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Summary of OSHA Requirements Surrounding Globally Harmonized System

This memorandum briefly summarizes the March 26, 2012 adoption¹ of the so-called "Globally Harmonized System" ("GHS") (hereinafter, "GHS Final Rule") by the Occupational Safety & Health Administration ("OSHA") to update its prior "Hazard Communication Standard" ("HCS") regulations for the classification and labeling of chemicals. In particular, this document focuses on: (1) the most significant changes to the HCS regulations that OSHA will implement through the GHS, as relevant to fertilizer producers, and (2) the established implementation dates for GHS regulatory requirements. First, to provide sufficient background on OSHA's HCS regime, this document briefly discusses OSHA's prior HCS regulations, its stated rationale for transitioning to the GHS, and the general provisions of the GHS Final Rule.

Background: The prior and current HCS² requires chemical "manufacturers" and "importers" to evaluate chemicals they produce or import to determine whether they present "physical" or "health" hazards. If so, they must develop appropriate container labels and, formerly, "Material Safety Data Sheets" ("MSDSs") to accompany the chemical products through the stream of commerce to "downstream" employers, employees, and other end-users. A familiar component of the prior HCS labeling regulations was the use of blue, red, yellow, and white "diamonds" and numerals to communicate the relative health, flammability, reactivity, and special hazards of particular products. These labels were integrated into MSDSs, and thus were one of the most recognizable features of OSHA's regulatory footprint among chemical manufacturers and end-users. Based on the relevant hazards communicated to downstream users through the prior HCS, employees were and are obligated by OSHA to provide appropriate hazard training to their employees. According to OSHA, these container labels, product MSDSs, and employee training requirements formed the foundation of the prior HCS, and will be preserved and enhanced by the implementation of the GHS Final Rule.³

Significantly for the fertilizer industry, the prior HCS allowed "manufacturers" and "importers" of "mixtures" of chemicals to use the MSDSs and hazard information for the individual chemicals in "mixtures" to infer the mixtures' likely health hazards, and thereby forgo a redundant analysis of the entire mixture.⁴ Specifically, under the prior rules, when data on mixtures as a whole were not available, the mixtures were considered to present the same health hazards as any ingredients present at a concentration of 1% or greater, or, in the case of carcinogens, concentrations of 0.1% or greater.⁵ However, where existing evidence showed that a health risk would remain at concentrations below these default regulatory "cut-offs," the

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¹ 77 Fed. Reg. 17,574 (Mar 26, 2012) ("Hazard Communication; Final Rule").

² See generally 29 C.F.R. § 1910.1200.

³ 77 Fed. Reg. at 17,574-77, 17,579.

⁴ *Id.* at 17,580.

⁵ See id.

mixtures still could be considered hazardous under the prior HCS.⁶

Summary of Significant Changes in the GHS Final Rule

Development of the GHS initially occurred in the United Nations, and was driven by the multiple, often-inconsistent chemical classification and labeling systems that existed (and that still exist) internationally. These systems historically have created confusion among exporters, importers, and downstream users of particular chemicals, and have led to inconsistent or redundant documentation and labeling requirements in commerce. In 1992, a United Nations mandate prompted an agenda to develop a world-wide GHS for the classification and labeling of chemicals with the primary objective of increasing the quality and consistency of information provided to workers, employers, and chemical end-users.

First, and most prominently for all regulated entities, the GHS Final Rule requires chemical "manufacturers" and "importers" to label chemical containers with: (1) harmonized signal words; (2) one or more GHS-based "pictograms;" (3) a hazard statement for each hazard class and category; (4) a precautionary statement; and (5) a supplier identification,⁷ as opposed to the former "diamond" labels under the HCS. Specific labels will be developed to correspond to the more detailed hazard information communicated in so-called "Safety Data Sheets "("SDSs"), which fulfill the same role as MSDSs.

The GHS Final Rule also changes the methods that must be used to determine the physical and health hazards for particular chemicals. For instance, "modifications have been made to the standards for Flammable and Combustible Liquids in general industry (29 CFR 1910.106) and construction (29 CFR 1926.152) to align the requirements of the standards with the GHS hazard categories for flammable liquids."⁸ And, significantly for many fertilizer producers, different procedures described in Appendices A and B to 29 C.F.R. § 1910.1200 will be required to classify the hazards of the chemicals, including determinations regarding when "mixtures" of the classified chemicals covered by the GHS Final Rule must be subject to more specific analyses.⁹ As set forth in Appendix A and B of the GHS Final Rule (now codified in § 1910.1200), OSHA will require hazard classification of mixtures for most hazard classes using the following sequence:

(a) Where test data are available for the *complete mixture*, the classification of the mixture will always be based on those data; (b) Where test data are not available for the mixture itself, the *bridging principles* designated in each health hazard chapter of this appendix shall be considered for classification of the mixture; (c) If test data are not available for the mixture itself, and the available information is not sufficient to allow application of the above-mentioned bridging principles, then the method(s) described in each chapter for *estimating the hazards* based on the information known will be applied to classify the mixture (e.g., application of

⁶ See id.

⁷ *See, e.g., id.* at 17,740-17,747 (examples of regulated "substances" and final HCS changes), 17,825-17,883 (listing pictograms, signal words, and other new labeling requirements).

⁸ *Id.* at 17,582.

⁹ *Id.* at 17,787.

cut-off values/concentration limits).¹⁰

In essence, based on the relevant hazard class, this will limit both the use of (1) inferences for classifying "mixtures" using existing hazard information for the individual chemical ingredients therein (*e.g.*, MSDSs or SDSs for individual ingredients), and (2) MSDSs or SDSs for all of the ingredients in a mixture, instead of a specific MSDS/SDS for the mixture.¹¹ Additionally, OSHA's GHS Final Rule defines a "mixture" somewhat differently than under the former HCS regulations: a "mixture" now will be defined as "a combination or a solution composed of two or more substances in which they do not react," wherein a "substance" will be defined simply as "chemical elements and their compounds."¹² On their face, these definitions appear to encompass combinations of non-reactive ingredients in a physical mixture, such as "blends" of fertilizer prills (which could possibly be re-segregated through physical sorting), as well as "mixed fertilizer."

As quoted from the GHS Final Rule above, the new approach to classifying chemical "mixtures" incorporates so-called "bridging principles" for particular GHS hazard classes, which will become a significant feature of hazard analyses under the HCS. In short, those principles include, but are not limited to: (1) Dilution ("If a mixture is diluted with a diluent that has an equivalent or lower toxicity, then the hazards of the new mixture are assumed to be equivalent to the original"); (2) Batching ("If a batch of a complex substance is produced under a controlled process, then the hazards of the new batch are assumed to be equivalent to the previous batches"); (3) Concentration of Mixtures ("If a mixture is severely hazardous, then a concentrated mixture is also assumed to be severely hazardous"); (4) Interpolation within One Toxicity Category ("Mixtures having component concentrations within a range where the hazards are known are assumed to have those known hazards"); and, (5) Substantially Similar *Mixtures* ("Slight changes in the concentrations of components are not expected to change the hazards of a mixture and substitutions involving toxicologically similar components are not expected to change the hazards of a mixture").¹³ OSHA anticipates that application of some of these principles to "mixtures" may "result in some mixtures that are currently considered to pose a particular hazard not being so classified under the GHS."¹⁴ However, application of the above sequence will require more detailed analyses of "mixtures" than under the former HCS.

¹⁰ See id. at 17,790, et seq. (emphasis added to show major elements of the sequence).

¹¹ See id. at 17,708 ("During implementation of the current HCS, OSHA allowed formulators of chemicals to develop an SDS by simply providing the SDSs for all the ingredients rather than compiling a specific SDS for the product. OSHA does not believe that this practice of providing the SDSs for all the ingredients is widely pursued, *but it will not be permitted under the final rule.*") (emphasis added). However, OSHA does indicate that a single SDS, with "[c]oncentration ranges, rather than concentrations," may be used for multiple mixtures with varying compositions "where [the] complex mixtures have similar hazards and contents (the ingredients are essentially the same, but the specific composition varies from mixture to mixture)." 77 FED. REG. at 17,731.

¹² *Id.* at 17,786-87.

¹³ See, e.g., *id.* at 17,811; United Nations, "A Guide to The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)" § 3.5 (OSHA Website Copy) ("What are bridging principles?"), available at http://www.osha.gov/dsg/hazcom/ghs.html#3.5.

¹⁴ 77 Fed. Reg. at 17,711.

Implementation Dates for the New GHS System

Effective Completion Date:	Requirement(s):	Who:
Dec. 1, 2013	Train employees on the new label elements and SDS format.	Employers
June 1, 2015* Dec. 1, 2015	Comply with all modified provisions of this final rule, except: Distributors may ship products labeled by manufacturers under the old system until December 1, 2015.	Chemical manufacturers, importers, distributors and employers
June 1, 2016	Update alternative workplace labeling and hazard communication program as necessary, and provide additional employee training for newly identified physical or health hazards.	Employers
Transition Period	Comply with either 29 CFR 1910.1200 (this final standard), or the current standard, or both.	All chemical manufacturers, importers, distributors and employers

Due to the GHS Final Rule's substantial modifications to the prior HCS regime, OSHA has established a phased implementation schedule, as set forth below:

* This date coincides with the European Union implementation date for classification of mixtures.¹⁵

Thus, during the "transition period" for this implementation schedule, OSHA explains that all "chemical producers" must "review hazard information for all chemicals produced or imported, classify chemicals according to the new classification criteria, and update labels and safety data sheets," while complying with either the prior HCS regulations, the GHS Final Rule, or both.¹⁶

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¹⁵ See 77 Fed. Reg. 17,740; OSHA Website, "Fact Sheet: Hazard Communication Standard Final Rule," <u>http://www.osha.gov/dsg/hazcom/HCSFactsheet.html</u> (last visited March 15, 2013).