



May 19, 2021

Comments of the

United States Beet Sugar Association, the National Grain and Feed Association, the North American Millers' Association, the Corn Refiners Association, the National Oilseed Processors Association, and the United States Chamber of Commerce

On The Proposed Amendments to the

Hazard Communication Standard, 29 C.F.R. § 1910.1200, published at

86 Fed. Reg. 9576 (February 16, 2021), by the

Occupational Safety and Health Administration in

Docket No. OSHA-2019-0001

RIN 1218-AC93

The United States Beet Sugar Association, the National Grain and Feed Association, the North American Millers' Association, the Corn Refiners Association, the National Oilseed Processors Association, and the United States Chamber of Commerce respectfully submit these comments to the Occupational Safety and Health Administration on the proposed amendments to its Hazard Communication Standard, 29 C.F.R. § 1910.1200, published at 86 Fed. Reg. 9576 (February 16, 2021) in Docket No. OSHA–2019–0001.

About the Commenters

The United States Beet Sugar Association (the “USBSA”) represents nine beet sugar companies, which operate twenty-two processing factories in eleven states. These firms refine white sugar from sugar beets grown by about 10,000 family farmers on about 1.2 million acres in eleven states. All member firms are farmer cooperatives, and every factory operates with organized union workers. A senior executive from each member-firm comprises the Board of Trustees, which sets policy and oversees the USBSA’s activities. The USBSA represents the industry before the legislative and executive branches of the Federal Government and monitors related activities in Washington, D.C.

The National Grain and Feed Association (NGFA), established in 1896, comprises more than 1,050-member companies that operate more than 7,000 facilities and handle more than 75 percent of the U.S. grain and oilseed crop. The NGFA’s membership encompasses all sectors of the industry, including country, terminal and export grain elevators; commercial feed and feed ingredient manufacturers; biofuels producers; cash grain and feed merchants; end-users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries. In addition, affiliated with the NGFA are 33 state and regional grain and feed trade associations. Canadian and Mexican firms also are NGFA members.

The North American Millers’ Association represents millers of wheat, corn, oats, and rye in the U.S. and Canada. Our members take raw grain and transform it into flour and other products that are used to make such favorite foods as bread, cereals, pasta, cookies, cakes, and snack foods. NAMA is the indispensable link

between raw grain and healthy and delicious products that have sustained and enriched people's lives for centuries. NAMA's 37 members have 149 locations across 31 states.

The Corn Refiners Association (CRA) is the national trade association representing the corn refining industry of the United States. CRA and its predecessors have served this important segment of American agribusiness since 1913. Corn refiners manufacture sweeteners, starch, advanced bioproducts, corn oil and feed products from corn components such as starch, oil, protein and fiber.

The National Oilseed Processors Association (NOPA) represents the U.S. soybean, canola, flaxseed, safflower seed and sunflower seed crushing industries. Its membership includes 13 companies that are engaged in the processing of oilseeds for meal and oil that are further utilized in the manufacturing of food, feed and renewable fuels as well as industrial applications. NOPA's member companies operate a total of seven softseed and 60 soybean solvent extraction plants across 22 states and crush approximately two million bushels of soybeans annually – or roughly 95% of all soybeans processed in the United States.

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and organizations of every size, in every industry, and from every geographic region in the country. An important function of the Chamber is to represent the interests of its members in matters before the courts, Congress, and the Executive Branch.

Request for Hearing

The commenters respectfully request under OSH Act § 6(b)(3) that a hearing be held in this matter.

Comments of the Associations

The Proposed Definition of “Combustible Dust.”

On page 9724, OSHA proposes to add to paragraph (c) of § 1910.1200 the following definition of “combustible dust”: “finely divided solid particles of a substance or mixture that are liable to catch fire or explode on ignition when dispersed in air or other oxidizing media.” At page 9696 OSHA states that this definition was adopted in 2017 by the United Nations Sub-Committee of Experts on the GHS (UNSCEGHS). OSHA also states that it has “preliminarily” determined that this definition is consistent with existing OSHA guidance on combustible dust hazards.

With respect, we submit that this “preliminary” determination is incorrect, that the proposed definition uses inaccurate terminology and has an unexplained overlap with terms that describe other physical hazards. These features of the proposed definition will cause avoidable confusion on the part of manufacturers, employees and the public.

We begin with the proposed definition: “finely divided solid particles of a substance or mixture that are liable to catch fire or explode on ignition when dispersed in air or other oxidizing media.”

“*Catch fire.*” Although the use of the phrase “catch fire” is accurate, it would cause the definition to substantially overlap the already-existing category of “flammable solids” (Category B.7 in Appendix B to § 1910.1200).¹ A substance might be classified as a combustible dust purely because of a flammability hazard (rather than an explosion hazard) even though it might have already been classified as a flammable solid for that very same reason. The proposed definition would therefore be unnecessarily alarming and confusing to users, would require redundant and repetitive warnings, and would render the Hazard Communication

¹ The Standard defines “flammable solids” and “readily combustible solids” as follows:

Flammable solid means a solid which is a readily combustible solid, or which may cause or contribute to fire through friction.

Readily combustible solids are *powdered, granular, or pasty* chemicals which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly. [Emphasis added.]

Standard difficult for manufacturers to implement and follow. With respect to flammability, OSHA needs to adopt criteria that permit manufacturers to distinguish between the categories of “combustible dust” and “flammable solids” in some consistent manner.

“*Explode.*” The use of the word “explode” is inaccurate and misleading, as confinement—an omitted criterion—is required to cause an explosion; if a dust is not confined, the proper term is “deflagrate,” as is shown by the term used elsewhere in the proposal (B.8.1, B.8.2.3, B.15.1.2, B.15.2.2), by the current Appendix B, and by a document that OSHA itself says that it relied upon in this rulemaking—OSHA 3371-08 (2009), *Hazard Communication Guidance for Combustible Dusts* (Document ID 0255). That document omits the criterion of confinement and states: “Combustible dust is defined as a solid material composed of distinct particles or pieces, regardless of size, shape, or chemical composition, which presents a fire *or deflagration hazard* when suspended in air or some other oxidizing medium over a range of concentrations.” (Emphasis added.)

That confinement is a necessary element for an “explosion” is stated by the agency in its own document, OSHA 3371-08 (2009), *Hazard Communication Guidance for Combustible Dusts* (Document ID 0255):

Five elements are necessary to initiate a dust explosion, often referred to as the “Dust Explosion Pentagon.” [Footnote omitted] The first three elements are those needed for a fire, i.e., the familiar “fire triangle”:

1. Combustible dust (fuel);
2. Ignition source (heat); and,
3. Oxygen in air (oxidizer).

An additional two elements must be present for a combustible dust explosion:

4. Dispersion of dust particles in sufficient quantity and concentration; and,
5. Confinement of the dust cloud.

If one of the above five elements is missing, an explosion cannot occur.

If a combustible dust is confined, then it would be accurate to say that it could “explode.” But then the absence of the term “confinement” from the proposed definition would make the proposed definition incomplete and wrong. The proposed definition would also be a poor fit with the other criteria in Appendix B and, worse of all, would make safety data sheets and labels inaccurate and misleading to the employees and the public who will read them.

In sum, the definition needs to be revised to include “explode” only if it defines combustible dust as dust that can “explode under certain conditions of confinement” or language to that effect. Purchasers and employees of users should not be given the false impression from safety data sheets or labels that substances poses a hazard of explosion even when they will not explode—when, for example, a substance is not confined. Employers who are manufacturers require a definition with more specific and accurate criteria. Furthermore, the proposal is incomplete, as OSHA needs to propose specific criteria in Appendix B, akin to those applicable to other physical hazards, that will permit manufacturers to accurately classify materials under this new category of physical hazard.

In this regard, we commend to OSHA the criterion in UNITED NATIONS, GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS, ANNEX 11, “GUIDANCE ON OTHER HAZARDS NOT RESULTING IN CLASSIFICATION (8TH REV’D ED., 2019). That criterion is whether the product contains particles of a nominal size less than or equal to 500 microns. *Id.* at 555, Figure A11.2.1: *Flow chart for decision on combustible dusts*. As is stated in § A11.2.3.2.7, “When assessing the particle size with regard to the risk of dust explosions, only the fine particles with a size $\leq 500 \mu\text{m}$ are relevant, even if the median particle size of the whole sample is larger than $500 \mu\text{m}$.” (Footnote omitted.)

This criterion is especially appropriate in the context of hazard communication. Although we are aware of theoretical concerns about deflagration from particles greater than 500 microns (§ A.3.3.8 in NFPA 652-2019, *Standard on the Fundamentals of Combustible Dust*, using the phrase “it can be inferred”),²

² Section A.3.3.8 in NFPA 652-2019 states in part (emphasis added):

particularly with flat-shaped particles of a certain length to diameter ratio, we are not aware of any evidence that particles greater than 500 microns pose a risk, let alone a significant risk, of an explosive event that would arise under confinement (that is, detonation). Yet, given the definition of combustible solid, that is the hazard of concern here.

We are aware that NFPA 652-2019, *Standard on the Fundamentals of Combustible Dust*, has a definition similar to the one proposed by OSHA (“A finely divided combustible particulate solid that presents a flash-fire hazard or explosion hazard when suspended in air or the process-specific oxidizing medium over a range of concentrations.”). That definition does not, as a practical matter, pose the difficulties that the proposed definition would because the NFPA committee that wrote the definition was concerned with issues of substantive safety rather than hazard communication and, for example, did not need to be so precise and limited so as to avoid confusion with “flammable solids” (Category B.7 in Appendix B to § 1910.1200). But employers who are manufacturers can be penalized for misunderstanding the confusion that would be created by the overlap and use of inexact terminology and undefined terms in SDS’s and labels.

In sum, the definition of “combustible dust” should include the two additional criteria advocated above—ability to explode under certain conditions of confinement and a maximum size of 500 micron—so that the definition reads (additions in italics): “finely divided solid particles, *of a nominal size less than or equal to 500 microns*, of a substance or mixture that are liable to catch fire or, *under certain conditions of confinement*, explode on ignition when dispersed in air or other oxidizing media.”

Combustible particulate solids with a minimum dimension more than 500 μm generally have a surface-to-volume ratio that is too small to pose a deflagration hazard. Flat platelet-shaped particles, flakes, or fibers with lengths that are large compared to their diameters usually do not pass through a 500 μm sieve, yet could still pose a deflagration hazard. Many particulates accumulate electrostatic charges in handling, causing them to attract each other, forming agglomerates. Often, agglomerates behave as if they were larger particles, yet when they are dispersed they present a significant hazard. Consequently, it can be inferred that any particulate that has a minimum dimension less than or equal to 500 μm could behave as a combustible dust if suspended in air or the process specific oxidizer. *If the minimum dimension of the particulate is greater than 500 μm , it is unlikely that the material would be a combustible dust, as determined by test.*

We believe that OSHA still adheres to the view that manufacturers may base their SDS’s on research rather than original testing.

The Need to Clarify A Statement by OSHA

We also ask that OSHA clarify a point that was obscured by OSHA’s statement in the preamble to the proposal—that it has “preliminarily” determined that the proposed definition is consistent with existing OSHA guidance on combustible dust hazards. The guidance cited, however, includes both guidance on substantive regulatory issues and hazard communication. See OSHA-2019-0001-0190.

The difficulty is that the term “combustible dust” (like other terms in both hazard communication and substantive standards) can have different meanings and test criteria depending on the purpose for which the substance is being tested. For example, we are informed that OSHA’s laboratory in Salt Lake City, when testing a dust for combustibility, may dry or otherwise process the dust before testing. This might make sense in some circumstances, but not in others, such as when testing dusts found in actual workplaces to determine whether engineering or work practice controls are needed. See David Michaels, PhD, MPH, former Assistant Secretary of Labor for Occupational Safety and Health, Remarks at EPA IRIS Workshop on the NRC Recommendations, esp. pp. 7-8 (Oct. 15, 2014) (attached), where he states that substantive regulatory decisions require a higher level of evidence than that required for hazard communication purposes.

We therefore ask that OSHA make clear that its definition of “combustible dust” for hazard communication purposes is not intended to affect determinations of whether dust is combustible for substantive regulatory purposes.

The Proposed Expansion of the Duty to Anticipate Downstream Use

OSHA has proposed that the following sentence be added to paragraph (d)(1): “The hazard classification shall include any hazards associated with a change in the chemical’s physical form or resulting from a reaction with other chemicals under normal conditions of use.” Concomitant proposed amendments would be made to Table D.1, “Minimum Information for an SDS,” by adding the following text: “including any hazards associated with a change in the chemical’s physical form under normal conditions of use”; and “(c) Hazards identified under

normal conditions of use that result from a chemical reaction (changing the chemical structure of the original substance or mixture)....”

The principal rationale for these amendments seems to be that discussed on page 9698 of the preamble, where OSHA points to epoxy resins, which are manufactured in two different containers (one with the resin and one with a hardener) and mixed in a syringe to, after curing, yield the intended product—hardened epoxy resin:

This issue has been raised, for instance, when multiple chemicals are sold together with the intention that they be mixed together before use. For example, epoxy syringes contain two individual chemicals in separate sides of the syringe that are mixed under normal conditions of use. ... OSHA intends for the hazards created by the mixing of these two chemicals to be considered in classification....

But the language OSHA has proposed to address this narrow matter is far broader than needed to address it, would vastly expand the duty of the chemical manufacturer, greatly increase the cost of chemical classification, and impose anticipation duties on manufacturers that cannot be justified and have not been justified by the agency in the preamble.

Today, manufacturers are feasibly able to describe the hazards of their products *as shipped*. This proposal, however, would require them to anticipate and then describe the hazards the product might attain if a downstream user were to change its physical characteristics, such as particle shape (not merely size). The proposed duty would not be limited to downstream uses, changes in physical form or reactions or reactants already known to the manufacturer. The duty is thus unqualified and therefore vast.

Placing this burden on the manufacturer is not only unjustifiable but unjustified by anything in the explanatory preamble. The responsibility for studying and stating the changes in hazard caused by the downstream user should be that of the downstream user who changed the product to create the hazard.

First, the example in the preamble given cannot justify the proposal because it involves no change in “physical form” but a chemical reaction and thus the proposed language about a change in “physical form” is unjustified by anything in the preamble. Stated simply, OSHA has not shown why the current language does not suffice, as is indicated by the letters of interpretation cited on page 9722.

Second, the chemical reaction that is mentioned in the preamble (like the one mentioned on page 9722) is not just some reaction in which some downstream user might involve the chemical, but a user-induced chemical reaction *intended by the manufacturer* to create a final product—an action far narrower than that described by the phrase “resulting from a reaction with other chemicals under normal conditions of use.” Thus, all that OSHA needs to do to address the noted problem is add the underlined phrase below to the second sentence of paragraph (d)(1): “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 under normal conditions of use (including user-induced chemical reactions intended by the manufacturer to create a final product) and foreseeable emergencies.” This would also permit elimination of the proposed third sentence.

We are aware of comments made by Maureen Ruskin, acting head of OSHA’s Directorate of Standards and Guidance, during an April 13 webcast hosted by the Society for Chemical Hazard Communication, defending the proposal essentially on the ground that it would enact nothing new, that the proposal embodies OSHA’s position expressed in a 2016 interpretation letter and even earlier sources. With respect, this view is profoundly wrong.

The 2016 interpretation is presumably that in a letter from Thomas Galassi, Director of Enforcement Programs, to Nicole Shoshenskiy of MSDSONline (May 20, 2016), at www.osha.gov/laws-regs/standardinterpretations/2016-05-20. The letter stated that, “A manufacturer’s or importer’s hazard classification must account for the hazards of by-products.... A manufacturer’s or importer’s hazard determination or hazard classification must *anticipate the full range of downstream uses of their products* and account for any hazardous by-products which may be formed.” (Emphasis added.) The interpretation cited for support *not* the words of the HazCom Standard but an OSHA compliance directive, CPL 02-02-079 (July 9,

2015), at www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-079.pdf. The examples given there as justification for the policy, however, were narrow and trivial. The directive stated:

For example, a manufacturer of gasoline must inform downstream users of the hazards of carbon monoxide, since carbon monoxide is a hazardous chemical and is “known to be present” as a by-product resulting from the use of gasoline. Similarly, manufacturers of diesel fuel must inform downstream users of the potential human carcinogenicity of diesel exhaust on the SDSs for diesel fuel.

Of course, knowledge that a fuel meant only to be burned generates carbon dioxide is common knowledge to all, including fuel manufacturers; the example is therefore trivial and cannot justify the proposal. The same is true of the potential human carcinogenicity of diesel exhaust, which had long been known to diesel manufacturers. See NIOSH Current Intelligence Bulletin No. 50 (Aug. 1988). Thus, the examples cannot justify a proposal requiring manufacturers to state matters *not* already known to them.

In fact, the only policy on this precise issue that OSHA ever adopted in a notice-and-comment HazCom rulemaking was exactly the one we now urge. When OSHA first adopted the HazCom Standard, it noted that chemical manufacturers feared that OSHA was imposing on them the broad duty that would be imposed by the current proposal. 48 Fed. Reg. 53280, 53307 (1983). In the final preamble, OSHA disavowed any such intention, as follows:

While chemical manufacturers did not generally take issue with assuming responsibility for preparing the sheets, they did raise two objections to the requirements as proposed. First of all, they were concerned that the chemical manufacturer would be held responsible for providing information on the MSDS that only the downstream employer could know based on the specific use of the product....

The first objection, concerning the provision of specific information in certain MSDS categories, resulted from a

misinterpretation of, or a lack of clarity in, the proposed requirements. Employers such as Phillips Petroleum company believed that the proposal required them to know every downstream use of their products, and provide specific information on the MSDS related to that use. Phillips stated (Ex. 19-177a):

Material safety data sheets are the most effective means of communicating technical and related data to employers who are chemical users. However, the data must be limited to general technical information concerning the chemicals or mixture and not attempt to be an assessment of specific hazards under every possible condition in a downstream workplace. Individual hazard communication programs must be tailored by each user employer.

OSHA agrees that the chemical manufacturer can only provide *general information* regarding certain items required to be on the MSDS. Nevertheless, this does not mean that the chemical manufacturer should not consider these categories, *and provide as much information as the manufacturer has*. [Emphasis added.]

Id. Thus, the HazCom Standard has long required manufacturers to state only what they already know, not delve into and evaluate downstream matters, events, processes, reagents and reactions they do not already know. This policy should be retained and the current proposal withdrawn.

On April 23, 2021, at the Small Business Administration's OSHA/MSHA Roundtable, Ms. Ruskin was also asked whether the proposed duty of the manufacturer would be confined to uses, byproducts and reactions already *known* to the manufacturer. At first she said "yes" but then stated that the proposed duty would apply to "reasonably anticipated" uses, byproducts and reactions. Those are two very different duties. A duty confined to what is already known is far narrower than a duty to "reasonably" "anticipate," for it pertains only to what has already *in fact* come to the manufacturer's attention, without any requirement to predict or seek out information about downstream events, reactions and reagents.

By contrast, “reasonably” is an enormously amorphous word while “anticipate” requires prediction. Those words would vastly expand the current duty, and in a way that is infeasible and unjustifiable. The proposed language on this issue should therefore be withdrawn.

The Proposed Amendment to the Exclusion of “Nuisance Particulates”

The proposal would amend the exclusion of “nuisance particulates” by adding the underlined words: “Nuisance particulates [are excluded] where *the chemical manufacturer or importer can establish* that they do not pose any physical hazard, health hazard, or other hazards covered under this section[.]” (Emphasis added.)

With respect, the phrase “can establish that” in this provision would, at least as to “other hazards,” be unlawful, for it would place on our members, and on manufacturers and importers, the burden of proof with respect to whether nuisance particulates present “other hazards” covered under the Standard. Doing so by standard or regulation would contravene the burden-of-proof provision of the Administrative Procedure Act, 5 U.S.C. § 556(d), which states: “Except as otherwise provided by *statute*, the proponent of a[n] ... order has the burden of proof.” (Emphasis added.) It would also contravene the authoritative construction of this provision in *Director, OWCP v. Greenwich Collieries*, 512 U.S. 267, 281 (1994), where the Supreme Court held that “the Department [of Labor] cannot allocate the burden of persuasion in a manner that conflicts with the APA.”

The legislative history of the APA burden-of-proof provision states that it reflects the “customary”³ or “standard”⁴ rule, and that “no agency is entitled to presume that the conduct of any person . . . is unlawful or improper.”⁵ The Court noted that the APA was intended “to introduce greater uniformity of procedure and

³ S. Rep. No. 79-752 (1945), as reprinted in STAFF OF S. COMM. ON THE JUDICIARY, 79TH CONG., ADMINISTRATIVE PROCEDURE ACT—LEGISLATIVE HISTORY 1944-46, S. Doc. No. 248, at 187, 228 (1946) (hereinafter APA LEG. HIST.). The Senate report states: “Section 7(c): The first sentence states the customary rule that the proponent of a rule or order shall have the burden of proof. Statutory exceptions to the rule are preserved.”

⁴ SENATE JUDICIARY COMMITTEE COMPARATIVE PRINT 15 (1945), reprinted in APA LEG. HIST., *supra* note 3, at 11, 31.

⁵ S. REP. NO. 79-752, reprinted in APA LEG. HIST., *supra* note 3, at 187, 208; H.R. REP. NO. 79-1980, at 36 (1946), reprinted in APA LEG. HIST. *supra* note 3, at 235, 270.

standardization of administrative practice among the diverse agencies whose customs had departed widely from each other.”⁶ Yet, under the Labor Department approach considered and rejected in *Greenwich Collieries*, “each agency would be free to decide who shall bear the burden of persuasion.”⁷

We are aware that OSHA has over the years adopted provisions in standards purporting to place the burden of proof on employers⁸ and that courts and the Occupational Safety and Health Review Commission have permitted such placements.⁹ None of these cases, however, considered the effect of 5 U.S.C. § 556(d), or its authoritative construction in *Greenwich Collieries*. Cases are not authority on points they did not consider.¹⁰ In addition, the underlying authorities on which these cases relied were inapposite. At bottom, they concerned *statutes*—not regulations—that imposed burdens of proof on private parties.¹¹ But the APA provision permits burdens to be imposed on private parties if “otherwise provided by *statute*.” (Emphasis added.)

Inasmuch as APA § 556(d) and *Greenwich Collieries* make clear that agencies may not impose the burden of proof by *regulation*, the addition of the phrase “or other hazards” to paragraph (b)(6)(x) of the Hazard Communication Standard would, at least as to “other hazards,” be unlawful.

⁶ 512 U.S. 267 at 280–81 (quoting *Wong Yang Sung v. McGrath*, 339 U.S. 33, 41 (1950)).

⁷ *Id.* at 281.

⁸ *E.g.*, 29 C.F.R. § 1910.269(q)(2)(iv) (“Unless the employer can demonstrate ...”).

⁹ *E.g.*, *Triumph Constr. Corp. v. Sec’y of Labor*, 885 F.3d 95, 98 (2d Cir. 2018); *Harry C. Crooker & Sons v. OSHRC*, 537 F.3d 79, 86 (1st Cir. 2008); *Wynnewood Refining Co.*, 27 BNA OSHC 1971, 1977 n.9 (OSHRC 2019), *aff’d without consideration of point*, 978 F.3d 1175 (10th Cir. 2020); *Stephenson Enters., Inc.*, 4 BNA OSHC 1702, 1705 (OSHRC 1976), *aff’d without consideration of point*, 578 F.2d 1021 (5th Cir. 1978).

¹⁰ *E.g.*, *Cagle’s Inc.*, 21 BNA OSHC 1738, 1744 (No. 98-0485, 2006) (previous cases did not consider issue); *Northwest Airlines, Inc.*, 8 BNA OSHC 1982, 1988 (No. 13649, 1980) (same); *see generally Brecht v. Abrahamson*, 507 U.S. 619, 630-31 (1993) (question must be “squarely addressed”); *Underhill Constr. Corp. v. OSHRC*, 526 F.2d 53, 54 n.3 (2d Cir. 1975) (issue neither briefed nor argued in prior decision).

¹¹ *E.g.*, *Meacham v. Knolls Atomic Power Lab.*, 554 U.S. 84, 91 (2008) (when a “proviso ... carves an exception out of the body of a *statute* ... those who set up such exception must prove it.”) (internal citation omitted; emphasis added), citing *FTC v. Morton Salt Co.*, 334 U.S. 37, 44–45 (1948) (“[T]he burden of proving justification or exemption under a special exception to the prohibitions of a *statute* generally rests on one who claims its benefits ...”) (emphasis added).

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Attachment: David Michaels, PhD, MPH, Remarks at EPA IRIS Workshop on the
NRC Recommendations (Oct. 15, 2014)

**Remarks by
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for Occupational Safety and Health**

**EPA IRIS Workshop on the NRC Recommendations
Arlington, VA
October 15, 2014**

Summary Points

- *Through implementation of the GHS and pilot exercises, OSHA has learned that guidance and tools are needed in order to ensure more accurate and consistent results in the application of the GHS criteria.*
- *OSHA continues to work toward consistency in hazard classification worldwide through the development of guidance and compliance assistance tools as well as continued involvement and coordination with the international community on the GHS*
- *Consistent with the concept of 'fit for purpose', the level of evidence required for hazard communication should not be as high as that required to support regulatory decisions.*
- *Hazard communication is most effective when manufacturers use a transparent and systematic approach to evaluating available hazard evidence, regardless of whether the approach relies on expert judgment or a more structured process.*

Remarks

It is my pleasure to be here for today's workshop, to discuss recommendations from the National Academies' National Research Council's May 2014 report on further improving the scientific quality of Integrated Risk Information System assessments.

I want to thank the EPA for holding this workshop and for its ongoing commitment to and success in improving the IRIS assessment process. The discussions we will have during this workshop should go a long way towards helping us attain the highest quality IRIS assessments.

I've been asked to talk specifically about the lessons we've learned at OSHA on developing hazard communication guidance. Our Hazard Communication Standard is designed to ensure that information about hazardous chemicals and their associated protective measures are provided to employers and workers. We do this by requiring that chemical manufacturers and importers evaluate the hazards of the chemicals they produce or import, and then provide that information to employers and workers through labels on shipped containers and safety data sheets, as well as employee training.

However, hazard communication works best when the information being shared is objective, replicable, accurate and consistent. So let me share what we have learned in trying to achieve this.

In March 2012, we revised our Hazard Communication Standard to align with the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (or GHS).

The GHS is an international approach to hazard communication that has been agreed to by many countries, international organizations, and stakeholders around the world. It harmonizes the criteria for classifying chemical hazards and standardizes the approach used to label elements and safety data sheets.

OSHA's alignment with the GHS provides a method to improve the quality and consistency of the information that would be provided to employers and workers. Now, instead of just

determining if a chemical is hazardous, we are able to provide specific criteria on how to classify chemical hazards through our Hazard Communication Standard.

Hazard classification is the identification and evaluation of available scientific evidence in order to determine the hazards of a chemical. The hazard classification then serves as the basis for the hazard communication information provided in labels, SDSs, and employee training. So, it is critically important that classification be performed accurately and consistently.

While the Hazard Communication Standard provides detailed criteria for classifying chemicals, expert judgment may still be needed to interpret test data for classification decisions. As the United States and many other countries around the world implement the GHS, one key implementation issue has emerged -- in some cases, different classification decisions have been made for the same chemical. To examine why this might happen, particularly when the same criteria are being used, the Organisation for Economic Co-operation and Development (or OECD) Taskforce on Hazard Assessment performed a pilot exercise on classification in 2013.

The Task Force selected three chemicals for assessment. All three chemicals had data available through assessments that were sent to the Cooperative Chemicals Assessment Meeting and had self-classifications available. The study found that the variances in classifications were due to several reasons. The primary reason was the use of different data sets for evaluation. Some of the classifiers used OECD's screening information data set (or SIDS) data solely, others didn't use SIDS at all and used different databases, and some used both. Other reasons included

differences in data interpretation, different use of read across, and inconsistent weighing of evidence.

An earlier pilot study was conducted by the UN Sub-Committee of Experts on the GHS in 2005 to assess the application of GHS classification criteria. The United States and the European Union participated in the study, which evaluated two pilot chemicals. Each country evaluated the same data on both chemicals, and proposed a GHS classification and label based on their independent evaluations. Although there was general agreement between both countries on the classifications of the chemicals, the study identified potential differences in interpretation of the GHS criteria. This exercise also showed that multiple factors can impact the outcome of hazard classifications, particularly the availability of complete and accessible data for all evaluators.

Through pilot exercises like these, it is clear that guidance and tools are needed in order to ensure more accurate and consistent results in the application of the GHS criteria.

The UN Sub-Committee of Experts has responded by developing the Practical Classification Issues (or PCI) informal correspondence group. This group's purpose is to clarify application of the GHS criteria by proposing changes to the GHS document and developing examples to illustrate application of the GHS criteria.

The PCI group works to make sure that classifiers understand the intent of the specific classification provisions of the GHS and how to apply them as accurately as possible in order to ensure appropriate and consistent hazard classifications. All GHS examples developed by the

PCI group are sent to the UN Sub-Committee of Experts for review and approval and all approved examples are published on the UN GHS guidance webpage.

The OECD has also responded to requests for guidance on consistent classification. In 2004, the OECD began development of the eChemPortal, a global portal of information on chemical substances. The portal allows users access to existing assessments and datasets for as many chemicals as possible through a variety of search options, including searches based on certain properties or effects, such as physical chemical properties, chemical identification, environmental fate and behavior, ecotoxicity and toxicity in the participating databases.

The OECD works with several member countries (the United States, Japan, Canada), the European Commission, the European Chemicals Agency, the International Council of Chemical Industry Associations, the Business and Industry Advisory Committee, the World Health Organization's International Programme on Chemical Safety, UNEP Chemicals and Environmental NGO's on this project.

A number of countries, particularly developing countries, have expressed the need for a globally harmonized list of classified chemicals to assist in the transition to their GHS-based regulations. The UN Sub-Committee of Experts has developed an informal correspondence group, which is being led by the United States, to explore how such a list could be developed. The group is currently developing a pilot classification exercise where classifications will be performed using available data and will be compared to classifications of existing lists.

OSHA has also responded to the need for more guidance on ensuring accurate and consistent classifications. We are currently developing two guidance products. One is designed to aid chemical manufacturers, importers, and employers in evaluating data and making weight of evidence determinations in a transparent and systematic manner. The other is a hazard classification guidance document. This document is designed to provide the regulated community with more guidance regarding the specific classification criteria to assist them in making classification decisions. The hazard classification guidance document is currently in the review process and we anticipate its publication by early 2015.

While we want to continue towards our goal of achieving consistency in hazard classification world-wide, we should also continue our efforts to ensure harmonized hazard classifications across the various federal agencies in the United States.

The United States has developed an interagency group to discuss issues related to the domestic implementation of the GHS. This group consists of OSHA, the Department of Transportation (or DOT), EPA, the Consumer Product Safety Commission (or CPSC), the U.S. Coast Guard, and the State Department. The group meets regularly to develop and coordinate positions for GHS documents presented to the UN Sub-Committee of Experts, and to ensure that the revisions adopted by the UN will continue to reflect key United States priorities, and will not conflict with our hazard communication requirements.

With OSHA's alignment with the GHS, manufacturers, importers, and distributors that transport chemicals should find that many chemicals classified for transport are classified similarly for the

workplace. OSHA worked with DOT during the rulemaking process, and we continue to work together to develop consistent guidance and interpretations.

We also worked with EPA during the rulemaking to identify how to label pesticides so that each agency's regulatory requirements would be satisfied. OSHA is also working with EPA to develop SDS guidance for chemical users that must comply with the Resource Conservation and Recovery Act. And we are working with the CPSC on dual labeling issues as we implement the changes to the Hazard Communication Standard.

A final point I'd like to make is that the level of evidence required for hazard communication should not be as high as that required to support regulatory decisions.

A key message from the National Research Council report *Science and Decisions* was that the level and complexity of hazard identification and other steps in the risk assessment process should be consistent with the action or decision that it is intended to address. This "fit to purpose" concept is an important consideration when applying systematic evidence evaluation schemes for hazard communication.

Regulatory decision-making, such as setting permissible exposure limits or IRIS reference concentrations, generally requires reasonably strong scientific evidence of hazard. The evidence that the chemical is causally associated with toxicity needs to be sufficiently convincing in order to estimate health risk for actions that impose costs and benefits to the regulated community. It would be inappropriate to apply this same high evidence 'bar' to hazard communication.

The purpose of hazard communication is to disclose information about chemicals and their potential hazards to employees. The degree of evidence to support a hazard finding for this purpose can rely on less certain evidence supported by studies of lesser quality. For this reason, the Hazard Communication Standard requires hazard statements on SDS and labels for substances that meet the GHS criteria for Category 2 ‘suspected’ carcinogens and reproductive toxicants, in addition to substances meeting the stronger evidence criteria for Category 1 ‘presumed’ or ‘known’ toxicants. The Category 2 hazard category covers chemicals where there is only limited evidence of an effect in animal or human studies.

Communication of hazard information on suspected toxicants allows employers and workers to exercise precautions before more definitive evidence required for regulatory action becomes available. This can avoid situations like what occurred with dibromochloropropane (DBCP) in the 1970s when manufacturers discounted early evidence of reproductive harm from experimental animal studies and failed to warn employees of the hazard. A decade later, it was shown that occupational exposures to this chemical caused sterility in male workers. DBCP is no longer used in the U.S.

More recently, OSHA has become aware of evidence in human and animal studies that the widely used industrial chemical, bisphenol A (BPA), is associated with reproductive effects. Several published reviews have concluded that BPA is a potential reproductive toxicant. Internationally recognized authorities have classified BPA as a Category 2 ‘suspected’ reproductive toxicant under GHS criteria. Despite this, some US manufacturers continue to

dismiss the evidence as insufficient to meet hazard requirements under the Hazard Communication Standard.

All of this is to say that in order to have the most effective hazard communication standard, you have to start with objective, replicable, accurate and consistent hazard classifications.

Regardless of how well we share the information, everyone has to be speaking the same language when it comes to hazards or else there is too much room for confusion, where inconsistent information can ultimately lead to workers' lives being put at risk. Hazard communication would also be made more effective if manufacturers use a transparent and more systematic approach to evaluating and integrating the available hazard evidence, regardless of whether the approach relies on expert judgment or a more structured process.

Thank you again to EPA for holding this workshop. I look forward to hearing what everyone else has to say and I'm confident we can continue making progress towards improving the quality and consistency of hazard classifications. This is very important, so that we all get on the same page – the right page – and put ourselves in a position to better help protect the health of all workers.