(11) "Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again."

[6] Directive p. 43. Shipped Containers. "All containers in the control of a distributor after December 1, 2017, must be HCS 2012 compliant labeled prior to shipping."

[7] 2015 ICR Supporting Statement, p. 20. Exhibit A 1 Basic Values for the Analysis 10. Labeling Shipping Containers (§ 1910.1200(f)) "There is no burden for affixing labels to off site containers because it is usual and customary practice for manufacturers to affix labels to containers being shipped."

2. OSHA was aware of, but nonetheless ignored, substantial occupational safety and health risks resulting from compliance requirements imposed on distributors to re-label products in warehouses that were correctly and compliantly labeled when produced.

3. OSHA does not discuss, much less demonstrably show, actual practical utility for any specific HCS 2012 provision containing a paperwork burden, as required by 5 CFR § 1320.3(l). [8] A prima facie case for actual practical utility requires evidence that occupational safety and health risks would decline because of the rule. OSHA's Supporting Statement for this ICR does not even mention practical utility,[9] and OSHA's Regulatory Impact Analysis (RIA) for HCS 2012[10] contained only speculative and hypothetical claims about social benefits, the economic analogue for practical utility.[11]

II. FURTHER INFORMATION ON THE REGULATORY IMPACTS OF HCS 2012 PRIOR TO AND AFTER OUR JULY 2015 COMMENTS ON THE ICR

In December 2014 we submitted to OSHA a request for a letter of interpretation that would have adopted the U.S. Environmental Protection Agency's (EPA) policy on re-labeling pesticides. This language would have dramatically reduced the burden of HCS 2012 while enabling CPDA members (and no doubt, many other employers) to avoid imposing on employees the serious new occupational safety and health risks that otherwise will result from by-the-book compliance.

A. CPDA's December 2014 Request for Interpretation

As noted previously, approximately 10 million individual "end-use" product containers of non-pesticide agricultural chemical products, such as jugs of adjuvant or bags of fertilizer, are produced each year. These packaged-for-shipment products are warehoused in distribution centers and sold through wholesale or retail sales to employers/farmers. Because of the long shelf-life character of these products, approximately 2.5 million of these containers (in boxes, on pallets, shrink-wrapped, etc.) are returned to distributors' (not manufacturers') warehouses for resale each year. This cycle of movement within distribution channels often continues for many years.

In December 2014, CPDA emailed Maureen Ruskin, Director of OSHA's Office of Chemical Hazards (Metals) requesting a letter of interpretation.[12] We asked OSHA to adopt an

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[8] "*Practical utility* means 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, and the agency's ability to process the information it collects (or a person's ability to receive and process that which is disclosed, in the case of a third party or public disclosure) in a useful and timely fashion…" (emphasis added).

[9] 2015 ICR Supporting Statement.

[10] HCS 2012 RIA, p. 59.

[11] The RIA makes qualitative claims for three types of benefits: (1) benefits from reduced government failure through the amelioration of inefficiencies resulting from HCS 1994, which may be overwhelmed by new regulatory failures in HCS 2012; (2) hypothetical reductions in occupational risk; and (3) speculative benefits from avoiding HCS 2012 through product reformulation motivated and reduced employee training costs.

[12] CPDA Letter to Maureen Ruskin *Re: Request for a Letter of Interpretation that Clarifies the Container Label for a Category of Non Pesticide Agrichemical Products, Labeled in Accordance with the HCS When Initially Shipped From the Manufacturer/Importer, as Compliant with HCS 2012 for the Life of the Product,"* December 14, 2014 (copy included as Attachment B).

interpretation of EPA's regulatory term of art "released for shipment." [13] EPA's language exempts manufactured pesticidal products already in commerce from individual container re-labeling. If OSHA adopted this language and policy, products in CPDA members' warehouses and distribution centers would not require re-labeling if they bore HCS 1994-compliant or HCS-2012 compliant labels, as applicable based on the date of manufacture. lf significant new information became available at any time subsequent to manufacture, distributors could supply downstream customers updated SDSs but would not be required to bear the extraordinary financial and significant occupational safety and health risks of re-labeling products in warehouses.

CPDA explained in detail that if text in HCS 2012 were not interpreted this way, warehouse workers of CPDA members may incur suffer physical, ergonomic, and health risks from breaking down pallets, opening boxes, removing old labels, hand-affixing new labels, re-boxing individual product containers, and manually shrink-wrapping stacked bags and boxes. Under our requested interpretation, those workers would experience none of these risks.

B. OSHA's First Interim Enforcement Guidance for the Hazard Communication Standard's June 1, 2015 Effective Date includes new regulatory requirements.

In response to numerous industry petitions and comments, OSHA attempted to provide temporary relief to manufacturers/importers and distributors of hazardous chemicals unable to comply with all requirements of HCS 2012 by the compliance deadlines. Prior to the June 2015 HC ICR renewal request, Thomas Galassi, Director, Directorate of Enforcement Programs, published a memorandum outlining the two enforcement exceptions for distributors and manufacturers/importers to the June 1, 2015 effective date of HCS 2012.[14] The Compliance Health and Safety Officers (CHSO) may determine if a manufacturer or importer has established "reasonable diligence" and "good faith efforts" to comply with HCS 2012 [15] and how long distributors of product with HCS 1994-compliant labels will be allowed to ship chemicals. Surely the Agency was aware at the time that by stating "a manufacturer or importer must provide documentation of its substantive efforts" to obtain classification information and SDSs from upstream suppliers, find hazard information from alternative sources and classify the data themselves, it was creating a significant paperwork burden. In addition, by limiting the time allowed for distributors to ship HCS 1994-compliant labeled hazardous chemical products, the implication was that any such product shipped after that date would have to be re-labeled prior to shipping.

[13] See 40 CFR § 152.3: "[A] product becomes released for shipment when the producer has packaged and labeled it in a manner in which it will be distributed or sold, or has stored it in an area where unfinished products are ordinarily held for shipment..."
[14] Thomas Galassi, Enforcement Guidance for the Hazard Communication Standard (HCS), February 9, 2015.
[15] The requirement to perform "reasonable diligence" is discussed in paragraph below. It constitutes a new paperwork burden not covered by the ICR under review by OMB.

C. OSHA's July 2015 Final Enforcement Directive also includes new regulatory requirements.

The Directorate of Enforcement efforts culminated in a final directive to guide OSHA inspectors.[16]

1. The Directive imposes a new and highly burdensome regulatory requirement of "reasonable diligence and good faith effort" in order to be eligible for enforcement forbearance beyond the June 1, 2015 deadline for HCS 2012 compliance.

The Directive allows regulated entities temporary enforcement relief from a determination of violation for failing to comply with HCS 2012 by June 1, 2015. However, this relief is highly conditional. To take advantage of it, regulated entities must comply with a new regulatory requirement to "demonstrate" that they "exercised reasonable diligence and good faith to comply" with the earlier deadline.[17]

The Directive makes clear that "reasonable diligence and good faith efforts" is a highly burdensome new regulatory requirement, though how burdensome is not made clear. A long list of required actions is enumerated. Manufacturers and importers must:[18]

- Obtain classification information and SDSs from upstream suppliers;
- Find hazard information from alternative sources (e.g., chemical registries); and
- Classify the data themselves.

To show that they have performed these tasks, regulated entities must:

- Develop and document the process used to gather the necessary classification information from upstream suppliers and the current status of such efforts;
- Develop and document their efforts to find hazard information from alternative sources (e.g., chemical registries);
- Provide OSHA inspectors a written account of their continued communications with upstream suppliers, including dated copies of all relevant written communication;
- Provide OSHA inspectors a written account of continued communications with their distributors, including dated copies of all relevant written communications informing them why they have been unable to comply with HCS 2012; and
- Develop the course of action they will follow to make the necessary changes to SDSs and labels once the information becomes available.

Apparently, all of these tasks are required since they are all linked by the "and" conjunction. What kind and quantity of documentation is required? The Directive is silent. OSHA inspectors are given the discretion to decide whether the manufacturer or importer has met the burden of

[16] Supra, note 3.
[17] Id. at pp 41 43. Policy on limited continued use of HCS 1994 compliant labels.
[18] Id. at pp 43 44. What are Reasonable Diligence and Good Faith Efforts? Though the text explicitly applies to manufacturers and importers, it also applies to distributors. This reflects the re definition of "distributor," discussed in paragraph I. 2. above, which converts distributors into manufacturers for hazard communication purposes.

"reasonable diligence and good faith efforts." This is an extraordinary claim of ad hoc rulemaking authority to field inspectors without any procedural or substantive accountability. [19]

2. For any products permitted by OSHA to be shipped with HCS 1994 -compliant labels, the Directive establishes a new and burdensome regulatory requirement to also provide hard-copy HCS 2012-compliant labels that have no practical utility.

The Directive imposes yet more new and highly burdensome regulatory requirements on distributors that attempt to take advantage of the temporary stay in enforcement of HCS 2012. Though they are permitted to ship products with HCS 1994 -compliant labels until December 1, 2017 - if they successfully navigate the new requirements discussed above - distributors must provide HCS 2012-compliant labels for each and every individual container shipped." [20] Reams of paper will be used to generate HCS 2012 -compliant labels for millions of individual containers. These labels cannot practically be affixed to a product container when the box is opened in retail, by the end-use farmer, or the consumer. [21] OSHA compliments itself on their allowance and encouragement of the use of electronic distribution of a single SDS per shipment, and clearly defines throughout the HCS 2012 Final Rule and Directive who must have access to the SDS at any point in distribution. Yet OSHA did not consider electronic distribution of HCS 2012-compliant labels for products temporarily permitted to be shipped with HCS 1994 - compliant labels.

Aside from the extraordinary burdens involved, we wonder what possible practical utility could be claimed for this new regulatory requirement. At a minimum, OSHA must show that there is substantial incremental occupational risk-reducing value of an HCS 2012-compliant label provided on paper beyond the value already provided by affixed HCS 1994 -compliant labels. No evidence of this is provided in the Enforcement Directive, which is not surprising given its scope. However, it bears remembering that the Supporting Statement for the ICR now under review includes no mention of practical utility for any of the burdensome requirements contained in HCS 2012.

3. The historical interpretation of distributors' re -labeling obligations is retained for some, but not all, products manufactured before June 1, 2015, and labeled in compliance with HCS 1994.

The Directive purports to maintain industry's longstanding understanding of re -labeling obligations. Products bearing HCS 1994 -compliant labels are allowed to be shipped from the manufacturer after June 1, 2015, but only under specific, limited circumstances involving missing information. Once this information is collected, however, HCS 2012 -compliant labels must be produced within 6 months of development of the new SDS and all containers shipped

[19] 5 CFR § 1320.9 requires collections of information to be "written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond." The "reasonable diligence and good faith" rule in the falls far short of satisfying this requirement. 5 CFR § 1320.5(d)(2)(iv) forbids agencies from requiring the public to retain records for more than three years, but the Directive does not bind OSHA inspectors to this limitation.
[20] Directive p. 43. Guidance for distributors of hazardous chemicals. This requirement is tempered by the "reasonable diligence and good faith efforts" provision discussed in C. 1. above.
[21] This also may be illegal. Attempting to affix an HCS 2012 compliant label to an end use product bearing an affixed HCS 1994 compliant label appears to violate other requirements forbidding affixed labels from being defaced.

after the 6-month period must be labeled with an HCS 2012-compliant label. The manufacturer may continue to ship downstream "existing stock packaged (e.g., boxed, palletized, shrink-wrapped, etc.) for shipment"[22] prior to June 1, 2015, but it "must provide HCS 2012-compliant labels for each and every individual container shipped and the appropriate HCS 2012-compliant SDS(s) with each shipment."[23] In addition, distributors, such as CPDA member companies, were granted a 6-month period during which they were permitted to ship packaged for shipment containers bearing HCS 1994-compliant labels with "no requirement to re-label."[24] After December 2015, distributors were permitted to ship existing stock packaged for shipment in compliance with HCS 1994, provided that they accompanied these shipments with individual HCS 2012-compliant labels for each and every individual container shipped.[25] This relief is temporary, however, for the Enforcement Directive also states:

> **All containers in the control of a distributor after December 1, 2017, must be HCS 2012-compliant labeled prior to shipping**.[26]

Industry's longstanding understanding of the exemption from applying the HCS to "work operations where employees only handle chemicals in sealed containers which are not opened under normal conditions of use (such as are found in marine cargo handling, warehousing or retail sales),"[27] or the "sealed container" provision for warehoused product, is now revoked for products prepared for shipment in compliance with HCS 1994 if they are not subject to final sale before that date. Distributors are now required to classify and re-label products that were prepared for shipment in compliance with HCS 1994, but not sold by December 2017, as the

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[22] Thomas Galassi. Interim Enforcement Guidance for Hazard Communication 2012 (HCS 2012) June 1, 2015 Effective Date (May 29, 2015). This is the first use of the OSHA term of art "packaged for shipment" and first use by OSHA of the term "re label.

[23] Directive p. 42. Shipped Containers; Policy on limited use of HCS 1994 compliant labels. Guidance for manufacturers and importers of hazardous chemicals. This requirement is tempered by the "reason able diligence and good faith efforts" provision discussed in C. 1. above. Though this is similar language as for distributors, for manufacturers and importers there appears to be no date after which they cannot ship HCS 1994 compliant labeled product and may or may not have to provide HCS 2012 compliant labels.

[24] Id. "HCS 2012 permits distributors to continue to ship chemicals with HCS 1994 labels until December 1, 2015. There may be distributors that are consequently unable to comply with the December 1, 2015 effective date where a manufacturer or importer cannot comply with the June 1, 2015 effective date despite its reasonably diligent and good faith efforts." This provision tracks OSHA's response to CDPA's request for a letter of interpretation.

[25] Directive p. 43. Guidance for distributors of hazardous chemicals. Although the Directive may be interpreted to imply labels need only be made available upon request, this is only true for the SDS.

[26] Id (emphasis added).

[27] 29 FR §1900.1200(b)(4). "In work operations where employees only handle chemicals in sealed containers which are not opened under normal conditions of use (such as are found in marine cargo handling, warehousing, or retail sales), this section applies to these operations only as follows :
(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;
(ii) Employers shall maintain copies of any material safety data sheets that are received with incoming shipments of the sealed containers of hazardous chemicals, shall obtain a material safety data sheet as soon as possible for sealed containers of hazardous chemicals received without a material safety data sheet if an employee requests the material safety data sheet, and shall ensure that the material safety data sheets are readily accessible during each work shift to employees when they are in their work area(s); and,
(iii) Employers shall ensure that employees are provided with information and training in accordance with paragraph (h) of this section (except for the location and availability of the written hazard communication program under paragraph (h)(2)(iii) of this section), to the extent necessary to protect them in the event of a spill or leak of a hazardous chemical from a sealed container."

SDSs and labels of these products are not in compliance with HCS 2012. This is a major new regulatory requirement; no clear reference can be found in the HCS 2012 Final Rule, and no cost estimate for it can be found in the accompanying RIA. For the purposes of OMB review of this ICR, we note that this astoundingly large paperwork burden is not mentioned in the Supporting Statement for this ICR or any of its predecessors. [28]

4. The historical interpretation of re-labeling obligations has been revoked for warehoused products manufactured or imported on or after June 1, 2015, and labeled in compliance with HCS 2012.

The historical interpretation of industry's re-labeling obligations is wholly revoked, as per paragraph 3. above, for manufacturers, importers and distributors with warehoused products manufactured and labeled in compliance with HCS 2012 if they become aware of significant new information. For products that have shelf lives exceeding six months, they must be classified and relabeled under the OSHA's new interpretation of labeling obligations under HCS 2012 if they cannot be sold within six months.

5. Compliance with HCS 2012 may become not just outrageously expensive, unnecessarily risky, or technically infeasible - it also may become illegal.

We have previously explained the technical challenges to (and occupational risks of) re-labeling in warehouses products manufactured and labeled for wholesale, retail sale or other end use. Many agricultural products have such long shelf lives that it is inevitable they will become technically noncompliant with HCS 2012 before final retail distribution because of the appearance of significant new information.

Re-labeling, especially in a warehouse that is neither designed nor intended to perform tasks normally associated with manufacturing, will have to be performed by employees for whom this is not, and never has been, a familiar task. We believe the intent of paragraph (b)(4) of the Hazard Communication Standard is to protect warehouse employees from the risks associated with re-labeling hazardous chemical containers. In fact, (b)(4)(i) precludes re-labeling from occurring in the warehouse:

> "[e]mployers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced." [29]

Re-labeling in a warehouse may be in direct violation of CFR 1910.1200(b)(4) but no enforcement discretion or guidance is provided in the Directive. To re-label in the warehouse, special training and supervision will be required adding new burdens that OSHA has not accounted for in the ICR. Moreover, distributors facing this re-labeling obligation will have to carefully coordinate the actual tasks so that they occur simultaneously or may be in direct violation of CFR 1910.1200(f)(9). This new regulatory requirement and paperwork burden is

[28] Burdens not mentioned in the ICR should not be covered by an OMB approval. Distributors penalized for failing to comply should have an affirmative defense under 44 USC 3512 and 5 CFR 1320.6.
[29] 29 FR §1900.1200(b)(4)(i).

imposed by the Directive.[30] Distributors cannot separately task one group of employees to remove labels and another to affix new ones. They must either be the same employees or work in teams, unless OSHA does not intend "immediately" to proscribe cost-effective or safety-enhancing delay.

Distributors that cannot successfully navigate onsite the internal inconsistencies and additional burdens imposed by the Directive, but still desire to comply, will face a potentially fatal roadblock. It may be illegal to ship these newly noncompliant products to a location that is equipped to re-label them. We are aware of discussions between OSHA and the Department of Transportation (DOT) regarding inconsistencies of HCS 2012 and DOT labeling requirements but it is not clear to us at this time what labels must be on products if they are shipped from warehouses for relabeling under HCS 2012. DOT regulations prohibit the shipment of hazardous chemicals that are not labeled in compliance with DOT at the time of shipment.[31]

6. The Directive adopts a new definition of "distributor" that is contrary to HCS 2012 and appears to overrule a critical provision in HCS 2012 .

The Enforcement Directive defines "distributor" in a way that is much broader than, and inherently contrary to, the definition that has existed since at least HCS 1994 and was not changed by HCS 2012. This is clear from the following table below:

Table 1:
The Definition of "Distributor" in HCS 1994, HCS 2012 and the Enforcement Directive

HCS 1994 and HCS 2012 Text	***Enforcement Directive Text***
"Distributor" means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to employers. Source: 29 CFR § 1900.1200(c) [unchanged by HCS 2012]	"Distributor" means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to **manufacturers**, other distributors, or to employers. Source: Enforcement Directive, § X(C)(8), p. 18, emphasis added

This definition has never been used before, and its provenance is unclear. Indeed, the Directive neither acknowledges that it is a regulatory change from the HCS 2012 Final Rule nor gives a credible explanation for it. Moreover, paragraph (a) of the re-definition is about manufacturers, not distributors:

a. A company that repackages, blends, mixes, or otherwise changes the composition of a chemical is considered a chemical manufacturer under the HCS.

[30] Directive p. 7. "Under HCS 2012, existing labels that have been removed or defaced and not immediately marked with the required information will be in violation of 29 CFR 1910 1200(f)(9)."
[31] 49 CFR §172.401(a) and (c).

A hint concerning OSHA's purpose is found in the bullets that follow paragraph (a):

> - Employees in these operations are considered to use hazardous chemicals.
> - Under these conditions, the distributor will not be able to claim the sealed container provision in section§ 1900.1200(b)(4) and will need to meet all applicable provisions of the HCS for manufacturers. [32]

HCS 2012 paragraph (g)(7) is cited under "Distributor" in the Directive to clarify that a "distributor" is not a "retail distributor," which sells to both employers and the general public. Retail distributors need only provide an SDS upon request. Wholesale distributors also need only manage SDSs and manufacturer contact information. But the Directive is silent on distributors, warehouse re-labeling, compliance and enforcement. It does not indicate in any way that distributors who are not manufacturers will not be found in violation of paragraph (b)(4)(i) if they are discovered re-labeling in a warehouse by a CHSO. If they "claim" the sealed container provision in § 1900.1200(b)(4) and don't re-label, they will not be able to ship non-HCS 2012 compliant labeled product out of the warehouse. The burden- and risk-reducing "sealed container" provision has been in place for decades, and nothing in HCS 2012 can reasonably be inferred to have taken it away. But the HCS 2012 first time ever requirements for prescriptive information to be on the label and that a label must be affixed to the immediate chemical container before shipping make it impossible for the distributor to ship the product out of the warehouse without re-labeling.

CDPA therefore surmises that the purpose of the new, expanded definition in the Directive is to surreptitiously revoke eligibility of some (or all) distributors. Indeed, CDPA members are quite reasonably concerned that an inspector might, based solely on the presumed authority of the Directive, deem both the manufacturing and distribution components of their businesses as "manufacturers," thereby denying the sealed-container exemption for their distribution operations as there is no other direction on distributors provided. How does a distributor prove that he does not supply a manufacturer?

OSHA may simply be trying to fit a square peg into a round hole. Rather than addressing where "packaged for shipment" product resides (i.e., in a warehouse) for purposes of enforcement of HCS 2012, the Agency is using a product life-cycle approach to impose labeling requirements on particular segments of the industry. For example (1) if a sealed, labeled, palletized bag of fertilizer is in a manufacturer's warehouse, it must be re-labeled before shipping, (2) if the same sealed, labeled, palletized bag is in a distributor's warehouse it is unclear whether the bag of fertilizer can or must be re-labeled before shipping, and (3) if the same sealed, labeled, palletized bag of fertilizer is in a retailer's warehouse it won't need to be re-labeled. The Enforcement Directive is clear on scenarios (1) and (3), but not on scenario (2).

For CDPA members, this re-definition of "distributor" and OSHA's lack of awareness of all distributors who are not a manufacturer distributor or retail distributor is deeply worrisome. As noted above, OSHA's response to our request for a letter of interpretation and the Directive together make transparent that HCS 2012 creates an obligation for dynamically compliant

[32] Directive p. 18. Distributor means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to manufacturers, other distributors, or to employers.

classification and labeling. This requirement is devastating for distr ibutors in possession of long shelf-life products containing hazardous chemicals. Thousands of tons of non -pesticide agricultural products, labeled in compliance with the hazard communication standard that was applicable when manufactured, will be residing in warehouses not equipped to host re -labeling operations. Any time a CDPA member becomes aware of significant new information, whether from a manufacturer, importer or another source, the affected products will become non - compliantly labeled six months after the new SDS is generated.[33] And, this is not merely a speculative, forecasted concern. Some distributors already have in their possession warehoused product, labeled after June 1, 2015, that is no longer in compliance due to significant new information provided by upstream manufacturers. These "packaged for shipment" products cannot be returned to the manufacturer for re -labeling and must be re -labeled in a distribution warehouse or disposed of as hazardous waste.

D. OSHA's Response to CDPA's request for interpretation includes new regulatory requirements.

Director of Enforcement Programs Thomas Galassi finally responded to our request for interpretation on OSHA's behalf by letter dated September 2015.[34] In this letter, he expressed OSHA's appreciation to CPDA for identifying the EPA "released for shipment" policy that precludes the need for re -labeling of hazardous pesticide products in distribution channels. However, the letter then immediately states "the Agency believes that the Hazard Communication standard, as currently designed, including the use of an HCS 2012 -compliant label, is necessary for the long -term safety of downstream consumers" (emphasis added).

We, and others,[35] are confused by this reasoning. Not only does it ignore the substantial occupational risk imposed by the re -labeling requirement on warehouse employees, it does so in deference to hypothetical risks to persons outside OSHA's regulatory jurisdiction. In addition, it directly contradicts the previously steadfast OSHA position on the sanctity of the sealed container provision in past letters of interpretation[36] and OSHA's own Guidance for Compliance publications.[37]

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[33] 29 CFR § 1900.1200(f)(11): "Chemical manufacturers, importers, distributors, or empl oyers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introd uced into the workplace again."

[34] Thomas Galassi, "Letter to Dr. Susan Ferenc, President of the Council of Producers & Distributors of Agrotechnology," September 11, 2015 (copy included as Attachment C).

[35] David Michaels, "Letter to Jay Timmons, President and CEO, The National Association of Manufacturers ." Undated. (copy included as Attachment D).

[36] John A. Pendergrass "Letter to the Honorable Dan Glickman, Member, House of Representatives," September 16, 1986 (copy included as Attachment E).

[37] Hazard Communication Guidelines for Compliance; U.S. Department of Labor, Occupational Safety and Health Administration, OSHA 3111, 2000 (Reprinted) "There are two types of work operations where coverage of the rule is limited. These are laboratories and operations wh ere chemicals are only handled in sealed containers (e.g., a warehouse). The limited provisions for these workplaces can be found in paragraph (b), scope and application. Basically, employers having these types of work operations need only keep labels on c ontainers as they are received, maintain material safety data sheets that are received and give employees access to them, and provide information and training for employees. Employers do not have to have written hazard communication programs and lists of

OSHA's response also imposed on CDPA members several new regulatory bur dens not found in HCS 2012, and thus of course not included in the ICR. This includes conducting a hazard assessment for the re-labeling of products that were properly labeled when manufactured that complies with 29 CFR § 1910.132(d).

OSHA further recommended that "CPDA reviews and shares with their [*sic*] members an ergonomic publication from the National Institute for Occupational Safety and Health (NIOSH) titled Ergonomic Solutions for Retailers."[38]

While we appreciate OSHA's attempted resolution o f the confusion that led to our simple request, it is our view that its response constitutes a highly burdensome new regulation on CDPA members—and no doubt many others who are unaware of it. Regulated entities could not have foreseen this new regulation from the notice of proposed rulemaking, nor has any other regulated party identified it prior to our request for a letter of interpretation. This is hardly surprising. The relevant text of HCS 2012 is virtually identical to the text of HCS 1994, and under H CS 1994 little or no re-labeling of manufactured products ever occurred. Moreover, regulated parties could not have expected OSHA to reinterpret longstanding regulatory text in a way that endangers warehouse workers. Finally, it does not appear that OSHA intended this result when it wrote HCS 2012. Neither the extraordinary burdens of re -labeling already manufactured products nor its occupational safety and health risks are even mentioned in the 2009 Notice of Proposed Rulemaking,[39] the 2012 Final Rule,[40] the RIAs prepared for the NPRM or the final rule,[41] or separate documents estimating labeling costs. [42] Finally, and most importantly for

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chemicals for these types of operations.
The limited coverage of laboratories and sealed container operations addresses the obligation of an employer to the workers in the operations involved, and does not affect the employer's duties as a distributor of ch emicals. For example, a distributor may have warehouse operations where employees would be protected under the limited sealed container provisions. In this situation, requirements for obtaining and maintaining MSDSs are limited to providing access to those received with containers while the substance is in the workplace, and requesting MSDSs when employees request access for those not received with the containers. However, as a distributor of hazardous chemicals, that employer will still have responsibility for providing MSDSs to downstream customers at the time of the first shipment and when the MSDS is updated. Therefore, although they may not be required for the employees in the work operation, the distributor may, nevertheless, have to have MSDSs to sati sfy other requirements of the rule."

[38] This NIOSH publication focuses on the grocery sector, but the easy to read format can be adapted to other scenarios including for those working in warehousing and storage facilities.

[39] Occupational Safety and Health Administration, "Hazard Communication; Proposed Rule," Federal Register 74:50280 50549 (September 30, 2009).

[40] Occupational Safety and Health Administration, "Hazard Communication; Final Rule," Federal Register 77:17574 17896 (March 26, 2012). To be clear, OSHA acknowledged that some public commenters had concerns about re labeling costs (see the preamble to the Final Rule, p. 17633), these concerns were distinct from the problem CDPA has raised the burden of relabeling long shelf life products that were properly labeled when manufactured.

[41] Policy Planning & Evaluation Inc., "Data and Analysis in Support of an Economic Analysis of Proposed Changes to the OSHA Hazard Communication Standard; Revised Final Report," Herndon VA: P olicy Planning & Evaluation, Inc. (September 30, 2009).

[42] Eastern Research Group, "Harmonization of Hazard Communication: Labeling Costs. Final Report. Submitted to Occupational Safety And Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis, Contract No. GS 10 F 0125P. Lexington MA: ERG (April 28, 2010); Eastern Research Group, "Final Report: Harmonization of Hazard Communication; Summary Of Labeling Costs," Lexington MA: ERG (March 23, 2011); Eastern Research Group, "Excel Spreadsheets in Support of OSHA Final Economic An alysis for GHS Rule. Submitted to Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis, Contract No. GS 10 F 0125P," Lexington MA: ERG (undated).

purposes of evaluating OMB's review of this ICR, these re-labeling burdens are not mentioned and/or are denied in the Supporting Statement or any predecessor.

For many CPDA members, warehouse re-labeling is either extraordinarily expensive or technically infeasible. For the employees of CDPA members, warehouse re-labeling poses an unacceptable occupational safety and health risk. Yet, based on OSHA's response to CDPA's request for a burden- and risk-reducing letter of interpretation, it is clear that OSHA fully understands these significant occupational safety and health risks and has no qualm with imposing them on our members and their employees. We are especially perplexed by OSHA's indifference to the risks its own rule imposes. If HCS 2012 were interpreted as OSHA's response appears to intend, the rule would be the cause of, rather than the remedy for, substantial new and wholly avoidable occupational safety and health risks - something that surely is not consistent with the purposes of hazard communication as Congress intended it.

CPDA'S CURRENT EFFORTS TO ACCURATELY QUANTIFY AND MONETIZE PAPERWORK BURDENS

To better inform OMB's review, CPDA and its members are working overtime to accurately quantify and monetize the paperwork burdens that OSHA failed to properly estimate in the ICR, as well as develop estimates of first impression for paperwork burdens OSHA willfully ignored. We will provide this information to OMB as soon as practicable.

In addition, we are also gathering information from other sectors of the chemical manufacturing and distribution industry to better gauge the scope and scale of new, burdensome regulatory requirements first clearly articulated by OSHA in its response to our request for a letter of interpretation and the Directive. We are focusing especially on the potentially massive new requirement for distributors to perform in-warehouse re-labeling of end-use products that have shelf lives well exceeding six months. We are attempting to estimate both the magnitude of these new paperwork burdens and develop an order of magnitude estimate of the new occupational safety and health risks OSHA is knowingly imposing.

CONCLUSION

Our industry works diligently to be in compliance at all times and is struggling to be so now. Already there is information that end-use product, formulated only using ingredients produced after June 1, 2015, are not compliantly labeled due inadvertent misclassification under HCS 2012. These products, sitting in warehouses now, are subject to the HCS 2012 re-labeling requirement, and they are not eligible to be shipped with accompanying HCS 2012-compliant labels - because the temporary enforcement stay in the Enforcement Directive applies only to products bearing HCS 1994-compliant labels.

We are deeply concerned that HCS 2012, as materially reinterpreted by OSHA through its response to our request for a letter of interpretation and the Directive, impose requirements that put our members in a regulatory no-man's land. Our products have long shelf lives, so they are manufactured in multiyear batches to reduce production cost and placed in warehouses until the need arises for their use. This is the only way to provide farmers with what they need, when they need it. This benefits production agriculture and consumers. But this longstanding and

economically efficient business model is at risk of destruction because of the extraordinary burdensome and questionable legality of re-labeling requirements that, based on OSHA's own analysis, appear to have no benefit to warehouse employees and in fact will expose thousands of them to substantial occupational risk.[43]

We realize that the issues raised in this supplementary public comment are highly complex. We have additional, interactive materials that make our concerns easier to appreciate. For that reason, I will call after the beginning of the New Year to set up an appointment to present this information to all relevant OMB staff.

[43] Hazard Communication Guidelines for Compliance; U.S. Department of Labor, Occupational Safety and Health Administration, OSHA 3111, 2000 (Reprinted). "There are two types of work operations where coverage of the rule is limited. These are laboratories and operations where chemicals are only handled in sealed containers (e.g., a warehouse). The limited provisions for these workplaces can be found in paragraph (b), scope and application. Basically, employers having these types of work operations need only keep labels on containers as they are received, maintain material safety data sheets that are received and give employees access to them, and provide information and training for employees. Employers do not have to have written hazard communication programs and lists of chemicals for these types of operations.
The limited coverage of laboratories and sealed container operations addresses the obligation of an employer to the workers in the operations involved, and does not affect the employer's duties as a distributor of chemicals. For example, a distributor may have warehouse operations where employees would be protected under the limited sealed container provisions. In this situation, requirements for obtaining and maintaining MSDSs are limited to providing access to those received with containers while the substance is in the workplace, and requesting MSDSs when employees request access for those not received with the containers. However, as a distributor of hazardous chemicals, that employer will still have responsibility for providing MSDSs to downstream customers at the time of the first shipment and when the MSDS is updated. Therefore, although they may not be required for the employees in the work operation, the distributor may, nevertheless, have to have MSDSs to satisfy other requirements of the rule."

Attachment A: Council of Producers & Distributors of Agrotechnology. 2015. *Letter to Office of Information and Regulatory Affairs Re: Agency Information Collection Activities; Submission for OMB Review; Comment Request; Hazard Communication Standard; Notice. (OMB Control No. 1218-0072); 80 FR 36856 (June 26, 2015),* July 30, 2015.

Attachment B: Council of Producers & Distributors of A grotechnology, "Letter to Maureen Ruskin *Re: Request for a Letter of Interpretation that Clarifies the Container Label for a Category of Non-Pesticide Agrichemical Products, Labeled in Accordance with the HCS When Initially Shipped From the Manufacturer/Importer, as Compliant with HCS 2012 for the Life of the Product,"* December 14, 2014.

Attachment C: Thomas Galassi, "Letter to Dr. Susan Ferenc, President of the Council of Producers & Distributors of Agrotechnology," September 11, 2015.

Attachment D: David Michaels, "Letter to Jay Timmons, President and CEO, The National Association of Manufacturers," Undated .

Attachment E: John A. Pendergrass "Letter to the Honorable Dan Glickman, Member, House of Representatives," September 16, 1986 .

Attachment A: Council of Producers & Distributors of Agrotechnology 2015 Letter to Office of Information and Regulatory Affairs.

COUNCIL OF PRODUCERS &
DISTRIBUTORS OF AGROTECHNOLOGY

July 30, 2015

VIA E-MAIL (OIRA_submission@omb.eop.gov)

Office of Information and Regulatory Affairs
ATTN: OMB Desk Officer for DOL-OSHA
Office of Management and Budget
Room 10235
725 17th Street, NW
Washington, DC 20503

Re: Agency Information Collection Activities; Submission for OMB Review; Comment Request; Hazard Communication Standard; Notice. (OMB Control No. 1218 -0072); 80 FR 36856 (June 26, 2015).

The Council of Producers & Distributors of Agrotechnology (CPDA) is pleased to provide these comments for consideration in response to the above referenced notice on the Information Collection Request (ICR) titled "Hazard Communication Standard" (HCS) [1] to the Office of Management and Budget (OMB).

CPDA is the preeminent U.S. based trade association representing the interests of the agrotechnology products industry including manufacturers, suppliers, formulators and distributors. More than 10 million agrotechnology prod uct containers such as tank-mix adjuvants and plant nutritionals are manufactured and distributed annually. Small, medium and large businesses involved in this distribution system are directly affected by HCS 2012. This represents almost 10% of the total number of shipped containers of hazardous chemicals identified by the Occupational Safety and Health Administration (OSHA). [2]

The main objective of the Occupational Safety and Health Act of 1970 (Act) [3] is to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions

[1] 29 CFR § 1910.1200.
[2] Supporting Statement For The Hazard Communication Standard (29 CFR 1910.1200, 1915.1200, 1917.28, 1918.90, 1926.59, and 1928.21), June 2015. ("2015 ICR Supporting Statement").
[3] 29 U.S.C. §§ 651 et seq.

(b) (6) [redacted]

and to preserve our human resources."[4] To achieve this objective, the Act authorizes "the development and promulgation of occupational safety and health standards."

The purpose of the HCS and its collection of information requirements is to ensure that the hazards of chemicals produced or imported are evaluated and that information concerning these hazards is transmitted to employers and employ ees. The collections of information requirements are approved by the OMB under OMB Control Number 1218 -0072. The HCS standard affects employers and employees in many different industries across the economy.

CPDA has analyzed OSHA's 30-day notice,[5] the Supporting Statement for this proposed ICR extension,[6] and the 2012 Supporting Statement for the Revised Hazard Communication Standard,[7] and is providing an outline of key deficiencies that are inconsistent with the requirements of the Paperwork Reduction Act (PRA).[8]

OSHA noted in its February 2012 Supporting Statement for the revised standard that the existing requirements were "not always consistent and often contain different definitions of hazards and varying provisions for what information is required on labels and safety data sheets" (SDSs).[9] The revisions conform to the internationally negotiated set of criteria and provisions. The final standard contains a number of changes to improve the performance of the United States hazard communication system including the revised criteria for more uniform classification of chemical hazards. OSHA also acknowledges that the final revisions impacting the HCS paperwork requirements include the revised criteria for classification of chemical hazards.

Under the PRA, OSHA must estimate the burden and costs associated with collecting the required information. Under PRA, "burden" is defined as the "time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal Agency."[10] The OMB will not approve a "collection" until OSHA provides an ICR that describes the information collection activities in detail.

OSHA's February 2012 ICR Is Flawed and Incomplete

OSHA's demonstration of practical utility and burden estimation methodology for the HCS 2012 ICR, referenced in the 2015 extension request, are fundamentally flawed in multiple ways, including:

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[4] Id. at § 651(b).
[5] 80 FR 36856 (June 26, 2015).
[6] Supra, note 2.
[7] Supporting Statement for t he Revised Hazard Communication Standard (29 CFR 1910.1200, 1915.1200, 1917.28, 1918.90, 1926.59, and 1928.21) Incorporating Globally Harmonized System of Classification and Labelling of Chemicals (OMB Control No. 1218 -0072), February 2012. ("2012 ICR Supporting Statement")
[8] 44 U.S.C. §§ 3501 et seq.
[9] Supra, note 7 at 3.
[10] Supra, note 8 at § 3502(2).

1. OSHA's failure to identify the safety issues or burden associated with relabeling individual product containers each time new information on chemical hazard becomes available or if the HCS is amended.
2. OSHA's failure to provide objectively supported estimates of burden by: a) ignoring significant burden components, such as the burden of relabeling existing product; b) incorrectly counting acknowledged burden components, such as excluding more than 60% of the burden of conducting hazard classification ; and c) incorrectly estimating the burden hours for the combination of hazard classification, revising labels and revising SDSs.

OSHA's dissemination of severely biased burden estimates, and its continued reliance on incomplete information in characterizing the practical utility and burden in seeking extension of the ICR, strongly supports the conclusion that OSHA did not adhere to applicable information quality guidelines with respect to objectivity and utility.

OSHA Still Has Not Demonstrated Practical Utility

According to CPDA members, approximately 10,000,000 individual "end-use" product containers of non-pesticide agricultural chemical products, such as jugs of adjuvant or bags of fertilizer, are produced each year. Up to approximately 2,500,000 of these containers (equivalent to 15-25% of annual production) are returned to distributors for resale each year.

The overwhelming majority of these products are manufactured, formulated, packaged and labeled in highly mechanized and automated processing plants. At those automated facilities, individual units are filled and sealed by an automated filling machine, conveyed and inserted into cases that are then palletized and shrink-wrapped or loaded into large shipping containers and sealed by automated machinery. These safely and securely "containerized" shipping units are transferred to warehouses and distribution centers for storage until sold and distributed into the market as shipping units. Shipping units may be returned to the distributor or warehouses and resold the following year or several years later. Shipping units may be in a distribution/redistribution cycle for 3-5 years or longer.

In order to redistribute warehoused agrotechnology products with HCS 2012 compliant labels in 2018, all individual "end-use" product containers would need to be relabeled. This would involve removing the shrink wrap, removing the sealed cases from the pallet, cutting/ripping open the cases, removing the individual labeled containers from the cases, and either removing and replacing the existing labels from the individual containers or applying a new label that would reliably adhere to the container and completely obscure the old label. The vast majority of distribution and warehouse facilities do not have the personnel or equipment to conduct such an operation. Without the machinery required to relabel previously filled containers, these containers would have to be manually relabeled.

There can be significant risks involved when attempting to relabel products, especially if the old label has to be removed. This removal process can cause failures in the container seal resu lting in leakage and worker exposure to hazardous chemicals. A very conservative estimate of the number of product containers that would have to be relabeled annually by distributors would be 1,250,000 containers on 13,500 pallets. For palletized product , based on a survey of CPDA members, it is estimated that this would involve workers spending 2 -3 hours per pallet to relabel approximately 15,000 tons of product by hand, which involves significant ergonomic issues because that tonnage must be lifted and moved multiple times (industry representatives indicated that back injuries are the most significant problem and common ergonomic issue associated with moving this material by hand). The employees engaged in these relabeling activities would clearly be exposed to unacceptable health, safety and ergonomic risks. Furthermore, distribution centers and warehouse facilities generally do not have the necessary inner containers, cartons, and cases or the equipment necessary to accomplish such a massive repacking endeavor; the space required to conduct these operations; or the equipment to return shipping units to the level of integrity created at a manufacturing facility, thus posing new risks as the resealed units are further distributed. The necessity to disca rd product, if relabeling is not a viable option, would result in significantly higher volumes of chemicals going to hazardous waste disposal facilities, posing a potential risk to the workers at that site as well as to the environment.

In the 2012 ICR Supporting Statement, OSHA failed to comprehensively characterize the practical utility of the information collection as required under the Paperwork Reduction Act. [11] OSHA also failed to identify in the standard and the ICR that hazardous chemical product containers would be required to be relabeled, both within the 3 -year phase-in period of the standard and in the future whenever new information on chemical hazard classification becomes known or HCS 2012 is amended. Moreover, the ICR Supporting S tatement did not address the significant costs and worker safety risks associated with relabeling containerized hazardous chemical products. If the practical utility of the collection is to support OSHA's stated goal to "assure so far as possible every working man and woman in the Nation *safe and healthful working conditions*..." [emphasis added], then omission of consideration of relabeling clearly leaves the Agency with the inability to fulfill its fundamental objective. Without consideration of the risks and cost s of relabeling, the information collection cannot have the "actual, not merely the theoretical or potential, usefulness" necessary to make a showing of practical utility.[12]

Though the Agency is fully aware of the worker safety risks posed during relabeling , the Supporting Statement for the ICR extension request provides no evidence it has considered this issue. For this reason, OSHA's insistence that the current information collection is necessary

[11] 5 CFR § 1320.3(l). Actual (as opposed to merely theoretical) practical utility is required by OMB's Information Collection Rule: "*Practical utility* means 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, and the agency's ability to process the information it collects (or a person's ability to receive and process that which is disclosed, in the case of a third -party or public disclosure) in a useful and timely fashion."
[12] Id.

and sufficient to allow OSHA to meet its policy objective i s inconsistent with its obligations under the PRA.

OSHA Has Not Adequately Estimated Burden

As noted previously, under the PRA, the term 'burden' means the "time, effort or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency...." OSHA correctly identifies the following revisions as impacting paperwork requirements: 1) revised criteria for classification of chemical hazards, 2) revised label provisions, and 3) a specified format for safet y data sheets. However, OSHA failed to accurately portray the time, effort and financial resources expended by industry to comply with the requirements.

2012 ICR Supporting Statement 's Hazard Classification Burden [13]

Under HCS 2012, chemical manufacturers and importers must evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with the standard. For each chemical, the chemical manufacturer or importer must determine the hazard classes, and, where appropriate, the category of each class that appl ies to the chemical being classified. OSHA estimated that, on average, a "professional" takes 8 hours to conduct a hazard classification and to develop the necessary labels and SDSs. Industry experience over the 2012-2015 phase-in period has proven this to be a gross underestimate of the time and cost actually expended by firms to conduct just the reclassification, either in-house or contracted for by a third party. OSHA also contended in both 2012 and 2015 supporting statements that, when deriving basic values for the analysis, a "previous analysis found that 60 percent of all establishments were in compliance with the basic provisions of the HCS, primarily as a result of state laws existing prior to the OSH A standard. Hence, HCS is assumed to account for (1-.6) or 40 percent of the burdens and costs since, in the absence of HCS, 60 percent of the burden would continue as a result of state statutes." [14] However, we could find no state law that prescribes classification/reclassification of chemical hazards by the c riteria established in HCS 2012. The criteria for classification under HCS 2012 are identified in Appendices A and B of the HCS 2012 and present a highly prescriptive process for chemical hazard clas sification over the previous hazard communic ation standard (1994). It is hard to conceive of *any* chemical product that would have been reclassified using the new criteria prior to the effective date of HCS 2012.

OSHA estimated that for the 3-year implementation period of the standard the total number of "affected" chemical products, 565,854, was determined by multiplying the total number of chemical products, 1,414,636, by 40%. The percentage of new chemical products annually was estimated to be 8% of the total affected chemical products which came to 45,268. OSHA provided no evidence or assumptions for excluding the remaining 32% of "affected" chemical products that were assumed not "in compliance with the basic provisions of the HCS. "

[13] 2012 ICR Supporting Statement Exhibit B. 5. Hazard Classification (§ 1910.1200(d)) .
[14] Id.

Burden hours: 45,268 new hazardous products x 8 hours = 362,144 hours
Cost: 362,144 hours x $66.00 = **$23,901,504**[15]

Under OSHA's assumptions only an estimated 3.2% of the total number of chemical products would need to be classified/reclassified under the new standard. Considering just the omitted 32% of products not in compliance, the cost would have been $298,770,912. If, assuming that only 80% of products would need to be reclassified (though we believe 90+% of products would need to be classified/reclassified), then the burden would be an astounding **$582,693,815** or **$194,231,272 per year** for the new standard. This total burden alone would have been incurred *within the 3-year phase-in period* of the standard.

CPDA believes the Agency has not met the intent of the OMB's Information Quality Guidelines, 5 CFR 1320.8(a), to provide a "specific, objectively supported estimate of burden" of the information collection. OSHA used simplistic and unsupportable assumptions, imported from previous hazard standard revisions, in their calculations that significantly impacted the results of the analyses. OSHA provided no objective rationale for the assumptions used in either the HCS 2012 ICR or the 2015 ICR extension request. By incorporating these unsupportable assumptions, OSHA calculated an unrealistically low information collection cost. By doing so, OSHA managed to convince the OMB that HCS 2012 is not a "major" rule, when it clearly is.

2012 ICR Supporting Statement's Burden Revisions To The SDSs and Labeling Requirements [16]

OSHA created significant confusion in the 2012 ICR when it provided additional estimates of the burden hours and costs of revising the SDSs and labels. These burdens and costs would appear to be in addition to the reclassification burden, despite OSHA's implied inclusion of this burden under Hazard Classification.

Table 2 of the 2012 ICR identifies OSHA's estimation of industry burden hours and costs for revising SDSs as **$228,434,880** or annualized over a three year period, **$76,144,960 per year.**[17] The only evidence provided by OSHA in support of the burden hours estimate is based on the actual experience of only 3 firms, all with 500 or more employees. These large firms, OSHA estimates, will purchase software packages to conduct the classification and revise the SDSs at a cost of $208 per SDS. OSHA apparently had/has made no attempt to identify or confirm the burden hours or costs to any firms of any other size. During the phase-in of HCS 2012, some of these same "large" firms have had to hire 50-60 new employees to conduct the hazard classification/reclassification and revise SDSs and labels.

[15] Id.
[16] 2012 ICR Supporting Statement Exhibit B.13.
[17] Id.

Table 2 - Burden Hours and Costs for Revisions to Safety Data Sheets and Labeling Requir ements

Establishment Size	# of SDSs	Hours/SDS	Hourly Wage	Pre-Compliance %	% Not in Compliance	Total Burden Hours	Total Burden Cost
1-19	164,102	7	$66	1%	99%	1,137,227	$75,056,982
20-99	122,764	7	$66	5%	95%	816,381	$53,881,146
100-499	205,415	5	$66	25%	75%	770,306	$50,840,196
500+	922,355	3	$66	75%	25%	691,766	$45,656,556
Total	**1,414,636**					**3,415,680**	**$228,434,880**

2015 ICR Supporting Statement's Burden for Revising and Sending Labels

In the 2015 ICR extension request, OSHA notes that "safety data sheets and labels were revised as a result of the *Hazard Communication Standard --Incorporating Globally Harmonized System of Classification and Labelling of Chemicals* rulemaking. The Agency estimated a few SDSs, and accompanying labels as necessary, will need to be revised." [18] OSHA states further that it "estimates that one-half of one percent .5% of the SDS would need to be revised. Given the standardized format of the SDS and that any new significant information that chemical manufacturers, importers, distributors, or employers would become aware of would not require a comprehensive revision of the SDS. For th e purposes of estimating burden hours, OSHA estimates it will take 15 minutes for a supervisor/manager to update the SDS, and if necessary the associated label."

Burden hours: 1,414,636 SDS x .5% x .25 hour = 1,768 hours

Cost: 1,768 hours x $64.36 wage hour professional = $113,788 [19]

Once again, OSHA failed to provide any evidence in support of its one-half of one percent of all chemical SDSs assumption or of the 15 minute assumption for revising an SDS. Perhaps the software purchased by very large firms enables this . OSHA has not provided any substantiation

[18] 2015 ICR Supporting Statement Exhibit A.4.
[19] Id.

of the assumptions used to estimate the burden hours and costs identified in the HCS 2012 ICR nor re-evaluated burden estimates based on experience over the 3-year phase-in period of the revised standard. Rather, OSHA persists in using the same approach (i.e., using burden analyses developed for earlier hazard standards) which undercounts most burden components and purposefully ignores others.

Conclusions:

In summary, CPDA believes that OSHA has not met the letter or intent of the requirements under the Paperwork Reduction Act to adequately characterize and evaluate the practical utility or the burden of the information collection for the HCS 2012 ICR or for the 2015 ICR extension request. We believe the Agency failed to understand and acknowledge the significant complexity and scope of the impact this expanded hazard communication standard program would have, and has had, on industry. Moreover, it is clear upon review of the HCS 2012 ICR that no new analyses were conducted for purposes of the essentially brand new standard. Rather, the analyses for much earlier hazard standards were simply copied and pasted into the HCS 2012 ICR.

CPDA also believes that sufficient information has been generated over the 3-year phase-in period of HCS 2012 to more accurately estimate the burden of the information collection and OSHA should revise the burden estimate accordingly before submitting a final 2015 ICR extension request to the Office of Management and Budget for consideration. Moreover, CPDA believes that the Agency fully recognizes that the HCS 2012 ICR failed to demonstrate the practical utility of the information collection in entirety and the Agency should revise the 2015 ICR extension request appropriately before submitting a final ICR extension request to the Office of Management and Budget for consideration.

APPENDIX B: September 2015 letter of Thomas Galassi, Director, Directorate of Enforcement Programs, OSHA.

U.S. Department of Labor

Occupational Safety and Health Administration
Washington, D.C. 20210

Reply to the attention of:

SEP 11 2015

Dr. Susan Ferenc, DVM, Ph.D.
Council of Producers & Distributors of Agrotechnology
1730 Rhode Island Ave., Suite 812
Washington, DC 20036

Dear Dr. Ferenc:

This is in response to your letter and follow-up meeting with the Occupational Safety and Health Administration (OSHA) regarding the Council of Producers & Distributors of Agrotechnology's (CPDA) request to resolve labeling concerns with the revised Hazard Communication Standard (HCS), 29 CFR 1910.1200. Your letter was forwarded to the Directorate of Enforcement Programs for a response. You requested clarification on the December 1, 2015, effective date for container labeling of non-pesticide agrichemical products shipped from the manufacturer/importer or returned through the distribution system. Specifically, you state that compliance with the extended labeling deadline for distributors of agricultural chemical products is incompatible with market distribution and consumption practices, and is infeasible.

We appreciate your voicing concerns regarding the Hazard Communication standard on behalf of your members. The Agency is mindful of the complexity and scale of the changes required of manufacturers, importers and distributors during this transition period. After a summary of the background you provided, your paraphrased question and our reply are below.

Background: Non-pesticide agricultural chemicals (e.g., tank-mix adjuvants and plant nutritional products) are shipped from U.S. manufacturers and formulators to U.S. distributors and others. Under long-standing commercial arrangements, customers are permitted to return unused product to the distributor (not the manufacturer) sometimes 4-5 years after purchase. After confirming the integrity of the returned product, the distributor then may ship the returned product to other customers. The manner in which these products are distributed, returned to the distributor, and redistributed results in the products remaining in commerce for years and certainly beyond the December 1, 2015, effective date. The U.S. Environmental Protection Agency (EPA) allows agricultural chemicals regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to follow labeling requirements by the "released for shipment"[1] approach as triggered under the EPA's modified container and containment (C&C) rule. In addition, the CPDA is concerned about the increased workplace hazards and risks involved for

[1] 40 CFR § 152.3. "...a product becomes released for shipment when the producer has packaged and labeled it in a manner in which it will be distributed or sold, or has stored it in an area where finished products are ordinarily held for shipment..."

workers that would dismantle pallets by hand, repackage, and re-label existing product containers.

Question: Will OSHA allow containers "leaving the workplace," which require labeling as per § 1910.1200(f)(1), to mean "released for shipment" as is used by the EPA's C&C rule?

Response: On February 9, 2015, OSHA had issued an interim enforcement memorandum which explained that in situations where a manufacturer or importer cannot comply with the June 1, 2015 effective date despite its reasonable diligence and good faith efforts, and a distributor is consequently unable to comply with the December 1, 2015 effective date, enforcement discretion would allow for limited continued use of HCS 1994-compliant MSDSs and labels provided that the distributor also exercised reasonable diligence and made good faith efforts to comply. Because of additional questions and requests for further clarification on the labels for existing stock, on May 29 2015, OSHA issued further interim guidance to address the limited continued use of HCS 1994-compliant labels.

The May 29th memorandum had stated, in part, distributors with existing stock that are packaged (e.g., boxed, palletized, shrink-wrapped, etc.) for shipment and are HCS 1994-compliant labeled before December 1, 2015, may continue to ship those containers downstream. In these instances, there is no requirement to re-label packaged for shipment containers with HCS 2012-compliant labels. Distributors must provide a HCS 2012-compliant label for each and every individual container shipped and the appropriate HCS 2012-compliant SDS(s) with any future shipments after December 1, 2015 or upon request, unless they can demonstrate reasonable diligence and good faith as discussed in the earlier February 9th memorandum. Additionally, distributors must provide HCS 2012-compliant SDSs to downstream users with the first shipment after a new or revised SDS is provided by the manufacturer or importer.

OSHA reviewed the EPA's "release for shipment" definition under their C&C rule and found that the February 9th and May 29th memoranda were closely aligned with it. Thank you for making us aware of the long-standing commercial arrangements for unused packages of agriculture chemicals to be returned to a distributor 4-5 years after purchase. However, the Agency believes that the Hazard Communication standard as currently designed, including the use of an HCS 2012-compliant label, is necessary for the long-term safety of downstream consumers.

OSHA has received a request to further clarify its HCS 2012 labeling requirements for manufacturers and importers in regards to the situations previously outlined in the February 9th and May 29th memoranda especially asking whether there is an end-date when all containers must be HCS 2012-compliant labeled. Consequently, OSHA now provides that, regardless of the date that a container was packaged for shipment, all containers shipped by the manufacturer or importer after June 1, 2017, and all containers in the control of a distributor after December 1, 2017, must be HCS 2012-compliant labeled prior to shipping.

As you are aware, on July 20, 2015, OSHA issued the revised *Inspection Procedures for the Hazard Communication Standard (HCS 2012)* directive, CPL 02-02-079 (copy enclosed). The revised directive incorporated the guidance from both the February 9, 2015 and May 29, 2015 enforcement memoranda. The revised HCS 2012 directive can be found at http://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-079.pdf.

In regards to the re-labeling of existing stock with HCS 2012-compliant labels where feasible, the employer should conduct a thorough hazard assessment, as required by 29 CFR 1910.132(d), to identify any potential hazard(s) (e.g., hand injury to workers from removing labels and relabeling), and then provide the type(s) of personal protective equipment that will protect workers from the hazard(s) identified (e.g., hand protection). The hazards associated with manual lifting can be lessened by developing and instituting an ergonomic lifting program. OSHA suggests that the CPDA reviews and shares with their members an ergonomic publication from the National Institute for Occupational Safety and Health (NIOSH) titled *Ergonomic Solutions for Retailers*. The link to the document is http://www.cdc.gov/niosh/updates/upd-11-25-14.html. This NIOSH publication focuses on the grocery sector, but the easy-to-read format can be adapted to other scenarios including for those working in warehousing and storage facilities.

Thank you for your interest in occupational safety and health. We appreciate CPDA's time to come in and meet with us to discuss the industry's concerns, and hope you find this information helpful. OSHA's requirements are set by statute, standards, and regulations. Our letters of interpretation do not create new or additional requirements but rather explain these requirements and how they apply to particular circumstances. This letter constitutes OSHA's interpretation of the requirements discussed. From time to time, letters are affected when the Agency updates a standard, a legal decision impacts a standard, or changes in technology affect the interpretation. To assure that you are using the correct information and guidance, please consult OSHA's website at http://www.osha.gov.

If you have further questions, please feel free to contact the Office of Health Enforcement at (202) 693-2190.

Sincerely,

Patrick J. Kapust

for Thomas Galassi, Director
Directorate of Enforcement Programs

Enclosure

APPENDIX C: Petition to Revise HCS 2012 to Clarify Application of the Sealed Container Exemption.

May 24, 2016

The Honorable Dr. David Michaels
Assistant Secretary of Labor for Occupational Safety and Health
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, D.C. 20210

Re: Petition to Revise HCS 2012 to Clarify Application of the Sealed Container Exception

Dear Dr. Michaels:

On behalf of the signatories below and pursuant to section 6(b) of the Occupational Safety and Health Act and 29 C.F.R. § 1911.3, this petition requests that the Occupational Safety and Health Administration (OSHA) revise the Hazard Communication Standard promulgated on March 26, 2012 (HCS 2012).[1] This revision is needed to clarify that when firms handling products in sealed containers in warehouses become aware of significant new information, they may comply with HCS 2012 label requirements by transmitting an updated label to downstream entities in the same way they transmit an updated safety data sheet (SDS) under 29 C.F.R. §1910.1200(g)(6), (7) and (8). The members of our organizations are manufacturers, importers, distributors and employers collectively in control of tens of millions of hazardous chemical product containers subject to HCS 2012 labeling provisions, and residing in thousands of warehouses awaiting shipment. These products have shelf lives of at least six months to upwards of six years or more.

We respectfully request the Agency undertake rulemaking to amend paragraph (f)(11) thusly:

Proposed Revision to 29 C.F.R. § 1900.1200(f)(11)

> Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals manufactured after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

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[1] 77 Fed. Reg. 17574 (March 26, 2012).

> For work operations where employees handle chemicals only in sealed containers that are not opened under normal conditions of handling (such as found in marine cargo handling, warehousing, or retail sales), the manufacturer, importer, distributor, or employer may comply with this section by ensuring that an updated label is provided at the time those containers are shipped.

Paragraph (f)(11) of HCS 2012 as written seems to imply that, once in possession of significant new information, the relabeling of individual hazardous chemical containers is required by manufacturers, importers, distributors or employers in order to ship product from warehouses, which are non-manufacturing workplaces. However, the rule prohibits warehouse employees from engaging in certain tasks associated with relabeling those products. OSHA has repeatedly justified such compliance conflicts ostensibly to protect "downstream consumers,"[2,3] which are neither "employees" nor a population OSHA is authorized statutorily to protect. Meanwhile, the rule endangers warehouse employees pressed into the work of relabeling, thereby undermining its mission of protecting workers from occupational safety and health risks. Employers' only avenue for compliance requires them to forego the important and long-standing sealed container exemption in 29 C.F.R. §1910.1200(b)(4)(i).

The recommended regulatory revision set forth herein demonstrates that these two aspects of hazard communication - providing updated label information while safeguarding warehouse employees' safety and health - need not be at odds in practice. If adopted by OSHA, it would have no effect whatsoever on the extent to which HCS 2012 achieves OSHA's legitimate statutory purpose, and would prevent employees from being subjected to avoidable occupational safety and health risks.

Background

In the vast majority of cases where hazardous chemical products have a shelf-life of years and production is cyclical, it is not technically or economically feasible to return product to the production plant for relabeling, even from on-site warehouse facilities. Absent that option, firms that own or operate warehouses can either ship millions of pounds of

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[2] OSHA denied an August 12, 2014 industry-submitted "Petition to Reopen Rulemaking On The Hazard Communication Standard, 29 C.F.R. § 1910.1200, To Extend Time For Implementation." In the undated response letter signed by you, the nine chemical industry trade organization signatories were separately told: "The Agency understands the complexity and scale of the changes required of manufacturers during this transition period. However, the Agency continues to believe that the Hazard Communication Standard as currently designed *is necessary for the long-term safety of downstream consumers* ." (emphasis added)

[3] Thomas Galassi, Director, Directorate of Enforcement Programs, OSHA, September 2015 response to an industry "Request for a Letter of Interpretation that Clarifies the Container Label for a Category of Non-Pesticide Agrichemical Products, Labeled in Accordance with the HCS When Initially Shipped From the Manufacturer/Importer, as Compliant with HCS 2012 for the Life of the Product."

hazardous chemicals to hazardous waste disposal facilities or relabel sealed containers in those warehouses. Relabeling of sealed hazardous chemical containers is not a common practice during production or storage, so the technology to safely relabel or repackage such containers does not exist. This must be done by hand. Warehouses lack the essential operational means to do this, and warehouse employees are especially unqualified to perform those tasks. Moreover, some product containers cannot be relabeled (e.g., pre-printed bags) and must be repackaged by hand. Significant physical and ergonomic injuries and risks from hazardous chemical exposure are inevitable. The tasks required - breaking down pallets, slicing open boxes containing individual product containers, removing old labels (where possible), hand-affixing new labels, re-boxing or re-palletizing the individual containers, and manually shrink-wrapping stacked bags and boxes - cannot be performed without creating significant occupational risks.

HCS 2012 made substantial changes to decades-long practices in occupational hazard communication. These changes include setting out specific elements for hazard classification (itself a change from the previous "hazard determination"), establishing a new format and content for the SDS, and standardizing the label elements (pictograms, signal words, hazard statements, and precautions) for hazardous chemical containers. OSHA's July 2015 Enforcement Directive [4] adds further regulatory burdens, which are discussed in greater detail below.

HCS 2012 Converts Relabeling into a Major, Recurring and Technically and Economically Infeasible Burden on Warehouse Operations

Relabeling obligations are set forth in paragraph 1910.1200(f)(11):

> Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

This text is substantially unchanged from HCS 1994, so its effects may not be obvious. Whereas the triggering event - the awareness of significant new information - under HCS

[4] See *OSHA Instruction Directive Number CPL 02-02-079: Inspection Procedures for the Hazard Communication Standard (HCS 2012)*; Effective Date July 9, 2015.

1994 (hazard determination) was exceedingly rare, under HCS 2012 the triggering event (hazard classification) will be frequent. In fact, hazard reclassification is expected to be a common activity, making the relabeling requirement in paragraph (f)(11) a "dynamic" (i.e., recurring) regulatory requirement.

When promulgating the final rule, OSHA appears to have been unaware of the impacts of new potential triggering events or the significant adverse effects relabeling would have on warehouse employees and the companies employing them, despite the repeated efforts of CPDA and others to explain to OSHA staff how the text of (f)(11) would have to be implemented in actual practice.[5]

The Enforcement Directive Imposes New Burdensome Regulatory Requirements

The relabeling requirements in HCS 2012 are complicated. The Enforcement Directive makes them more so.

HCS 1994-compliant labeled products

As of June 1, 2015, manufacturers or importers that package containers of hazardous chemicals for shipment have been required to label each such container with an HCS 2012-compliant label prior to shipping.[6] However, achieving compliance for existing stock packaged and awaiting distribution is significantly more complicated. HCS 2012 allowed only distributors to ship containers of hazardous chemicals with HCS 1994-compliant labels until December 1, 2015.[7] The Enforcement Directive clarified that distributors with "existing stock packaged (e.g., boxed, palletized, shrink-wrapped, etc.) for shipment prior to June 1, 2015 that are HCS 1994-compliant labeled" are permitted to ship these downstream until December 1, 2017, without the need to relabel the containers.[8] However, the Enforcement Directive further states that distributors must provide an HCS 2012-compliant label "*for each and every individual container*" of HCS 1994-compliant labeled product shipped after December 1, 2015.[9]

OSHA responded partially to industry concerns through the Enforcement Directive by allowing distributors to ship existing HCS 1994-compliant labeled stock until December 1,

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[5] Supra, note 1 at 17633. In the preamble to the final rule, EPA stated that "Procter & Gamble reported that they felt 'the largest economic impact of GHS compliance to our business will be in the area of re-labeling…' and numerous other commenters echoed those concerns… OSHA anticipates that the four-year phase-in for the revisions to the OSHA HCS (increased from three years in the proposed rule) will provide adequate time for companies to deplete inventory and replace in-house containers that are labeled in accordance with the original OSHA HCS and therefore will mitigate any costs associated with relabeling in-house containers or products in inventory."
[6] 29 C.F.R. § 1910.1200(j)(2).
[7] 29 C.F.R. § 1910.1200(j)(2)(i).
[8] Supra, note 4 at 42-43.
[9] Id. (emphasis added).

2017. However, the document also states that containers bearing HCS 1994-compliant labels in the control of a distributor thereafter must be labeled in compliance with HCS 2012 prior to shipping. OSHA thereby confirms that distributors are required to affix new labels to individual sealed containers, but still fails to acknowledge that this would be done by under qualified personnel in warehouses lacking appropriate technology.

HCS 2012-compliant labeled products

On December 1, 2015, compliance requirements changed for all product labeled after June 1, 2015. Paragraph (j)(2)(ii) of HCS 2012 states that a "distributor shall not ship containers labeled by the chemical manufacturer or importer unless the label has been modified to comply with paragraph (f)(1) of this section." Paragraph (f)(1) imposes the core labeling requirement: "[t]he chemical manufacturer, importer, or distributor shall ensure that *each container* of hazardous chemicals leaving the workplace is labeled, tagged, or marked" (emphasis added).

The problem is that OSHA's switch from hazard determination to hazard classification results in a vast change in scope. Paragraph (f)(11) now applies to an unknown and unpredictable (but unambiguously large) number of products manufactured and labeled in compliance with HCS 1994 or HCS 2012, and to virtually every firm in the supply chain prior to retail. It requires manufacturers, importers, distributors, *or employers* to revise labels within six months of becoming aware of significant new information (or receiving a new SDS) before product can be shipped.[10] In short, as interpreted by OSHA in the Enforcement Directive, HCS 2012 prohibits the shipment of product after six months of receiving a new SDS unless the individual containers have been relabeled. There are no provisions in the final rule that address *how* label modifications are to be accomplished, and the Enforcement Directive offers no insight.

Burdensome new relabeling requirements in the Enforcement Directive

Unfortunately, in an effort to "solve" some of the apparent compliance contradictions in HCS 2012, the Enforcement Directive imposes several new and burdensome regulatory obligations on manufacturers, importers and distributors. For example, covered firms now must conduct "reasonable diligence" - affirmatively search for and obtain significant new information, or document why it could not be found.[11] "Reasonable diligence" entails a host of new information collection and recordkeeping burdens, and the Enforcement Directive provides no objective standard concerning how much "reasonable" diligence is enough. The document also requires covered entities to provide a paper copy of an HCS-2012 compliant label for each and every HCS 1994-compliant labeled container after

[10] 29 C.F.R. § 1910.1200(f)(11) (emphasis added).
[11] Supra, note 4 at 43.

December 1, 2015,[12] even though the Agency supports the electronic transmission of SDSs.[13] Finally, as discussed later in more detail, the Enforcement Directive effectively revokes the sealed container exemption in paragraph (b)(4)(i), thereby exposing covered entities to new unaccounted-for regulatory costs and their employees to unwarranted and avoidable new risks.

Substantively, none of these new regulatory requirements resolves the contradictory relabeling provisions in HCS 2012. They do not substantially reduce burden or avoid the increase in occupational safety and health risks that relabeling under HCS 2012 creates. Procedurally, OSHA cloaks them under guidance rather than promulgating them as regulations in compliance with the Administrative Procedure Act. [14]

Burdensome new relabeling requirements will be triggered by forthcoming guidance and other foreseeable regulatory actions

OSHA has failed to examine adequately the implication for workers and the compliance pitfalls that its approach to relabeling invites or the economic feasibility of large and small entities to relabel product in a warehouse. [15] The Enforcement Directive instead creates even more burdensome regulatory requirements.

The potential impacts of OSHA's "dynamic" relabeling requirements are enormous and unbounded. Hazardous chemical products frequently will require relabeling in light of significant new information. This triggering event can happen at any time in the future life of a boxed, palletized, shrink-wrapped or otherwise packaged set of sealed containers in warehousing. This will happen regardless of whether they are under the control of a chemical manufacturer, importer, distributor, or employer, and for long shelf-life products this could happen more than once.

There are at least three highly predictable future scenarios in which substantial relabeling burdens can be expected. First, OSHA has stated that it will undertake new rulemaking on

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[12] Id. at 42.
[13] Id. at 60.
[14] See, e.g., *Chamber of Commerce* v. *Dep't of Labor,* 174 F.3d 206 (D.C. Cir. 1999) (striking down an OSHA Directive as legislative rule requiring notice and comment). Government-wide administrative policy on guidance is set forth by the Office of Management and Budget in *Final Bulletin for Good Guidance Practices* , 72 Fed. Reg. 3432, 3440/1 (2007). Significant guidance documents shall "[n]ot include mandatory language such as 'shall,' 'must,' 'required' or 'requirement,' unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties."
[15] Over 95% of "manufacturing" sector firms writing SDSs, and 97.5% of firms associated with warehousing and transportation ("non-manufacturing" sector), are small firms (<500 employees). Information provided by the hazardous chemical manufacturing, importing and distribution sectors of the chemical industry reveals that the cost of relabeling individual containers represents 10%-200% of the value of a container residing in a warehouse and awaiting shipment.

the label and SDS aspects of HCS 2012 to align with current and future revisions to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). [16] Each such revision will directly trigger new relabeling requirements under HCS 2012 as promulgated.[17]

Second, OSHA has only recently sought comment on weight-of-evidence (WoE) guidance for classifying hazardous chemicals. According to the proposal, "[t]he 'weight of evidence' approach assists manufacturers, importers and employers to evaluate scientific studies on the potential health hazards of a chemical and determine what information must be disclosed on the label and safety data sheet (SDS) for compliance with the Hazard Communication Standard." [18] How much help WoE guidance provides remains to be seen, but there is no doubt that its adoption will increase the frequency with which hazardous chemical products and containers have to be relabeled. OSHA clearly recognizes that manufacturers are still encountering difficulties in appropriately classifying chemical hazards. In fact, some product now residing in warehouses, manufactured only with inputs bearing HCS 2012-compliant labels produced on or before June 1, 2015, is already out of compliance due to receipt of significant new information from upstream manufacturers. However, the Enforcement Directive does not address these products, which therefore cannot be shipped after six months of receipt of an updated SDS unless each product container is relabeled with the new information. [19]

Third, Congress is now debating changes to the Toxic Substances Control Act (TSCA) to make it more similar to the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program. The enactment of any such legislation could significantly change the classification of many chemicals, thus triggering massive relabeling requirements under HCS 2012 as promulgated.

OSHA "Resolves" the Impossibility of Regulatory Compliance by Quietly Revoking the Sealed Container Exemption

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[16] Supra, note 1 at 17578. "This final rule is based on Revision 3 of the GHS. The adoption of the GHS will improve OSHA's current HCS standard by providing consistent, standardized hazard communication to downstream users. However, even after the U.S. and other countries implement the GHS, it will continue to be updated in the future. These updates to the GHS will be completed as necessary to reflect new technological and scientific developments as well as provide additional explanatory text. Any future changes to the HCS to adopt subsequent changes to the GHS would require OSHA's rulemaking procedures."

[17] Based on OSHA's regulatory analysis in support of HCS 2012, which unreasonably assumed that relabeling was a costless undertaking, the public, including stakeholders, can expect that OSHA will count none of the relabeling costs resulting from these new regulations.

[18] OSHA Trade News Release, U.S. Department of Labor, OSHA, Office of Communications, February 12, 2016.

[19] Such relabeling, by default, must be accomplished in the warehouse - and likely in one neither designed nor intended as a facility for tasks normally associated with manufacturing. These tasks now are to be performed by employees for whom this new work is not now, and never has been, familiar.

As interpreted by the Enforcement Guidance, paragraph (f)(11) conflicts with paragraph (b)(4)(i). Whereas (f)(11) requires *manufacturers', importers' and distributors'* employees to relabel products that become non-compliant with HCS 2012 after manufacture, (b)(4) prohibits *warehouse* employees from defacing or removing labels from sealed containers - a prerequisite to relabeling.

OSHA "resolves" this internal inconsistency by directly and indirectly revoking the sealed container exemption for all warehoused product under the control of a manufacturer, importer, or distributor. OSHA accomplishes this directly in the Enforcement Directive by substantially broadening the regulatory definition of "distributor" [20] so as to deny some distributors access to the sealed container exemption and indirectly by affirming that manufacturers do not have access to the sealed container exemption. [21]

HCS 1994 and HCS 2012 Text	***July 9, 2015, Enforcement Directive Text***
"Distributor" means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to employers. Source: 29 C.F.R. § 1900.1200(c) (unchanged by HCS 2012).	"Distributor" means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to **manufacturers**, other distributors, or to employers. Source: Enforcement Directive at 18, § X(C)(8) (emphasis added).

Subsection (a) of the expanded definition confirms for manufacturers that:

> A company that repackages, blends, mixes, or otherwise changes the composition of a chemical is considered a chemical manufacturer under the HCS.

However, the warehouse exception in paragraph (b)(4) clearly applies to warehouse employers and their employees, not to manufacturing operations or to their employees, but it is not clear that a manufacturer's warehouse cannot be considered a "warehouse" under paragraph (b)(4). Thus, subsection (a) is irrelevant to distributors even though it is supposed to explain the Enforcement Directive's new definition of "distributor." The bullets in subsection (a) provide a glimpse into OSHA's apparent purpose:

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[20] The provenance of this expanded definition is unknown as well as non-transparent. The Enforcement Directive does not acknowledge that it is different from HCS 2012. This is a substantive regulatory change with significant and burdensome regulatory effects.
[21] Supra, note 4 at 18.

- "Employees in *these* operations are considered to use hazardous chemicals." (emphasis added)

- "Under *these* conditions, the distributor will not be able to claim the sealed container provision in paragraph (b)(4) and will need to meet all applicable provisions of the HCS for manufacturers." (emphasis added)

Obviously, *these* operations and *these* conditions refer to manufacturing, and if a distributor engages in manufacturing (" *these* operations"), the distributor's employees are "using" hazardous chemicals ("under *these* conditions"), and not handling unopened and bulk-packaged containers as do typical manufacturing, importing and distribution warehouse employees. The Enforcement Directive has decreed that manufacturers' warehouse employees are not eligible for the sealed container exemption because they are defined as all being manufacturing sector employees.

If the bulleted text quoted above applies to manufacturers, then its presence in a section explaining the (new and expanded) definition of "distributor" is puzzling. There is no evidence to indicate this is an error or was otherwise unintended. Paragraph (b)(4)(i) prohibits *warehouse employees* from removing or defacing container labels in a warehouse, *even for the purpose of subsequent relabeling.* We cannot but surmise that the purpose of the new and expanded definition in the Enforcement Directive is surreptitiously to revoke the eligibility of some (or all) manufacturers, importers and distributors for the sealed container exemption.[22]

The burden- and risk-reducing sealed container exemption has been in place since promulgation of HCS 1987 and does not differentiate based on the owner of the product in the warehouse.[23] Nothing in HCS 2012 reasonably can be inferred to have altered this exemption in any way. Nevertheless, through the Enforcement Directive OSHA has imposed on manufacturers, importers and distributors a regulatory obligation that heretofore they have never known. For the first time, they must ensure that significant new information appears on the label of each sealed container within their control. After December 1, 2015, they may not ship products that were HCS 2012-compliant labeled

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[22] Id. at 54-55.

[23] The exemption was described some thirty years ago in a September 16, 1986 letter from John A. Pendergrass, Assistant Secretary of Labor, OSHA, to Congressman Dan Glickman. "If a wholesaler/distributor receives containers from a manufacturer which do not have the appropriate labels, the wholesaler/distributor is under no obligation actually to create labels. Rather, since the shipping manufacturer is in violation of the requirements, the wholesaler/distributor is required only to contact the manufacturer immediately and request that the labels be provided for these containers and that all future shipments be properly labeled. Since the wholesaler/distributor does not repackage these materials, the original label should remain affixed to the container."

when manufactured if they become aware of significant new information that would have otherwise required a different label at manufacture.

The sensible way to resolve this conflict is to exempt sealed containers from relabeling, *regardless of where they are or who owns them* , if they were HCS-compliant labeled when manufactured. There are few (and possibly no) places where such relabeling can be performed safely, and warehouses are clearly inappropriate venues. The work of warehouse employees involves efficiently and safely handling "existing stock packaged (e.g., boxed, palletized, shrink-wrapped, etc.) for shipment" [24] and then moving those products out as needed. Relabeling each individual container within such a shipment means slicing into secure packaging without harming the contents or the workers; unpacking and staging the containers within a warehouse not ordinarily equipped for industrial operations; replacing the existing label on each container with the updated versions; restacking on pallets; and hand shrink-wrapping the pallet; and doing all of this safely and securely. However, reestablishing the integrity of automated packing for shipment that is created on the production line is not feasible in a warehouse.

OSHA Implicitly Imposes New Occupational Safety and Health Risks on Employees

Because HCS 2012 prohibits relabeling in a warehouse, OSHA's estimation of the purported "incremental"[25] workplace health and safety benefits to be gained by the rule [26] over HCS 1994 cannot apply to warehouse employees. These purported incremental benefits would, in fact, be dwarfed by the inevitable physical, ergonomic and chemical exposure risks posed to thousands of full- or part-time warehouse employees opening, relabeling, and repackaging sealed hazardous chemical containers. By blending the Enforcement Directive guidance with the provisions of HCS 2012, OSHA is imposing new regulatory obligations while shielding itself from the responsibility to conduct notice-and-comment rulemaking and provide a reasoned basis for its regulatory action. OSHA apparently has determined that relabeling in compliance with HCS 2012 supersedes the importance of protecting warehouse employees from the substantial occupational safety and health risks they must bear to accomplish it. In fact, in the written response to an industry request, OSHA acknowledged and approved the relabeling of hazardous chemical products in a warehouse, stating that "the Agency believes that the Hazard Communication standard as currently designed, including the use of an HCS 2012-compliant label, is necessary for the long-term safety of downstream consumers." [27] As stated previously, we believe this is outside OSHA's given authority and purview.

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[24] Supra, note 4 at 42.
[25] Supra, note 1 at 17621.
[26] Id. at 17606. "OSHA estimates that if the rule could capture one percent of the benefits estimated for the original 1983 and 1987 HCS rules, the revisions would result in the prevention of 318 non-lost-workday injuries and illnesses, 203 lost-workday injuries and illnesses, 64 chronic illnesses, and 43 fatalities annually."
[27] Supra, notes 2 and 3.

Our Recommended Amendment Accomplishes the Goal of Providing Downstream Employers and Workers with Updated Label Information While Protecting Employees from Avoidable Occupational Safety and Health Risks

We are requesting an extraordinarily simple solution to the untenable situation the rule and Enforcement Directive have created. We therefore request that OSHA revise paragraph (f)(11) in a way that safeguards the well-being of thousands of current and future warehouse employees without compromising the benefits downstream users, employers and employees might gain from up-to-date label information. Our proposed revision would require rulemaking to amend the regulatory provision involved, and we would welcome OSHA's initiation of rulemaking for this purpose. The table below presents existing paragraph (f)(11) alongside our suggested revision:

Existing Paragraph (f)(11) and Our Requested Revision

Existing Paragraph (f)(11)	***Suggested Revision to Paragraph (f)(11)***
Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.	Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals manufactured after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again. For work operations where employees handle chemicals only in sealed containers that are not opened under normal conditions of handling (such as found in marine cargo handling, warehousing, or retail sales), the manufacturer, importer, distributor, or employer may comply with this section by ensuring that an updated label is provided at the time those containers are shipped.

This recommended revision of HCS 2012 would ensure that warehouse employees remain fully protected from occupational safety and health risks resulting from activities outside the normal scope of their employment. It would accomplish this in a manner fully consistent with the HCS framework and preserve the long-standing prohibition on the removal or defacing of labels, as set forth in paragraph (b)(4)(i). Further, it would incorporate the instructive parenthetical examples from paragraph (b)(4) ("such as are found in marine cargo handling, warehousing, or retail sales"). Timely transmission of updated label information to downstream employers would be achieved by providing one paper (or electronic, print ready file) label with each shipment. This approach to informing employees of new health and safety information is no different than the long-established approach in paragraphs (g)(6), (7) and (8) for providing access to and transmitting SDS information, including updates, throughout the chemical supply chain to employers, employees, and users. Not every change in an SDS will necessitate a corresponding update in the product label, but this does not alter the merit of harmonizing the approaches to the transmission of significant new information when required. Without this change, employers cannot feasibly or safely comply with section (b)(4)(i) as currently written.

Conclusion

For the reasons discussed, we respectfully request that OSHA initiate a rulemaking to amend 29 C.F.R. §1910.1200 (f)(11) to incorporate the language set forth herein.

Respectfully submitted,

(b) (6)
President
Agricultural Retailers Association

(b) (6), DVM, Ph.D.
President
Council of Producers & Distributors of Agrotechnology

(b) (6)
Executive Director
ISSA, The Worldwide Cleaning Industry

(b) (6)
President
Society of Chemical Manufacturers and Affiliates

From: Aguilar, Brenda
Sent: Tuesday, May 24, 2016 4:31 PM
To: Shelanski, Howard; Mancini, Dominic; Orris, Allison
Cc: Higgins, Cortney; Brammer, Josh
Subject: RE: Council of Producers & Distributors Petition to OIRA

Howard

Looks like a PRA petition on an OSHA collection associated with the GHS rule. We've been aware of the issue, as other stakeholders have recently reached out. The collection is currently under review. (b) (5) [redacted]

We'll dig into this and let you know what we think. I copied the statutory and regulatory text they cite in the petition.

Brenda

44 U.S. Code § 3517 - Consultation with other agencies and the public

(a) In developing information resources management policies, plans, rules, regulations, procedures, and guidelines and in reviewing collections of information, the Director shall provide interested agencies and persons early and meaningful opportunity to commen t.

(b) Any person may request the Director to review any collection of information conducted by or for an agency to determine, if, under this subchapter, a person shall maintain, provide, or disclose the information to or for the agency. Unless the request is frivolous, the Director shall, in coordination with the agency responsible for the collection of information

(1) respond to the request within 60 days after receiving the request, unless such period is extended by the Director to a speci fied date and the person making the request is given notice of such extension; and

(2) take appropriate remedial action, if necessary.

§ 1320.18 Other authority.
(a) OMB shall determine whether any collection of information or other matter is withi n the scope of the Act, or this Part.
(b) In appropriate cases, after consultation with the agency, OMB may initiate a rulemaking proceeding to determine whether an agency's collection of information is consistent with statutory standards. Such proceedings shall be in accordance with the informal rulemaking procedures of the Administrative Procedure Act.

From: Shelanski, Howard
Sent: Tuesday, May 24, 2016 4:00 PM
To: Aguilar, Brenda <Brenda_Aguilar@omb.eop.gov>; Mancini, Dominic <Dominic_J._Mancini@omb.eop.gov>; Orris, Allison <Allison_B_Orris@omb.eop.gov>

Subject: FW: Council of Producers & Distributors Petition to OIRA
Importance: High

??

From: Susan Ferenc [mailto:sferenc@cpda.com]
Sent: Tuesday, May 24, 2016 3:48 PM
To: Shelanski, Howard
Cc: Mancini, Dominic
Subject: Council of Producers & Distributors Petition to OIRA
Importance: High

Please find attached a cover letter and petition seeking certain determinations and actions by the Office of Management and Budget.

Susan Ferenc, DVM, Ph.D.
President

Council of Producers &
Distributors of Agrotechnology

1730 Rhode Island Ave., NW | Suite 812 | Washington, DC 20036
Phone: 202-386-7407 | Email: sferenc@cpda.com | Web: >www.cpda.com<

From: Shelanski, Howard
Sent: Tuesday, May 24, 2016 5:10 PM
To: Aguilar, Brenda; Mancini, Dominic; Orris, Allison
Cc: Higgins, Cortney; Brammer, Josh
Subject: RE: Council of Producers & Distributors Petition to OIRA

Thanks, Brenda.

From: Aguilar, Brenda
Sent: Tuesday, May 24, 2016 4:31 PM
To: Shelanski, Howard; Mancini, Dominic; Orris, Allison
Cc: Higgins, Cortney; Brammer, Josh
Subject: RE: Council of Producers & Distributors Petition to OIRA

Howard

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