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July 30, 2015 (Amended August 21, 2015)

Hon. Howard Shelanski
OIRA Administrator
Office of Management and Budget
Room 10235, 725 17th Street NW
Washington, DC 20503
Email: OIRA_submission@omb.eop.gov

RE: ICR for OSHA Hazard Communication Standard
OMB Control Number 1218-0072

Dear Administrator Shelanski:

We timely submitted an initial set of comments on OMB's review of the referenced ICR for the OSHA Hazard Communication Standard ("the HCS") under the Paperwork reduction Act ("the PRA") on July 30, 2015. We are now filing an amended set of comments to supplement the points made in our initial filing on behalf of a number of large trade associations, manufacturers and users of products subject to the HCS.

For convenience, we refer to the HCS, as amended by the GHS Update adopted in March 2012, as HCS 2012, and we refer to the previous version of the HCS as HCS 1994. It took OSHA more than three years following promulgation of HCS 2012 to develop its 123-page HCS compliance directive ("the 2015 HCS CPL")[1] explaining how it would interpret HCS 2012. The 2015 HCS CPL was not made available to the public until July 20, 2015, only 10 days before the ICR comment deadline. Given those facts, the enormous variance between the actual implementation of HCS 2012 and the implementation of HCS 2012 as described in the ICR, and the unique circumstances of the HCS 2012 rulemaking, we believe the time period allowed for submission of comments on this ICR was inadequate and that consideration of this additional information would clearly be in the greater public interest as well as the interest of the regulated

[1] OSHA Directive CPL 02-02-079, Inspection Procedures for the Hazard Communication Standard (HCS 2012), Effective Date: July 9, 2015.

community. Accordingly, we ask that OMB consider the additional information contained in this filing in acting on the HCS ICR.

We have three objectives in filing these comments. First, and most important, we seek OMB's assistance in working with OSHA to clarify the requirements of HCS 2012 and ensure that OSHA's interpretations of HCS 2012 are appropriate. If reasonable interpretations of any provisions of HCS 2012 subject to the PRA would otherwise be precluded by the language of the HCS, then OMB approval for enforcement of those provisions should be selectively denied where practical to achieve a reasonable interpretation and granted where appropriate for a period of no more than six months to allow OSHA time to amend the rule. An amendment of the rule is clearly necessary to address its shortcomings.

Second, we believe it is prudent to respectfully question how OSHA could have: (1) presented the proposed rule leading to HCS 2012 to OMB, SBA and the regulated community as something other than a Major Rule; and (2) submitted an ICR for approval that we believe both materially understates the burden of compliance with the HCS and fails to acknowledge that the paperwork transition from HCS 1994 to HCS 2012 is far from complete and will take most if not all of the next three years.

Finally, before the next revision to the HCS is proposed, we wish to make it clear that our experience with the development of the GHS and HCS 2012 indicates that the American business community was not and is not being provided with an adequate opportunity for meaningful comment on the development of the GHS or the OSHA rule adopting the GHS.

Keller and Heckman LLP is a law firm with an extensive regulatory practice in many areas, including workplace safety and health, and chemical control. We believe we have a special expertise in commenting on and critiquing HCS 2012 and the interim guidance provided by OSHA to date on how it plans to enforce the phased compliance deadlines of HCS 2012. Our firm has extensive experience with pre-2012 versions of the HCS. We participated in earlier HCS rulemakings; we provided extensive client counseling on HCS compliance; we have written and/or reviewed many HCS programs; we have provided HCS training to many covered facilities; and we have handled a significant number of OSHA enforcement actions involving citations of the HCS.

Keller and Heckman LLP was extensively involved in the analysis and critique of the ANPRM and the NPRM in the HCS 2012 rulemaking. We prepared comments, testimony, post-hearing comments and post-hearing briefs to make recommendations and critique many aspects of the draft proposed rule and the proposed rule; we testified at the informal public hearing; and we represented the American Petroleum Institute in its pre-enforcement challenge to HCS 2012. Along with many other industry interests, our participating clients strongly advocated that OSHA adopt the two-stage approach adopted by the European Union for the GHS transition from HCS 1994 to HCS 2012— applying the new rules to substances during the first stage and mixtures in

a second stage. During the HCS 2012 rulemaking, we also pointed out that there are multiple tiers of formulators that would take even longer to complete the transition.

The situation that calls for comments of this nature is the unfortunate consequence of a dysfunctional rulemaking process and Supreme Court decisions on deference that invite what we hope will soon be viewed as unconstitutional mischief. OSHA has, in effect, extended the HCS rulemaking for three years and four months following adoption of the final rule on March 26, 2012, through the development and adoption of the 123-page compliance directive ("the 2015 HCS CPL"), dated July 9, 2015 Except for the settlement of petitions for review and compelling requests for interpretation, OSHA has done this on a unilateral basis.

The fundamental shortcomings of the HCS 2012 and the extended development of the HCS 2012 CPL made it extremely difficult to effectively participate in the ICR for the HCS in a timely manner. A party interested in filing a comment on the ICR was materially handicapped in doing so because the HCS 2012 CPL, dated July 9, 2015, did not become publically available until July 20, 2015, long after the April 27, 2015 initial notice, and only 10 days before the filing deadline for the June 26, 2015 notice. The supporting statement for the ICR was not available to us for review until 11:03 am on July 1, 2015 through an email from OSHA staff. We do not know when it was first available through regulations.gov. We view this filing as a constructive effort designed to avoid a repeat of the HCS 2012 rulemaking.

I. INTERPRETATION OF HCS 2012

A. Background

Our clients will be significantly affected by the enforcement positions taken by OSHA with respect to the implementation of the chemical classification, safety data sheet (SDS) and labeling requirements of the HCS. Our clients seek to ensure that, in transitioning from HCS 1994 to HCS 2012, they remain in compliance with the HCS, that compliance is neither unreasonably burdensome nor infeasible, and that compliance does not impose a greater hazard on employees than extended adherence to HCS 1994.

B. Issues

OSHA adopted HCS 2102 in March of 2012. It took the agency until July 2015 to issue a 124 page compliance directive to clarify what it theoretically intended to require when it adopted the rule in March of 2012. We did not have sufficient time to address all of the issues raised by the July 9 2015 HCS CPL, which was not publically available until July 20, 2015. More are likely to come to light as the rule is implemented over the next few years.

1. If Product Was Packaged for Shipment in Containers Labeled in Compliance with the HCS at the Time of Packaging, Manufacturers and Distributors Must be Permitted to Ship that Product Downstream for the Life of the Product Without Relabeling

Our client-manufacturer's immediate concern (shared by most of the chemical industry of the US) with respect to this issue is avoiding the following scenario. Either our client or a distributor of our client's products is holding inventory of our client's product, packaged prior to the June 1, 2015 "effective date" of HCS 2012 with HCS 1994-compliant labeling. OSHA takes the position that the product may not be shipped by our client (after June 1, 2015) or the distributor (after December 1, 2015) unless the container is re-labeled with HCS 2012-compliant labeling. Our client-user's immediate concern with respect to this issue is avoiding a situation where it may have OSH Act liability if it accepts what OSHA asserts is improperly labeled product from a manufacturer or distributor.

In adopting HCS 2012, OSHA addressed (albeit in an incomplete manner) the issue of when the initial HCS 2012-compliant container labels would need to be developed and available. It did not address how the inventory of product packaged prior to June 1, 2015 in containers with HCS 1994-compliant labeling would be treated.

Section 1910.1200(f)(11) of HCS 2012 provides as follows:

> 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.

Our client-manufacturer's concern (which we believe is also shared by most of the chemical industry of the US) with respect to this provision is avoiding the following scenario. Either our client or a distributor of our client's products, is holding inventory of our client's product, packaged in compliance with HCS 2012 at the time it was packaged. New information requiring modifications to the SDS and label for the product is received by the manufacturer. The manufacturer develops an updated SDS within the 3 months specified in 1910.1200(g)(5) and an updated label within the 6 months specified in 1910.1200(f)(11) for new production. OSHA takes the position that, at the end of the 6 month period, the product with the now-outdated HCS 2012 label may no longer be shipped by our client or the distributor until the container is relabeled.

We presented these issues to OSHA in the attached March 25, 2015 Request for Interpretation to OSHA Administrator David Michaels, and several follow-up communications.

Those communications make the point that relabeling the inner packages of product that are packaged for shipment would be a nightmare disaster from the standpoint of workplace safety (greatly increased risk of chemical exposures and ergonomics problems from manual handling activities), technical feasibility (manufacturing lines are not capable of receiving filled containers for re-labeling), employment, waste (huge amounts of scrapped packaging material) and economics. We were pleased that, in its May 29, 2015 Interim Enforcement Guidance for HCS 2012, and its July 2015 compliance directive for HCS 2012, OSHA acknowledged the validity of our concerns, at least with respect to the HCS 1994 to HCS 2012 transition, and adopted the following position in the HCS 2012 CPL:

> Manufacturers or importers of hazardous chemicals (including businesses that repackage) that have existing stock packaged (e.g., boxed, palletized, shrink-wrapped, etc.) for shipment prior to June 1, 2015, that are HCS 1994-compliant labeled, may continue to ship those containers downstream. In such instances, there is no requirement to re-label packaged for shipment containers with HCS 2012-compliant labels. The manufacturer or importer must provide HCS 2012-compliant labels for each and every individual container shipped and the appropriate HCS 2012-compliant SDS(s) with each shipment, unless the manufacturer or importer can demonstrate that it exercised reasonable diligence and good faith as discussed in this policy.

We read this to say that manufacturers may continue to ship existing stock packaged for shipment prior to June 1, 2015, with HCS 1994-compliant labels, to customers for the life of the product without relabeling the product. However, two concerns remain. First, repeating language contained in the May 29 Interim Enforcement Guidance, the 2015 HCS CPL also states:

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

Second, the 2015 HCS CPL does not address the post-transition scenario where the HCS 2012-compliant label becomes outdated and must be updated. The same problems of technical and economic infeasibility and greater hazards to employees are equally applicable.

When the May 29 Interim Enforcement Guidance was issued, we sent the following June

4, 2015 email to Dr. Michaels to address our clients' continuing concerns:

> Dear Dr. Michaels:
>
> Thank you for the May 29 Interim Enforcement Guidance for HCS 2012, which addresses the HCS 2012 labeling dilemma for pre-June 1 inventory and confirms that "Manufacturers or importers of hazardous chemicals (including businesses that repackages) that have existing stock packaged (e.g., boxed, palletized, shrink-wrapped, etc.) for shipment prior to June 1, 2015, that are HCS 1994-compliant labeled, may continue to ship those containers downstream." In issuing the "final" compliance directive, we request that DOL/OSHA clarify that distributors who receive that "pre-existing stock" (stock "packaged for shipment prior to June 1, 2015") may also continue to ship those containers downstream with the HCS 1994-compliant label and need not relabel them. Given that manufacturers may continue to ship pre-existing stock to distributors, it follows that distributors must also be permitted to ship that pre-existing stock to other distributors and the ultimate users. However, the following sentence, which could be taken out of context, raises the potential for concern and confusion: "All containers in the control of a distributor after December 1, 2017, must be HCS 2012-compliant labeled prior to shipping." Accordingly, we request that it be modified along the lines of the following: "With one exception, all containers in the control of a distributor after December 1, 2017, must be HCS 2012-compliant labeled prior to shipping. Distributors that have product that was packaged (e.g., boxed, palletized, shrink-wrapped, etc.) for shipment by the manufacturer prior to June 1, 2015, and that is HCS 1994-compliant labeled, may continue to ship those containers downstream."
>
> ……
>
> Thank you for your consideration.
>
> Respectfully submitted,
>
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When we later noted that the HCS 2012 CPL did not address either of the two remaining issues, we first spoke with OSHA staff and then sent the following July 27, 2015 email to Dr. Michaels to address our clients' continuing concerns:

> Dear Dr. Michaels:
>
> This follows up on a critical clarification sought in our June 4 Request for Interpretation.
>
> As we noted in our original communication, it would be infeasible and/or pose a greater hazard to employees to replace the HCS 1994-compliant label on containers that were packaged for shipment prior to June 1, 2015 with an HCS 2012-compliant label. Accordingly, given the extended shelf life of many products, we requested that OSHA clarify that product packaged for shipment with an HCS 2012-compliant label prior to June 1, 2015 could continue to be shipped for the life of the product in that container. In response, OSHA adopted the packaged for shipment interpretation in the May 29 Interim Enforcement Guidance for HCS 2012, which we believe provided the requested clarification with respect to inventory in the hands of the manufacturer. That language was carried forward to the July 9, 2015 compliance instruction as follows:
>
> h. Policy on limited continued use of HCS 1994-compliant labels.
>
> □ Guidance for manufacturers and importers of hazardous chemicals
>
> Manufacturers or importers of hazardous chemicals (including businesses that repackage) that have existing stock packaged (e.g., boxed, palletized, shrink-wrapped, etc.) for shipment prior to June 1, 2015, that are HCS 1994-compliant labeled, may continue to ship those containers downstream. In such instances, there is no requirement to re-label packaged for shipment containers with HCS 2012-compliant labels. The manufacturer or importer must provide HCS 2012-compliant labels for each and every individual container shipped and the appropriate HCS 2012-compliant SDS(s) with each shipment, unless the manufacturer or importer can

demonstrate that it exercised reasonable diligence and good faith as discussed in this policy.

The foregoing interpretation would extend for the life of the product in those containers. However, we were concerned that there was a separate sentence in the interim guidance dealing with distributors, retained in the July 9 compliance instruction, that reads as follows:

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

We believe this standalone sentence for distributors could be misinterpreted – e.g., that manufacturers may ship the product packaged for shipment prior to June 1, 2015 with HCS 1994-compliant labeling for the life of the product, but distributors may not distribute that product after December 1, 2017. It seemed clear that the agency had confused the "packaged for shipment" issue with the unrelated "reasonable diligence and good faith" issue, a wholly independent reason for a distributor not having an HCS 2012-compliant label on its products.

Accordingly, our June 4 Request for Interpretation contained the following request:

In issuing the "final" compliance directive, we request that DOL/OSHA clarify that distributors who receive that "pre-existing stock" (stock "packaged for shipment prior to June 1, 2015") may also continue to ship those containers downstream with the HCS 1994-compliant label and need not relabel them. Given that manufacturers may continue to ship pre-existing stock to distributors, it follows that distributors must also be permitted to ship that pre-existing stock to other distributors and the ultimate users. However, the following sentence, which could be taken out of context, raises the potential for concern and confusion: "All containers in the control of a distributor after December 1, 2017, must be HCS 2012-compliant labeled prior to shipping." Accordingly, we request that it be modified along the lines of the following:

> With one exception, all containers in the control of a distributor after December 1, 2017, must be HCS 2012-compliant labeled prior to shipping. Distributors that have product that was packaged (e.g., boxed, palletized, shrink-wrapped, etc.) for shipment by the manufacturer prior to June 1, 2015, and that is HCS 1994-compliant labeled, may continue to ship those containers downstream.

For some reason, that request was not addressed in the July 9 compliance directive.

In previous correspondence, we also noted that while it should be feasible to develop a new container label within six months of the receipt of new information, the need for an extended period of time beyond six months to exhaust old inventory with outdated labels was not limited to the HCS 1994 to HCS 2012 transition. Rather, it would present itself in the future every time a manufacturer of a product with a shelf life of more than six months received new information requiring a label change. We respectfully request that OSHA revise the July 9, 2015 compliance directive to address the critical need for additional time to exhaust inventories with labels that were compliant with the HCS at the time they were packaged for shipment.

Given that the time period for commenting on the ICR for the HCS pending before OMB is about to expire, we are copying OMB staff on this request.

Thank you for your consideration. Respectfully submitted,

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The two issues discussed in this section remain unresolved. A prohibition on the distribution of a chemical product packaged and labeled in compliance with the then applicable HCS, and accompanied by an updated label and SDS, because the label on the container is outdated, is not reasonably necessary or appropriate to workplace safety, is not necessary for the

proper performance of the functions of OSHA, and fails to minimize the burden of the collection of information. Every manufacturer and importer in the US that holds inventory for more than 6 months is potentially at risk of being out of compliance on an ongoing basis. We believe the holding of inventory by a manufacturer for more than 6 months is a pervasive practice, especially for products (such as construction materials/chemicals) that are seasonal and require an advance build-up of inventory. OSHA could not have intended to put manufacturers and importers in this type of situation.

Accordingly, we respectfully urge OMB to condition its approval of the HCS ICR on an interpretation that permits the continued distribution of the product by the manufacturer and distributors for the life of the product, provided the manufacturer and distributor provide HCS 2012-compliant labels for each individual container shipped and the appropriate HCS 2012-compliant SDS(s) with each shipment. If OMB is not in a position to do that, then it should reject the ICR because it would impose an unreasonable and inappropriate burden on U.S. chemical manufacturers and importers, and that burden is not recognized in the ICR filed with OMB.

2. It Appears that OSHA Has Arbitrarily and Unreasonably Limited the Ability of a Party in the Chain of Distribution to Rely on the Chemical Hazard Information Developed by an Upstream Manufacturer

The ability of a customer -- whether a distributor, a downstream user or a downstream manufacturer -- to rely on the SDS and label of the upstream manufacturer is a critical element of HCS implementation. In the absence of the ability to rely on the SDS and label of the upstream manufacturer, a downstream party would be legally obligated to repeat the obligations of the upstream manufacturer, which are to : determine the composition of the chemical (no testing is required), perform the hazard classification and prepare the SDS and label.

Section 1910.1200(d)(1) and 1910.1200(d)(3)(ii) state:

> (d)(1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with this section. For each chemical, the chemical manufacturer or importer shall determine the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified. Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer for the chemical to satisfy this requirement [emphasis added].
>
> (d)(3)(ii) When classifying mixtures they produce or import, chemical manufacturers and importers of mixtures may rely on the information provided on the current safety data sheets of the

> individual ingredients except where the chemical manufacturer or importer knows, or in the exercise of reasonable diligence should know, that the safety data sheet misstates or omits information required by this section.

The terms “chemical manufacturer” and “employer” are defined as follows:

> "Chemical manufacturer" means an employer with a workplace where chemical(s) are produced for use or distribution [emphasis added].
>
> "Produce" means to manufacture, process, formulate, blend, extract, generate, emit, or repackage.
>
> "Employer" means a person engaged in a business where chemicals are either used, distributed, or are produced for use or distribution, including a contractor or subcontractor.

The following discussion identifies the types of situations that arise and seeks an appropriate clarification as to how HCS 2012 will be applied so that the rule is interpreted in a reasonable manner and is fairly applied.

Assume Company A produces Product X to Company A’s specifications, performs the hazard classification, prepares the SDS and container label, puts Company A’s name and contact information on the container label and SDS as the responsible party for obtaining further information, and sells Product X to Company B. Company B distributes Product X. In that scenario, we believe Company A is the manufacturer of Product X and Company B is a distributor of Product X. Company A would be responsible for the hazard classification, the content of the SDS or label, and providing any further information in response to an inquiry; Company B would not have any of those responsibilities.

Assume Company A produces Product X to Company A’s specifications for Company B, performs the hazard classification, prepares the SDS and container label, and puts Company B’s name and contact information on the container label and SDS as the responsible party for obtaining further information. Company A’s name does not appear anywhere on the container label or SDS. Under HCS 2012, we believe Company A is the manufacturer of the product (responsible for the hazard classification, SDS and label) and Company B is the distributor and (although not the manufacturer) the responsible party for providing any additional information, but is not responsible for the hazard classification or the content of the SDS or label.

Assume Company A produces Product X to Company B’s specifications for Company B, performs the hazard classification, prepares the SDS and container label, and puts Company B’s

name and contact information on the container label and SDS as the responsible party for obtaining further information. Company A's name does not appear anywhere on the container label or SDS. Under HCS 2012, we believe Company A is the manufacturer of the product (responsible for the hazard classification, SDS and label) and Company B is the distributor and (although not the manufacturer) the responsible party for providing any additional information, but is not responsible for the hazard classification or the content of the SDS or label.

Assume Company A produces Product X to Company A's specifications, performs the hazard classification, prepares the SDS and container label, puts Company A's name and contact information on the container label and SDS as the responsible party for obtaining further information, and sells Product X to Company B. Company B relabels the product in the existing packaging to substitute a new product name and identify Company B as the responsible party and remove all Company A identifiers (e.g., name, address) from the label. Company B also revises the SDS to substitute itself as the responsible party and remove all Company A identifiers (e.g., name, address) from the SDS. Under HCS 2012, we believe Company A is the manufacturer of the product (responsible for the hazard classification, SDS and label) and Company B is the distributor and (although not the manufacturer) the responsible party for providing any additional information, but is not responsible for the hazard classification or the content of the SDS or label.

Assume Company A produces Product X to Company A's specifications, performs the hazard classification, prepares the SDS and container label, puts Company A's name and contact information on the container label and SDS as the responsible party for obtaining further information, and sells Product X to Company B. Company B repackages the product with a new label and new SDS that use a new product name and identify Company B as the responsible party. There is no reference to Company A in the label or SDS. Under HCS 2012, we believe Company A is the manufacturer of the product (responsible for the hazard classification, SDS and label) and Company B should be viewed as a distributor and (although not the manufacturer) the responsible party for providing any additional information, but is not responsible for the hazard classification or the content of the SDS or label.

In other words, in all of these scenarios, based on the language of the standard and the requirements in the OSH Act and the PRA to minimize paperwork, we believe Company A should be treated as the manufacturer and only party responsible for the hazard classification and preparation of the SDS and label as long as the downstream customer chooses to rely on Company A's hazard determination, and SDS and label for the product.

But that does not seem to be OSHA's position, which states in the expanded definition of "manufacturer" on pp. 21-22 of the 2015 HCS CPL:

> The first employer [that would be Company A in the above scenarios] meeting the definition of a manufacturer will be

> **responsible** for **performing the hazard classification, developing or obtaining the SDSs,and labeling containers of the hazardous chemicals**[emphasis added].

but then goes on to say:

> If a downstream employer meeting the definition of a manufacturer alters a product (e.g., chemically react) and/or removes the original manufacturer's name and/or contact information, then the downstream user **becomes the responsible party for the product and needs to consider all the known or intended uses of the product** [emphasis added].

Unfortunately, the term "responsible party" is not defined in the HCS. As a result, OSHA has taken the liberty of creating a definition outside the rulemaking process. OSHA adopted the following definition, which does not state or imply that the "responsible party" is responsible for the hazard determination and content of the SDS and label:

> *Responsible party* means someone who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary. This could be the manufacturer or importer or a company contracted to provide more information. The name and address of the responsible party MUST be the same on the SDS and the label.

The quoted language in the definition of "chemical manufacturer" seems designed to impose the obligations of the chemical manufacturer (Company A) on each downstream party that relabels or repackages the chemical although there is no change in the composition or other characteristics of the chemical. There are two huge problems with OSHA's apparent position. First, it clearly is not reasonably necessary or appropriate to prohibit a re-packager from relying on the manufacturer-supplier's hazard classification, SDS and label, and to require the re-packager to repeat those activities, which requires applying a multiplier to the estimated paperwork burden to account for the additional burden imposed on each customer . It is important to note that the ICR does not include any burden for that redundant and unnecessary activity. Second, OSHA's rationale for that position is not that Company B is now a manufacturer, but that Company B, by repackaging the chemical, has now become "the responsible party." Is that the same "responsible party" that Company B becomes when Company A manufacturers a chemical for Company B and Company B is the only party identified on the label and SDS. If so, that suggests that all "responsible parties" are required to repeat all of the HCS requirements – hazard determination and creation of SDS and label -- performed by the first manufacturer (multiplying the paperwork burden on a much greater scale). Certainly, OSHA could not be suggesting that there are different types of responsible parties.

An examination of the provision applicable to mixtures further illustrates the inconsistent and excessive paperwork burdens that would be imposed by OSHA's interpretation of HCS 2012. It would be an anomaly to allow a manufacturer of a mixture of two or more ingredients to rely on the SDS of each ingredient supplier, but not allow an entity that simply relabeled or repackaged a mixture (which is a single ingredient) without change to rely on the SDS and/or label of the supplier and to require it to assume the burden of classifying the chemical and developing the SDS and label. Unfortunately, that appears to be the outcome of applying paragraph "17.a" on p. 22, paragraphs "m" and "n" on page 58 and paragraph 3.c on page 61 of the 2015 HCS CPL.

Furthermore, the language of Section 1910.1200(d)(3)(ii) applies only to mixtures. Literally read, as suggested by the foregoing analysis, that would mean that a manufacturer that simply repackaged a substance (or simply relabeled it, if the manufacturer's obligations also become the "responsible party's obligations") could not rely on the supplier's hazard classification, SDS and label because the manufacturer would be classifying a substance rather than a mixture. It would further be an anomaly to force a party seeking to rely on its supplier's hazard classification, SDS and label to go to the trouble of adding a small portion of a second ingredient, with no hazardous properties, to the referenced substance so it would then be a mixture falling within the scope of Section 1910.1200(d)(3)(ii).

The OSH Act is a regulatory statute designed to impose reasonably and necessary compliance measures on employers with the expectation of compliance. It does not authorize OSHA to impose burdensome and redundant compliance obligations based on tort law principles of joint and several liability.

3. Contrary to its Stated Intent, OSHA Adopted Classification Criteria for Flammable Aerosols that Conflict with the GHS Revision 3 Criteria, the applicable DOT Regulations and the Criteria Adopted by our Trading Partne

In a May 27, 2015 email, we advised OSHA/DOL staff that, contrary to OSHA's stated intent, the criteria for classification of flammable aerosols in Table B.3.1 was inconsistent with the GHS and DOT regulations. We indicated that we believed a rulemaking would be needed to correct this problem and suggested that OSHA amend the table as follows (changes are shown in italicized red font):

Table B.3.1: Criteria for flammable aerosols *(only applicable if aerosol contains a component classified as flammable)*

Category	Criteria
1	Contains ≥ 85% flammable components and the chemical heat of combustion is ≥ 30 kJ/g; *OR* ~~*or*~~ a) For spray aerosols, in the ignition distance test, ignition occurs at a distance ≥ 75 cm (29.5 in), *OR* ~~*or*~~ b) For foam aerosols, in the aerosol foam flammability test (i) The flame height is ≥ 20 cm (7.87 in) and the flame duration ≥ 2 s; or (ii) The flame height is ≥ 4 cm (1.57 in) and the flame duration ≥ 7 s
2	~~*Contains>1% flammable components, or the heat of combustion is ≥ 20 kJ/g; and*~~ a) For spray aerosols, *i) the heat of combustion is ≥ 20 kJ/g; OR* ii) in the ignition distance test, ignition occurs at a distance ≥ 15 cm (5.9 in); *OR* ~~*or*~~ (iii) in the enclosed space ignition test, the (i) Time equivalent is < 300 s/m3; or (ii) Deflagration density is 00 g/m3 b) For foam aerosols, in the aerosol foam flammability test, the flame height is ≥ 4 cm and the flame duration is ≥ 2 s and it does not meet the criteria for Category 1.

Unofficially, we heard that OSHA agrees that the standard needs to be amended to correct this problem. OSHA has not provided any guidance on what should be done in the meantime.

4. There Is A Conflict Between The Requirement In Section 1910.1200(g)(2) to Create and Maintain SDS In A Standardized Format and Section 1910.1200(g)(10) Allowing The SDS To Be Kept In Any Format

We have asked OSHA to modify 1910.1200(g)(10) because it appears to authorize an alternative to SDSs that would conflict with: (1) the format and heading requirements in Section 1910.1200(g)(2) and Appendix D; and (2) the concept of a separate SDS for each chemical or grouping of complex chemicals. This point was raised in a June 3, 2015 email to DOL/OSHA staff and we are still waiting for a response.

Section 1910.1200(g)(2) states:

> The chemical manufacturer or importer preparing the safety data sheet shall ensure that it is in English (although the employer may maintain copies in other languages as well), and includes at least the following section numbers and headings, and associated information under each heading, in the order listed (See Appendix D to §1910.1200--Safety Data Sheets, for the specific content of each section of the safety data sheet)....

Section 1910.1200(g)(10) states:

> Safety data sheets may be kept in any form, including operating procedures, and may be designed to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer shall ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in their work area(s).

The following discussion in the preamble to the initial 1983 rule (48 FR 53337, col. 3) appears to be addressing 1910.1200(g)(10):

> As was the case with labels, alternatives to MSDSs within a plant are also permitted as long as they provide the appropriate information, and are readily accessible to employees. These would be expected to take the form of written operating procedures, manuals, etc. The employer may also use this alternative approach to address the hazards of a process, rather than individual chemicals. However, information must still be available to employees for each hazardous chemical involved.

A rulemaking also will be required to address this issue.

II. OSHA'S ESTIMATE OF THE BURDEN OF THIS INFORMATION COLLECTION IS MATERIALLY UNDERSTATED

A. OSHA's Assertion that 60% of Employers Were Already in Compliance with HCS 2012 at the time it Was Adopted is Clearly Erroneous

We respectfully submit that OSHA has chronically and materially underestimated the burden of this information collection from the time the HCS was first adopted through the

current ICR. It began with what we believe to be an erroneous assertion in the early 1980s that 60% of employers should be deemed to be in full compliance with the original HCS on the day it was adopted because they were subject to state hazard communication laws with essentially the same requirements. That meant that only 40% of employers would have any additional compliance obligations under the newly adopted HCS. First, while we strongly disagree with OSHA's premise, we chose not to go through the unnecessary exercise of researching the laws of that era to prove our point. We believe OSHA's 60% analysis was based on the application of state laws to the manufacturing sector. The Third Circuit later directed OSHA to expand the scope of the HCS to all of General Industry without any further analysis of its impact on, for example, the construction or grain industries. Therefore, the 60% analysis was incorrect at the time the rule was initially implemented.

Even if that 60% estimate was somehow valid for the original HCS, it had no continuing validity for the greatly expanded rule known as HCS 1994, which, according to OSHA, applied to hazardous chemical wastes not subject to EPA regulation, in-process intermediates, experimental laboratory R&D products and combustible dusts. According to the Supporting Statement for the ICR, the total number of chemical products covered by the HCS is 1,414,636, which is the total number of SDSs shown in the Final Economic Analysis. There is nothing to suggest that number includes any SDSs for hazardous chemical wastes or in-process intermediates, and we doubt it includes any SDSs for experimental laboratory R&D products or combustible dusts. If one considers the infinite number of in-process chemicals (requiring hazard classifications, SDS and labels) that may be created in the process vessels[2] in all of the manufacturing processes in the US, and the infinite number of chemical mixtures (requiring hazard classifications, SDS and labels) that might be created in the disposal of hazardous chemical wastes into containers (including common activities such as putting waste saw dust and sand in dumpsters or waste saw dust, flour or sugar in trash receptacles, all of which would apparently require HCS container labels) in the US, the original OSHA estimates are clearly erroneous. If each shade of paint is treated as a separate chemical, our understanding is that each major paint company would have hundreds of thousands of chemicals.

Finally, even if the 60% estimate had some validity for HCS 1994, it could not possibly have any validity for HCS 2012, which is based on a completely different and incredibly more demanding approach to chemical hazard communication, with a huge increase in the associated burden of the information collection under any objective measurement.

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[2] We believe many in the chemical processing industry will be very surprised to read that, without rulemaking, OSHA has adopted a new definition of "stationary process container" (paragraph 25 on page 23 of the HCS 2012 CPL) that excludes storage tanks connected to a process from its scope so that the alternative labeling methods are not available for them.

B. OSHA's Assertion that Only 1 Out of Every 200 Products Will Require an Updated SDS and Label Each Year and that a Supervisor/Manager Can Implement Those Changes in One Hour Per Product Results in Greatly Understated Estimates of the Paperwork Burden for Compliance with HCS 2012

OSHA estimates that, on an annual basis, only 0.5% of the products covered by the HCS will be affected by new information requiring revisions to their labels and SDSs, and that it "will take [only] 15 minutes for a supervisor/manager to update the SDS, and if necessary the associated label." There are several fundamental flaws in that analysis.

First, OSHA based its ICR estimate on the unsupported assertion that only 0.5% of products covered by the HCS will be affected by new information requiring revisions to their labels and SDSs. In other words, OSHA is asserting that, on average, the SDS and label for any product is changed once every 200 years. In providing that estimate, OSHA appears to discount the dramatically different findings of the consultant it relied upon in developing HCS 2012. The consultant stated:

> All chemical firms we interviewed stated that they have a policy to comprehensively review each product periodically by gathering physical and health hazard data for all ingredients, redoing the classification calculations, and changing the associated SDSs and labels. Health and safety reviews often are one part of the product stewardship reviews or other such assessments. Some firms conduct stewardship reviews every 3 years, others do it every 4 or 5 years. Notwithstanding the stewardship reviews, almost every company stated that it revises its SDSs and labels regularly; SDSs every three years or so and labels every 18 to 24 months. This report assumes that these periodic reviews take place once every 3 years for all products. This means one third of all SDSs and labels are reviewed every year. [Economic Feasibility Analysis, p.59.]

We believe it is appropriate to assume that commercial enterprises conduct product stewardship reviews and revise SDSs and labels because they are necessary rather than for some other reason. That indicates that OSHA has understated the annual number of SDS and label changes by a factor of approximately 67. Furthermore, OSHA apparently limited the time burden to the time required to change the electronic file for the SDS and label once it was clear that changes were needed. OSHA did not include any time burden for the research required to discover and analyze the information needed to determine whether changes are necessary and what they should be.

Second, OSHA's estimate fails to explain how a single supervisor would be qualified to update labels and SDSs. In general, as stated by the consultant relied upon by OSHA in adopting HCS 2012:

> Based on our interviews, it is apparent that, in most companies, a team of toxicologists, industrial hygienists, SDS writers, and computer programmers will conduct the task of reclassifying chemicals and modifying SDSs and labels. They will have to gather the existing data on the hazard and other characteristics of their chemicals, apply the GHS criteria to determine the hazard categories (using sophisticated computer programs and systems, if necessary – see the next paragraph), establish a uniform system for revising existing SDSs and labels (and set up standard templates for making the changes, if necessary), and make the necessary revisions. [Economic Feasibility Analysis, p.49.]

Third, once a determination has been made as to the required SDS and label changes, they need to be implemented. At a minimum, to ensure quality control, we would expect one person to enter the agreed-upon SDS and label changes into the SDS and label data base, and a second person to confirm they are correct. For several reasons, label changes are far more complicated than SDS revisions. There is often a limited area in which to place the required information on a label. We do not believe it would be appropriate to assume that a software package will automatically print out a revised label on a packaging line. It would be more realistic to assume that, in many cases, the relevant information will be sent to an outside labeling house, which will work with in-house personnel in developing a revised label layout that will be pre-printed on label rolls and often on bags and other containers. Then there are the material and energy costs of creating and distributing the new SDSs and labels. The costs will be substantially greater if old preprinted labels and containers on which they have been preprinted must be discarded.

C. OSHA's ICR Fails to Include Any Burden Estimate For The Transition From HCS 1994 to HCS 2012

In the ICR, OSHA requested a downward adjustment of 4,063,336 hours, apparently on the assumption that the transition from HCS 1994 to HCS 2012 would have been completed by the June 1, 2015 effective date. The provisions in the 2015 HCS CPL providing for an extension of the compliance deadlines (as interpreted by OSHA) for "Reasonable Diligence" and "Good Faith Efforts" represent an explicit acknowledgement that those deadlines were and remain infeasible for a substantial portion of the regulated community. The 2015 HCS CPL acknowledges that, in the case of distributors of hazardous chemicals, efforts to achieve compliance with HCS 2012 are likely to continue until at least December 1, 2017.

Underlying the extensive discussion in the 2015 HCS CPL on extended compliance dates is the reality that the employers in the US have a long way to go before achieving full implementation of HCS 2012. As we explained in comments that the agency chose to discount, this was one of the most massive paperwork undertakings in US history.

We believe it is unfortunate that, in adopting a single effective date for both substances and mixtures for phasing in compliance with HCS 2012, OSHA did not look to the expertise of either the affected chemical industry sectors or the expertise of its government agency counterparts in the 28 member countries that form the EU. If the deadline for updated SDS for substances was June 1, 2015, and the purchasers of those substances were going to rely on their suppliers' SDSs in preparing SDSs for products that incorporated those substances (second tier products), there was no way that the SDSs or labels for the second tier products would be ready on June 1, 2015. Furthermore, it was pointed out to OSHA that there would be further cascading tiers of products dependent on the SDSs from the tier above and that it would take years for full implementation of HCS 2012, and by the time that occurred there would be new information requiring changes to the initial HCS 2012 compliant SDSs.

OSHA estimated there are over 1.4 million products subject to the HCS that would require their own SDS and label. As we noted previously, that estimate does not include a potentially infinite number of in-process chemical intermediates created in chemical processes in the US, a potentially infinite number of chemical mixtures formed in containers of chemical waste not regulated by EPA, or the almost infinite number of paint colors that are created in the US. It does not appear that OSHA made any effort to determine how many of the estimated 1.4 million products are substances and how many of those products are mixtures. That breakdown is critical because completion of hazard classifications and HCS-2012-compliant SDSs and labels by June 1, 2015 generally would have been feasible for substances and infeasible for mixtures prepared by formulators who were relying on the information in their suppliers' SDSs.

We believe there are approximately 65,000 substances listed in the chemical inventory established under the Toxic Substances Control Act that are being actively produced or distributed in the US. For the sake of discussion, if one assumes that, on average, each substance is produced by 10 manufacturers, it would mean that approximately 750,000 of the estimated 1.4 million products would be mixtures.

D. The 2015 HCS CPL Added a Material if not Enormous New Paperwork Burden that is not Acknowledged Anywhere in the ICR

The 2015 HCS CPL added what we believe is a material if not enormous new layer of paperwork burden that is not acknowledged anywhere in the ICR or the supporting statement made available on July 1, 2015. OSHA was aware of this burden no later than February 9, 2015 when it issued interim enforcement guidance that contained the following language, which was incorporated into the 2015 HCS CPL:

> Where a manufacturer or importer has asserted that it was unable to comply with the June 1, 2015 compliance date, the CSHO must determine if the manufacturer or importer has exercised reasonable diligence and good faith to comply with the terms of the standard. CSHOs shall not cite a manufacturer or importer for failing to meet the June 1, 2015 deadline to have updated labels under 29 CFR 1910.1200(f)(1), or updated SDSs under paragraph (g)(1), if the chemical manufacturer or importer exercised reasonable diligence and good faith in attempting to obtain HCS 2012-compliant SDSs and classification information from its upstream raw material supplier(s). This guidance only applies where the mixture's material safety data sheet (MSDS) and label comply with HCS 1994.

* * * *

"Reasonable Diligence" and "Good Faith Efforts"

In order to determine if a manufacturer or importer has established "reasonable diligence" and "good faith efforts," the CSHO must review its overall efforts, attention, and action(s) taken to comply with HCS 2012. **Upon request from a CSHO, 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 (e.g., chemical registries); and,**
- **Classify the data themselves** [emphasis added].

Establishing reasonable diligence and good faith effort requires that the manufacturer or importer demonstrate attempt(s) to obtain the necessary SDSs through both oral and written communication directly with the upstream supplier. For each mixture shipped by a manufacturer or importer after June 1, 2015 that does not comply with HCS 2012, the CSHO shall consider whether the manufacturer or importer:

(a) **Developed and documented the process** used to gather the necessary classification information from its upstream suppliers and the status of such efforts;

(b) **Developed and documented efforts** to find hazard information from alternative sources (e.g., chemical registries);

(c) **Provided a written account of continued dialogue** with its upstream suppliers, **including dated copies of all relevant written communication** with its upstream supplier**s;**

(d) **Provided a written account of continued dialogue** with its distributors, including dated copies of all relevant written communication with its distributors informing them why it has been unable to comply with HCS 2012; and,

(e) Developed the course of action it will follow to make the necessary changes to SDSs and labels.

Clearly, compliance with these conditions adds a substantial if not enormous paperwork burden to HCS 2012. Again, we are not aware of any logical basis for assuming 60% of the affected employers were in compliance with this questionable aspect of the HCS 2012 regulatory scheme apparently created in 2015.

Depending on how the ambiguous language of Section 1910.1200(d)(3)(ii) is interpreted (see our discussion of this provision in the attached March 25 letter to David Michaels), these "reasonable diligence" and "good faith efforts" requirements were either improperly created outside of the rulemaking process (which we believe to be the case) or adopted during the rulemaking, but not a logical outgrowth of the rulemaking. Nevertheless, they are being imposed by the agency without any recognition of the enormous paperwork burden. The NPRM contained the following provision:

> (ii) A chemical manufacturer or importer of a mixture shall be responsible for the accuracy of the classification of the mixture even when relying on the classifications for individual ingredients received from the ingredient manufacturers or importers on the safety data sheets.

Industry interests criticized that ambiguous language because it appeared to eliminate any ability to rely on the hazard classification provided by the chemical ingredient manufacturer, and it failed to recognize the longstanding ability of formulators to rely on all information in the SDS provided by the chemical ingredient manufacturer. During the rulemaking, OSHA staff responded that they intended to preserve the ability to rely in good faith on the supplier's SDS. The understanding was that hazards that were known or should have been known by the formulator could not be ignored.

The final rule contains the following previously-quoted provision:

> (ii)When classifying mixtures they produce or import, chemical manufacturers and importers of mixtures may rely on the information provided on the current safety data sheets of the individual ingredients, except where the chemical manufacturer or importer knows, or in the exercise of reasonable diligence should know, that the safety data sheet misstates or omits information required by this section.

If the quoted language of Section 1910.1200(d)(3)(ii) had been interpreted by OSHA in the way industry understood it would be interpreted, there would not be a huge new paperwork burden. But that is not what OSHA has done. Based on the interim compliance guidance and the language of the 2015 HCS CPL, it seems clear that OSHA has interpreted that quoted provision to mean that a "safety data sheet misstates or omits information required by this section" if it is not an HCS 2012-compliant SDS. There is no mention of that intent in the preamble to the final rule because at the time the preamble was written OSHA apparently had not yet recognized the infeasibility of compliance by June 1, 2015. It seems highly unlikely that OSHA drafted Section 1910.1200(d)(3)(ii) to address a problem it did not know existed. That suggests that it was reinterpreted between March 26, 2012 and February 9, 2015. Again, that suggests the need to eliminate the principles of deference to an agency's interpretation of the rules it adopts, which give rise to unconstitutional mischief.

E. THE BURDEN OF COMPLIANCE WITH HCS IS SUBSTANTIALLY GREATER THAN THE BURDEN OF COMPLIANCE WITH HCS 2012

Incorporation of Revision 3 of the GHS into the HCS has converted the HCS from a relatively simple, performance-based system to a complex, highly-detailed specification-based system governing the hazard classification, labeling and preparation of SDS for hazardous chemicals.

As we stated in comments filed with OSHA during the HCS 2012 rulemaking, it is clear that the adoption of HCS 2012 required a complete review and revision of the chemical classification of every hazardous chemical in commerce in the US. It also required a complete review, revision and expansion of the content and format of every label and SDS for every hazardous chemical in commerce in the US. It was not simply a matter of cherry picking information from one data sheet or label and inserting into a new format. Compliance with HCS 2012 requires the application of complex classification criteria, often requiring the evaluator to research for new information that was not obtained and/or available when the chemical was classified under HCS 1994. Given the explosive growth of the internet, there is far more information to search and evaluate in classifying hazardous chemicals than was available when the HCS was first adopted. Yet OSHA continues to base PRA burden estimates on the erroneous analysis underlying the adoption of the HCS in the 1980s.

Under HCS 1994, the mandatory hazard classification for a particular health hazard was effectively complete if the evaluator found a single positive study evidencing a statistically significant positive association (not an actual cause and effect relationship) between exposure to the chemical and the hazard. Under HCS 2012, the evaluator is required to take on the far greater burden of finding, evaluating, and weighing all of the available evidence in determining whether a chemical has a particular effect, and documenting that determination. OSHA has previously asserted that the evaluator had to perform a weight of evidence analysis under HCS 1994 to determine which of the hazards posed by the chemical would be listed on the label. There is simply no merit to that position. HCS 1994 was a performance-based standard. Whatever non-persuasive, academic argument might be made by OSHA on that point, we are confident that OSHA never issued a single citation under HCS 1994 alleging that a hazard properly listed on an SDS was inappropriately listed on a container label. In performing a weight of evidence analysis, HCS 2012 directs the evaluator to engage in an analysis of Structure Activity Relationships, synergistic effects, and interactive effects. In addition to identifying a hazard class, HCS 2012 also requires the evaluator to determine the severity of the hazard, which requires an even more in-depth weight of evidence analysis.

Under HCS 1994, in the absence of test data on the mixture as a whole, the evaluation of the health hazards of a mixture generally turned on the hazards of the individual ingredients and whether they were present in the mixture in excess of a threshold concentration cutoff level. Under HCS 2012, the evaluator may not rely on the threshold cutoff levels until first exhausting a decision tree of other options, which includes complicated bridging principles that knowledgeable people have described as “unintelligible” and very few individuals currently understand. For example, the evaluation of acute toxicity “requires substantial supplemental technical information, and a highly trained and experienced expert, to reliably estimate acute toxicity.” A.1.3.6.2.2, 74 FR 50447, col. 2.

Unlike HCS 1994, HCS 2012 requires the person preparing the SDS to identify appropriate uses of the chemical and inappropriate uses of the chemical and, as discussed below, OSHA seems to be taking the inappropriate position that the SDS must address all hazards of any reasonably foreseeable use of the product. Under HCS 1994, the formulator of a mixture created by a physical mixing of ingredients, with no chemical reaction, was permitted to create the SDS for the mixture by assembling the SDS for the individual ingredients into a package with a cover sheet. That is no longer permitted under HCS 2012. Our understanding of OSHA’s position is that the manufacturer must have an integrated SDS for each chemical or group of chemicals with the same hazard classification (in terms of both the class and severity). For a major paint company and coatings manufacturer, this would mean creating potentially hundreds of thousands of individual SDS for each product, or first performing the hazard classification that would justify combining those products into groups based on their classifications. We are not aware of any studies indicating that the old system was insufficient to address the hazards posed by this category of chemicals. In any event, given that OSHA has taken this position, it seems clear that it has greatly understated the number of chemicals covered by the HCS.

Whereas HCS 1994 has a finite number of physical hazards, HCS 2012 includes an additional category known as hazards not otherwise classified, which might only become known when OSHA brings enforcement actions that identify them.

As a result of the adoption of HCS 2012, some chemicals not previously classified as hazardous are now classified as hazardous, and some chemicals previously classified as hazardous have "new" and previously undisclosed hazards due to: (1) reduced threshold concentration triggers -- for mutagens, reproductive toxins and respiratory sensitizers (including levels between 0.1% and 1%); and (2) expanded acute toxics coverage. All of these changes must be reflected in hazard classifications, SDS and container labels. None of these changes can be achieved without an enormous amount of training of the personnel responsible for performing the hazard classification and preparing the SDS and container labels, initially, with changes in personnel, with changes in hazard information, and with the release of new guidance materials from OSHA.

III. THE REGULATED COMMUNITY WAS NOT AND IS NOT BEING PROVIDED WITH AN ADEQUATE OPPORTUNITY FOR MEANINGFUL COMMENT ON THE GHS OR THE OSHA RULE ADOPTING THE GHS

Effective advocacy before the UN Subcommittee on the GHS in Geneva is difficult. Our understanding is that direct participation is limited to state representatives and that the limited advocacy that is available is restricted to international organizations that are not set up to do the type of advocacy work that is required to represent the interests of US industry. The senior OSHA representative heading the US delegation is the chair of the UN Subcommittee and, therefore, understandably must focus her energy on achieving a working consensus within the Subcommittee rather than advocating US interests, and the interests of OSHA and US industry are not always perfectly aligned.

OSHA holds meetings with US stakeholders shortly before attending UN GHS Subcommittee meetings in Geneva to discuss matters pending before the Subcommittee. Unfortunately, by the time of those stakeholder meetings, our experience is that the important decisions have already been made by the member states on the various work groups and the Geneva meetings following the US stakeholder meetings generally serve as the point of ratification rather than further discussion and debate. Certainly, that was what we experienced when we filed comments with OSHA and appeared before the OSHA stakeholders meeting to discuss changes being proposed to the GHS SDS guidance document in November of 2012, eight

months AFTER OSHA promulgated HCS 2012, for the stated purpose of addressing combustible dust.[3]

The document under discussion, titled "Dust explosion hazards guidance," stated that it was "Transmitted by the expert from the United States of America on behalf of the informal correspondence group on dust explosion hazards." Although the document proposing these changes had the quoted references to combustible dust, we noted that the proposed changes to the SDS guidance were going to be inserted into the official GHS guidance document on the preparation of SDS without any reference to combustible dust. The most critical language being added to the guidance would direct the preparer of the SDS to provide advice that "draws attention to [downstream] operations and conditions which create new risks by altering the properties of the substance or mixture, and to appropriate countermeasures."

The quoted language may have been appropriate in the limited context of physical particle reduction creating combustible dust. We believe it was highly inappropriate when adopted in this open-ended context without any reference to combustible dust. The quoted language could be interpreted to apply to any downstream operations in which the properties of the substance or mixture are altered in any conceivable fashion that would change, not the inherent hazard of the chemical, but the level of risk posed by its use. The impact of nanotechnology comes to mind although the UN Subcommittee has a separate task force addressing that issue. In other words, OSHA and the UN Subcommittee, without amending the text of the GHS, and after HCS 2012 was adopted, were re-interpreting the GHS to require a relatively broad use of risk assessment in a standard that, with one limited exception, was thought to be based entirely on inherent hazards rather than the use of risk assessments.

The EU members of the UN Subcommittee had no reason to object to this change because risk assessment is an integral component of the EU regulatory scheme and this type of analysis is often included in the extended SDS required by the EU REACH Regulation. Our objections to what we believe the FTC would have describe as an egregious "bait and switch" activity carried out through the office of the UN Subcommittee were not well received during the OSHA stakeholders meeting. The inappropriate language is now contained in Section A.4.3.7.1.1 of Annex 4, Guidance on the Preparation of Safety Data Sheets (SDS), of Revision 5 of the GHS.

While the revised SDS guidance language in the GHS is expansive, it is limited to changes in the risks resulting from altering the properties of the substance or mixture without changing its chemical composition. OSHA’s expansive interpretation of the scope of HCS 2012, as stated in the 2015 HCS CPL, appears to be far broader. Literally read, OSHA’s position

[3] The EU declined to treat combustible dust as a classified hazard because it is not an inherent hazard of the material, but one that depends on the conditions of use.

appears to be that the manufacturer or importer of a chemical is responsible for discovering all uses of its product, including all planned and unplanned chemical reactions that would (or might?) occur during that use:

> The manufacturer or importer must provide the information required by the standard on any hazardous chemicals which they manufacture or import. This information must cover the normal conditions of use and foreseeable emergencies of the product. A manufacturer or importer is out of compliance if it does not provide hazard information on a known use, or [a use it] should have reasonably been expected to know may occur, even if it is not the intended use under normal conditions of use or foreseeable emergency [emphasis added]

We believe this position would impose an unreasonable and inappropriate burden on chemical manufacturers and importers that was never contemplated by the rulemaking.

OSHA provides the following as an example of how this interpretation would be applied:

> For example, a product forms a combustible dust when ground into a powder, and the manufacturer knows this, but the manufacturer intends its product to be melted, not ground, and it perceives that there is no hazard from combustible dust if used as intended. However, the manufacturer must still warn downstream users of the known potential hazards from combustible dust.

Unfortunately, OSHA's example seems to add to the confusion rather than clarify the situation. First, the example simplistically describes a physical process (grinding) and a change in one physical characteristic (converting a large solid particle into a combustible dust). The use of that example does not cure the over-reaching scope of the quoted language, which, if literally interpreted, would appear to require discovering and addressing the hazards presented by downstream chemical reaction processes in which the chemical is used.

Second, the conclusion reached in the example is troubling because, as stated, it goes beyond the language of the already overbroad guidance. Apparently, based simply on the technical feasibility of converting the product to a combustible dust by grinding it into a powder, OSHA states that it must be classified and treated as presenting a combustible dust hazard. OSHA does not say this grinding is either a known use or one the manufacturer should have reasonably been expected to know may occur; nor does it explain why grinding should be viewed either a known use or one the manufacturer should have reasonably been expected to know may occur. In other words, as written, it appears that OSHA would have the manufacturer

or importer classify the solid item as a combustible dust simply because it is capable of being ground into a dust.

IV. CONCLUSION

We believe the foregoing analysis demonstrates the following:

(1) OSHA has interpreted and/or reinterpreted the HCS 2012 paperwork requirements in ways that: (a) are not supported by the HCS 2012 rulemaking, and (b) would impose an unreasonable and inappropriate paperwork burden on the regulated community.

(2) OSHA has interpreted the HCS 2012 paperwork requirements in ways that, even if they could be viewed as otherwise permitted or supported by the deficient HCS 2012 rulemaking, would impose an unreasonable and inappropriate paperwork burden on the regulated community, but more importantly, are infeasible and/or would impose a greater hazard on employees. Among others, we are referring to an interpretation that would require manufacturers, importers and distributors, before distributing product, to relabel the inner containers of any product that bears an outdated label more than six months after the manufacturer or importer acquired information requiring a label revision. Under this interpretation, the relabeling would be required despite the fact that the existing label was compliant with the HCS at the time the product was packaged for sale and the product has a shelf life in excess of 6 months. The regulated parties should not be placed in the uncertain and burdensome position of having to assert an infeasibility or greater hazard defense in an enforcement proceeding to protect themselves from this improper interpretation of the HCS.

(3) OSHA has dramatically underestimated the paperwork burden imposed by the transition from HCS 1994 to HCS 2012, the time required for that transition, and ongoing compliance with HCS 2012.

(4) OSHA adopted provisions in HCS 2012 that conflict with the GHS and can only be cured by a rulemaking.

(5) Provisions of the HCS are internally in conflict and can only be cured through a rulemaking.

(6) The regulated community was not and is not being provided with an adequate opportunity for meaningful comment on the GHS or the OSHA rule adopting the GHS, and that fundamental shortcoming needs to be cured.

OSHA could assert that the regulated community might have invested greater resources in the HCS 2012 rulemaking. However, the reality is that OSHA discounted much of the information submitted to it by industry during the rulemaking. In adopting a single effective date for both substances and mixtures for phasing in compliance with HCS 2012, OSHA also discounted the expertise of its government agency counterparts in the 28 member countries that form the EU. Furthermore, industry participation was understandably discouraged by the statements of the OSHA professional initially heading up the OSHA GHS rulemaking who, on more than one occasion, was heard to say that this is a "take it or leave it" proposition if we are to achieve harmonization, which, as everyone now knows, is not the same as uniformity. In the case of HCS 2012, we found OSHA to be more open to discussing and addressing the challenges of implementing HCS 2012 after the rule was finalized than during the period when it was being developed.

In short, we recognize OSHA faces significant challenges in conducting a major rulemaking. However, we believe the agency needs to be more open to industry input during the rulemaking process, to make more realistic assessments of PRA and other compliance burdens and to continue to constructively address the significant problems posed by HCS 2012. This appears to be an opportunity for OMB to use its authority under the PRA to help to remedy the many significant remaining implementation problems presented by the adoption of HCS 2012.

Thank you for your consideration.

Respectfully submitted,

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Attachment

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Hon. David Michaels, Assistant Secretary of Labor
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