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The Globally Harmonized System of Classification and Labelling of Chemicals (GHS):

Implementation Planning Issues for the Office of Pesticide Programs

PURPOSE/EXECUTIVE SUMMARY

The purpose of this paper is to describe the current thinking of the Office of Pesticide Programs (OPP) with respect to the application of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) to pesticide labels, to outline possible implementation mechanisms that are under consideration, and to solicit initial public input on the options presented.

The GHS establishes classification criteria for physical, health and environmental hazards, along with associated hazard communication elements, notably pictograms, signal words, and hazard statements for use on labels. It is based on harmonizing major existing systems for classifying and labeling of chemicals in transport and in the workplace, in pesticides, and in consumer products. A key guiding principle of the GHS harmonization effort was that harmonization should be accomplished without lowering the level of protection afforded by existing systems. It was also acknowledged that changes in all systems would be required to achieve a single, globally harmonized system.

To implement the GHS for pesticides, OPP would need to modify certain of its classification and labeling requirements to be consistent with the GHS, and to take steps to ensure that pesticide labels are revised accordingly. OPP is particularly interested in comments on policies and mechanisms that will achieve implementation within a reasonable time frame in an equitable and efficient manner, minimizing the burden on agency and stakeholder resources. The paper presents two basic options for implementation: establishing a separate approval process or integrating GHS label changes into ongoing registration and re-registration actions. We are also seeking comments on the possible benefits of instituting a pilot project before final changes implementing the GHS are in place, how such a pilot might be structured, and what educational and outreach activities would be most effective.

In light of the comments received and other relevant information and analysis, OPP will evaluate next steps. We also plan to continue to consult within the North American Free Trade Agreement Technical Working Group on Pesticides (NAFTA TWG) in an effort to coordinate implementation activities in all three NAFTA countries: Canada, the United States, and Mexico.

The paper is organized into four major sections: (1) background on the GHS, its contents and how it was developed; (2) comparison of the GHS with current OPP classification and labeling policies; (3) initial implementation considerations; and (4) outreach activities and plans.

I. BACKGROUND

For over a decade, the U.S. and other countries and stakeholders worked to develop the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), a major activity mandated by the 1992 UN Conference on Environment and Development and endorsed by the 2002 World Summit on Sustainable Development (WSSD) and the Intergovernmental Forum on Chemical Safety (IFCS). The GHS is designed to provide a common and coherent approach to defining and classifying hazards and communicating hazard information on labels and safety data sheets. The anticipated benefits of harmonization include:

- Enhanced protection of human health and the environment: GHS will help ensure more consistency in the classification and labeling of all chemicals, thereby enhancing safer transportation, handling and use of chemicals in transport, in the workplace, and in consumer use settings.
- Sound management of chemicals worldwide: GHS will provide a harmonized basis for the first step in sound management of chemicals, identifying/classifying hazards and communicating them. This will be particularly useful for countries without well-developed regulatory systems.
- Trade Facilitation: GHS will reduce costly and time-consuming activities needed to comply with multiple classification and labeling systems, promoting more consistency in regulation and reducing non-tariff barriers to trade.

The GHS is now complete and was formally adopted by the United Nations Economic and Social Council (UN ECOSOC) in July 2003. For a fuller discussion of the history and organization of the GHS negotiations, see the *Federal Register*, Volume 62, Number 64 (April 3, 1997) pp. 15951-15957.

Scope of the GHS

The GHS is based on harmonization of major existing systems for chemicals in transport and in the workplace, pesticides, and consumer products, without lowering the level of protection afforded by those existing systems. Its scope includes all chemicals; however, it does not cover pharmaceuticals, food additives or pesticide residues in food, or cosmetics in the “consumer use setting.” (These types of chemicals are covered in transport and in the workplace, consistent with the current U.S. regulatory framework.) “Articles,” as defined by the Occupational Safety and Health Administration’s hazard communication standard or by similar definitions are also outside the scope of the system (GHS 1.3.2.1.2)

Elements of the GHS

The GHS includes classification criteria and standardized hazard communication elements for physical hazards (flammability, explosivity, etc.), health hazards, and one environmental hazard

(aquatic toxicity). The health hazards covered by the system are acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, and target organ/systemic toxicity (TOST). (Essentially, TOST includes effects not covered by other classes, whether caused by a single exposure or repeated exposures. Examples include neurotoxicity, immunotoxicity, liver damage, etc.)

The standardized label elements include symbols/pictograms, use of two signal words (danger and warning), and hazard statements for each hazard class and category. To be consistent with the GHS, labels should also include product and supplier identifiers and precautionary statements, although these have not been standardized. In addition, it is consistent with the GHS to include supplemental information on the label, to give more detail or cover additional hazards, provided the supplemental information does not undermine the GHS label information. The system further specifies format and contents for hazard communication in Safety Data Sheets, used primarily in the workplace.

The comprehensive GHS document also contains guidance on how some related issues should be addressed for a system to be judged consistent with the harmonized system, e.g., with respect to ingredient disclosure and protection of Confidential Business Information (CBI), precedence of hazard, and use of only one signal word per label.

Basis of Classification and Labeling

GHS classification criteria are based on intrinsic hazard, not risk. Classification is essentially equivalent to the hazard identification step in risk assessment paradigms. Consistent with EPA/OPP policy, a weight of evidence approach is used in making classification determinations based on the best available data. The GHS is not intended to harmonize risk assessment or risk management measures.

The GHS is testing-, and test method-, neutral for health and environmental hazards. Implementation does not require use of any particular test protocols or imposition of any new data requirements. Classification is based on available data, but the GHS acknowledges that agencies with authority to require data will continue to do so. (For example, pesticide authorities, including OPP, would be expected to continue to require acute toxicity studies for pesticide formulations and this would be consistent with the GHS.) The GHS does specify test methods in criteria for physical hazards.

The complete current text of the GHS is posted on the Internet at <http://www.unece.org/trans/danger/publi/ghs/officialtext.html>.

The GHS Development Process and Stakeholder Involvement

The GHS was developed and approved based on a tripartite consensus of participating government representatives, industry representatives, and representatives of other non-governmental organizations, principally labor unions and professional organizations of

emergency responders. Overall management of the GHS development process was the responsibility of the Coordinating Group for the Harmonization of Chemical Classification Systems (CG/HCCS), under the auspices of the Inter-organization Program for the Sound Management of Chemicals, which reported to the Intergovernmental Forum on Chemical Safety (IFCS).

Under the direction of the CG/HCCS, the work of developing the elements of the GHS was assigned to three focal points, which also operated on a tripartite, consensus basis. A task force of the Organization for Economic Cooperation and Development (OECD) developed classification criteria for health and environmental hazards. A joint working group of the UN Committee of Experts on the Transport of Dangerous Goods (UNCETDG) and the International Labour Organisation (ILO) developed the classification criteria for physical hazards. The hazard communication elements of the system were developed by an ILO Working Group on Hazard Communication. The Coordinating Group set overall policy directions for development of the system, resolved issues referred to it by the focal points, and assembled the final GHS package in a single document.

U.S. government agencies and stakeholders participated actively in the work of the focal points and the CG/HCCS, and joined in the consensus on the final GHS. Overall U.S. government positions were coordinated by an interagency group consisting of representatives of key regulatory and trade agencies and led by the State Department. The interagency group encouraged public participation through public meetings before major international meetings, *Federal Register* notices, and maintenance of an electronic mailing list of interested stakeholders. Key regulatory agencies took the lead for the technical work of GHS development. The Department of Transportation was the lead agency for the work on physical hazards. The Environmental Protection Agency Office of Pollution Prevention, Pesticides and Toxic Substances was the lead for health and environmental hazard classification criteria. The Department of Labor Occupational Safety and Health Administration was the lead for GHS hazard communication activities and chaired the CG/HCCS.

The permanent home of the GHS is the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UN SCEGHS), which reports to the UN ECOSOC through the joint Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labelling of Chemicals. The U.S. is a member of the Sub-Committee and the full Committee. U.S. stakeholder organizations participate through observer organizations. The UN SCEGHS has continued the roles of OECD and the Sub-Committee of Experts on the Transport of Dangerous Goods as focal points for future technical work on health and environmental hazards and physical hazards, respectively. The UN Institute for Training and Research (UNITAR) is the focal point for international capacity-building activities. The U.S. government and some stakeholder organizations are also members of the GHS Partnership created under the auspices of the WSSD to promote GHS implementation worldwide.

General Implementation Expectations at the International Level

The GHS is a voluntary international system, in that it does not impose binding treaty obligations on countries. The intent is that countries with existing systems will harmonize them with the GHS, and countries that do not have systems will adopt the GHS as their basic system. To the extent that regulatory agencies change their requirements to be consistent with the GHS, however, those changes will be binding on regulated industry in the same way as current regulatory regimes are binding.

It is important to note that one of the fundamental premises of the GHS is a “building block” approach. Countries are not obligated to cover all GHS classes and categories in order to be considered consistent with the GHS, just as current regulatory systems do not cover all GHS hazards (e.g., the Department of Transportation does not cover chronic effects, OPP does not generally label chronic effects based on hazard), but for those effects that are covered, it is expected that countries will consistently apply GHS criteria for classification and require GHS hazard communication elements. Countries that choose the risk-based labeling approach for consumer products (the approach currently used by the U.S. Consumer Product Safety Commission) would also be expected to use the GHS classification criteria and label elements. Some hazards may not be on the label, based on a risk assessment combining exposure with the GHS classification criteria, but those effects that are on the label should be identified in accordance with the GHS.

There is no detailed, internationally agreed-upon GHS implementation schedule. The WSSD confirmed the IFCS goal of adoption by countries in each region by 2008, and the Chemicals Dialogue of the Asia-Pacific Economic Cooperation Forum (APEC), of which the U.S. is a member, set a goal of implementation by 2006 to the extent possible. Different systems are likely to require different implementation schedules. Not all regulatory systems require preapproval of labels, as OPP does. It has also been noted that some transitional provisions (e.g., accepting both new and old labels in the marketplace at the same time) will be important to avoid trade disruptions.

GHS implementation for pesticides is included in the NAFTA TWG Five Year Strategy (available on the Internet at <http://www.epa.gov/oppfead1/international/naftatwg/twgstrategy.pdf>). The NAFTA TWG Executive Board approved a project to promote coordinated approaches to implementation at its meeting in Vancouver, Canada, in December 2003.

II. SUMMARY COMPARISON OF GHS WITH CURRENT OPP CLASSIFICATION AND LABELING POLICIES

This section provides a narrative summary comparison of the GHS with current OPP policies, drawing on EPA’s label regulations in Title 40 of *Code of Federal Regulations* Part 156 (40 CFR 156) and the OPP Label Review Manual (<http://www.epa.gov/oppfead1/labeling/lrm/>). A

separate document is available that includes a side-by-side comparison of the GHS and corresponding OPP policies [\[GIVE WEBSITE INFO\]](#) Neither this paper nor the side-by-side comparison attempts to include all exceptions or special circumstances that might lead to divergent classifications, which could lead to different label requirements and would still be considered consistent with the GHS.

General Comparison of OPP Policies and the GHS (these points apply across hazard classes)

1. GHS organizes the hazard characteristics of chemicals based on “hazard classes” (specific physical, health or environmental effects, such as flammability, skin corrosion/irritation, aquatic toxicity) which are subdivided into numerical “hazard categories” based on the severity of the hazard. The use of the term “category” is thus essentially the same as current OPP practice. The GHS uses Arabic numerals consistently, while OPP uses Roman numerals.
2. OPP uses the skull and crossbones symbol for severe acute toxicity and products containing methanol at concentrations above 4%, and a flame symbol for highly flammable total release foggers (40 CFR 156.78(d)(3)). The GHS uses symbols for all hazard classes (but not all categories).
3. GHS pictograms are composed of the appropriate symbol surrounded by a red diamond-shaped border, except that authorities may allow a black diamond border if the chemical is for domestic use only. OPP does not prescribe borders around symbols.
4. OPP uses three signal words (danger, warning, and caution); the GHS only two (danger and warning). OPP prohibits the use of signal words for environmental or physical hazards; the GHS mandates their use for some categories (e.g., extremely flammable liquids).
5. GHS “hazard statements” are simple statements of hazard, a subset of what OPP calls “precautionary statements.” GHS does not specify any precautionary statements (e.g., first aid, personal protective equipment) beyond hazard statements. An annex to the GHS document gives examples of precautionary statements currently in use in a number of systems, including OPP’s. The UN SCEGHS is working to develop proposals for greater harmonization of precautionary statements.
6. The GHS calls for all chemical labels to include a product identifier (a name or number that provides a unique means by which users can identify a chemical substance or mixture) and a supplier identifier, but does not provide detailed specifications. It also calls for disclosure on the label of ingredients that contribute to hazard classification, but provides that national rules governing

disclosure of Confidential Business Information (CBI) will take precedence over ingredient disclosure provisions.

7. No change in OPP test requirements for health and environmental effects is necessary to achieve consistency with the GHS. The GHS is testing-, and test-method-, neutral for health and environmental hazards and is designed to permit self-classification to the maximum extent possible, while recognizing that some systems, such as those governing pesticides, do require testing, independent of the GHS.
8. The GHS includes conservative “bridging principles” for classifying untested chemical mixtures based on the availability of data on very similar mixtures, or on the ingredients of the mixture, that permit adequate characterization of the hazards of the mixture (for example, for acute toxicity, see GHS Section 3.1.3.5). OPP generally requires certain data based upon the end-use product, while other data can be “bridged” in certain circumstances when scientifically appropriate.
9. The GHS specifies test methods for physical hazards. To be consistent with the GHS, OPP would need to ensure that its guidelines are consistent with these methods and that its regulations specify GHS classification criteria and label elements where appropriate.
10. Except as detailed in the specific hazard class comparisons that follow, other OPP label information requirements appear consistent with the GHS’ allowance for “supplemental information,” beyond the specified GHS label elements, so long as the supplemental information does not undermine the GHS label information. On pesticide labels, supplemental information would include, among other things, additional precautionary statements, requirements for personal protective equipment, re-entry intervals, and first aid statements.

Acute Toxicity

1. The GHS has five categories for acute toxicity. OPP currently uses four categories. GHS Categories 1-2 correspond to OPP Category I. GHS Category 3 includes chemicals with toxicities up to 300 mg/kg by the oral route, while OPP Category II extends up to 500 mg/kg. GHS Category 4 covers oral LD₅₀ values > 300 mg/kg ≤ 2000 mg/kg, compared to OPP Category III’s range of > 500 mg/kg ≤ 5000 mg/kg. GHS Category 5 covers chemicals with toxicities expected to fall in the range of oral and dermal LD₅₀ of 2000 mg/kg - 5000 mg/kg, or equivalent doses for inhalation toxicity. OPP Category IV has no upper limit.
2. The basis of classification in both systems is the same: LD₅₀ values or “acute toxicity estimates” of the LD₅₀.

3. OPP uses the “danger” signal word and skull and crossbones symbol for chemicals in Categories I and II (e.g., oral LD₅₀ of up to 50 mg/kg). GHS uses the “danger” signal word and skull and crossbones symbol for chemicals in Categories 1-3 (e.g., oral LD₅₀ of up to 300 mg/kg) and the exclamation point symbol for Category 4 (e.g., oral LD₅₀ >300 ≤ 2000 mg/kg). [NOTE: if the skull and crossbones symbol applies under the GHS based on any route of exposure, the exclamation point should not also appear on the label.]
4. The GHS specifies different classification criteria for inhalation toxicity based on whether the chemical is (1) a gas, (2) a vapor, or (3) a dust or mist. OPP does not distinguish among different types of inhalation toxicants. [The GHS document notes that additional work remains to be done, notably in defining dusts, mists and vapors; and in addressing technical limitations in generating and maintaining dusts and mists in respirable form.]

Skin Corrosion/Irritation

1. Both OPP and GHS have a single category for skin corrosion. The GHS subdivides this category based on duration of exposure, but the label elements are the same.
2. GHS includes eye damage in the hazard statement for chemicals that are corrosive to the skin. OPP does not, although in practice the statements are often combined for these effects based on data or other information (e.g., pH values).
3. OPP defines skin irritation qualitatively (severe, moderate, and mild/slight/no irritation) based on 72 hour exposures. The GHS classification criteria specify scores and exposure times from commonly-used test protocols. These are consistent with OPP policy.
4. OPP has three irritant categories: severe, moderate, or mild/slight/no irritation. GHS has two irritant categories: irritant and mild irritant.
5. OPP requires no symbols for skin corrosion/irritation. GHS uses a corrosion symbol for Category 1 (corrosives), an exclamation point for Category 2 irritants, and no symbol for Category 3 (mild) irritants.
6. Both OPP and GHS use the signal word “danger” for skin corrosives. OPP requires the signal word “warning” for severe irritants and “caution” for moderate irritants. GHS specifies the signal word “warning” for all chemicals that cause irritation and does not classify or prescribe label elements for chemicals that do not meet the criteria for irritation.

Serious Eye Damage/Eye Irritation

1. Both OPP and the GHS have one category for corrosion/serious eye damage/irreversible effects on the eye and use the signal word “danger” for this category. The GHS also requires the corrosion symbol. OPP requires no symbol.
2. OPP uses three categories for eye irritants. GHS uses one category that is further divided into two subcategories, “irritant” and “mild irritant.” Mild irritant effects are those that are fully reversible within seven days.
3. OPP uses the “warning” signal word and no symbol for irritants in Category II and “caution” and no symbol for Category III. GHS uses “warning” and the exclamation mark symbol for Category 2A irritants and “warning” but no symbol for Category 2B mild irritants.
4. Both OPP and GHS classification criteria are based on severity and duration of effects. OPP classification criteria for severity are described more qualitatively in the Label Review Manual. The GHS specifies scores from commonly used tests; these are consistent with OPP practice.
5. OPP Category IV covers minimal effects that clear in less than 24 hours. No signal word, symbol or hazard statement is required for this category. Registrants may choose to use the Category III hazard statement. The GHS does not subdivide irritant effects beyond the distinction between those that reverse within 21 days and those that reverse within seven days.

Skin/Dermal Sensitization

1. Both OPP and the GHS essentially use one category, though OPP does not use the term “category” for this effect. A chemical is either classified as a skin sensitizer or it is not.
2. The GHS uses the signal word “warning” and the exclamation mark symbol for skin sensitizers. OPP uses no symbol and no signal word.

Environmental Hazards

1. GHS covers only one environmental hazard: aquatic toxicity. Work to develop terrestrial toxicity as a GHS hazard class may proceed in the future. In the meantime, OPP labeling for hazards other than aquatic toxicity (e.g., bees, mammals) may be considered “supplemental information,” consistent with but not part of the GHS.
2. The GHS has three acute and four chronic categories for aquatic toxicity. Categories 1-3 of chronic toxicity are based on combining the criteria for Categories 1-3 acute toxicity with criteria for persistence in the aquatic

environment. Category 4 chronic toxicity is based on persistence alone, in the absence of toxicity data. OPP only covers acute aquatic toxicity.

3. OPP requires no signal word or symbol for aquatic toxicity. The GHS specifies the “dead fish and tree” symbol and the signal word “warning” for Category 1 acute toxicity and Category 1 chronic toxicity. For Category 2 chronic toxicity, the GHS specifies the symbol but no signal word.
4. OPP requires the hazard statement “this pesticide is toxic to fish” based on studies showing that the active ingredient has a fish acute toxicity LC-50 of 1 ppm or less, if the pesticide is intended for outdoor use. OPP requires the statement “this pesticide is extremely toxic to fish” if there are field studies or incident data (such as reports received under Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act) showing fish kills. OPP also requires specific hazard/precautionary statements for some individual pesticides. The GHS sets out toxicity and persistence criteria for each hazard category, and accompanying hazard statements.
5. GHS-related testing protocols for aquatic toxicity are still in the process of validation through the OECD focal point. The GHS also includes lengthy guidance on aquatic toxicity in Annex 8 of the GHS document.

Flammability

1. Both OPP and GHS specify test methods and set criteria based on test results.
2. OPP classification criteria are based on flashpoint (all pesticides) and flame extension tests (pressurized containers). There are three categories for pressurized containers, and four for nonpressurized containers.
3. GHS specifies criteria and label elements for two categories of flammable gases, two categories of flammable aerosols, four categories of flammable liquids, and two categories of flammable solids. OPP does not distinguish based on physical state.
4. OPP uses no signal words and no symbol, except that a flame symbol is required for highly flammable total release foggers (40 CFR 156.78(d)(3)). GHS uses the “danger” signal word for Category 1 flammable solids, gases and aerosols and Categories 1 and 2 flammable liquids; and the signal word “warning” for Category 2 flammable solids, gases and aerosols and Categories 3 and 4 flammable liquids. The GHS uses the flame symbol for Category 1 flammable gases, Categories 1 and 2 flammable aerosols, Categories 1-3 flammable liquids, and Categories 1 and 2 flammable solids.

Other Physical or Chemical Hazards

1. OPP does not specify classification criteria, symbols, signal words or label statements for physical hazards other than flammability but notes that when data demonstrate such hazards, (for example, explosivity), appropriate hazard statements must appear on the label.
2. Part 2 of the GHS document specifies classification criteria and label elements for explosives, oxidizers, compressed gases, self-reactive and self-heating substances, pyrophoric liquids and solids, substances which emit flammable gases in contact with water, organic peroxides, and metal corrosives.
3. To be consistent with the GHS, OPP would need to adopt the GHS criteria and label elements, as well as the associated test methods, for each physical/chemical hazard class and/or category it decides to cover.

III. INITIAL IMPLEMENTATION CONSIDERATIONS

In the summer of 2003, soon after formal international adoption of the GHS by UN ECOSOC, an internal EPA/OPPTS working group was formed and began meeting to analyze and compare the GHS to current policies and to develop initial implementation recommendations. The working group includes representatives of all OPP divisions, other key EPA offices, and state regulators and educators. This section of the paper outlines the group's initial recommendations and reflects current OPP thinking. We have shared these recommendations and a draft of this paper with our NAFTA counterparts and plan to continue to consult with them throughout the implementation planning process. These consultations, as well as discussions at the broader international level, may lead to additional refinements or modifications in the approaches under consideration, with the goal of further advancing the objectives of international harmonization.

How the GHS will affect U.S. pesticide labeling**General:**

OPP's general approach to initial GHS implementation is to limit changes in the current system of pesticide regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to those necessary to achieve consistency with the GHS. EPA will need to revise its hazard classification and label requirements, in those areas that EPA currently has requirements, but does not intend to expand the scope of its requirements to include all elements that are part of the GHS. This is consistent with the "building block approach" as described in Sections 1.1.3.1.5.1-3 of the GHS document:

Consistent with the building block approach, countries are free to determine which of the building blocks will be applied in different parts of their systems The harmonized elements of the GHS may thus be seen as a collection of building blocks from which to form a regulatory approach. While the full range is available to everyone, and should be used if a country or organization chooses to cover a certain effect when it adopts the GHS, the full range does not have to be adopted.

OPP plans to implement the GHS for all types of pesticides, as defined by FIFRA (including microbial pesticides), and to adopt GHS hazard classification criteria and label elements for all hazard classes for which OPP currently requires hazard labeling for pesticide products, i.e., acute toxicity, skin and eye irritation/corrosion, skin sensitization, acute aquatic toxicity, flammability and other physical hazards. Pesticides which do not meet the classification criteria for any of the hazard categories specified in the GHS would be unclassified for that hazard and would not bear any of the GHS hazard label elements.

GHS-prescribed label elements (pictograms, signal words and hazard statements) should appear together on the label. The pictograms would include a red border, as specified by the GHS. Although the GHS provides discretion for regulatory authorities to permit products not intended to be traded internationally to use a black border, OPP believes that using a red border in all cases would benefit U.S. pesticide users by drawing greater attention to the label information. It would also simplify implementation, in that it would not be necessary to make this distinction when reviewing labels for compliance. Only one signal word would appear on each label, consistent with current OPP policy; if the signal word “danger” applies, the signal word “warning” should not appear. If the skull and crossbones pictogram applies, the exclamation point pictogram should not appear for any health hazards. If the corrosion pictogram applies, the exclamation point pictogram should not appear for skin or eye irritation. (For example, if a product is classified as Category 1 for severe eye damage and Category 2 for skin irritation, it should be labeled with the corrosion pictogram and the signal word “danger” only. The label should not bear the exclamation point pictogram or the signal word “warning.”)

Specific considerations by hazard class:

- For acute toxicity, OPP plans to adopt all five GHS categories and corresponding label elements, including the use of the signal word “danger” and skull and crossbones pictogram for Categories 1-3 and the signal word “warning” and exclamation point pictogram for Category 4. In addition, consistent with FIFRA Section 2(q)(2)(D), OPP would continue to require the word “poison” to appear prominently in red on a background of distinctively contrasting color for pesticides that meet criteria for classification into the two highest categories of acute toxicity, Categories 1 and 2 (e.g., oral LD₅₀ of up to 50 mg/kg).
- For skin corrosion/irritation and serious eye damage/irritation, OPP plans to adopt the GHS hazard categories and label elements, including the corrosion pictogram for Category 1 and the expanded hazard statement for skin corrosives (“causes severe skin

burns and eye damage”). With respect to current OPP Category IV eye irritants (minimal effects clearing within 24 hours), OPP plans to propose that these products either be considered unclassified or that registrants be permitted the option of labeling them with the signal word and hazard statement prescribed for Category 2B eye irritants.

- For skin sensitization, OPP plans to revise its hazard statement to be consistent with the GHS and to adopt the GHS signal word “warning” and the exclamation point pictogram.
- For aquatic toxicity, OPP plans to adopt the classification criteria and label elements for Categories 1-3 of acute aquatic toxicity, including the use of the signal word “warning” and the fish and tree pictogram for Category 1.
- For flammability and other physical hazards, OPP plans to adopt all GHS hazard classes and categories and the corresponding label elements, including the use of pictograms and signal words.

Other label elements prescribed but not standardized by the GHS: In addition to pictograms, signal words and hazard statements, labels should contain precautionary statements (beyond the hazard statement itself, for example, first aid statements, storage and disposal statements, etc.), product identifiers, and supplier identifiers in order to be consistent with the GHS. The GHS does not prescribe specific, standardized language for these label elements. OPP believes that its current label requirements generally satisfy GHS provisions in this regard.

Existing EPA requirements for product and chemical names and registration numbers are consistent with GHS product identifier provisions. While OPP ingredient disclosure policies may differ somewhat from the GHS in terms of inert ingredients, the GHS provides that national CBI disclosure provisions will take precedence, as noted in the previous section, and therefore these OPP policies are also consistent with the GHS. OPP’s requirements for supplier names, addresses and establishment numbers generally satisfy the GHS with respect to supplier identifiers. In addition, however, the GHS calls for labels to include telephone numbers as part of the supplier identifier. OPP strongly encourages this, and many pesticide labels do contain telephone numbers to assist users seeking additional information. We plan to seek comments on whether this should be made a requirement to improve the usefulness of pesticide labels and achieve greater consistency with the GHS.

Options for possible implementation mechanisms

Clearly, implementation of the changes described above to make all pesticide labels consistent with the GHS will require substantial commitment and resources from OPP and other stakeholders. In considering possible implementation mechanisms, OPP has two fundamental guiding principles: the mechanisms used should be fair to the regulated community and should minimize the resource burden placed on OPP and on stakeholders to the extent possible.

Rule-making

EPA's current hazard classification criteria and labeling requirements are contained in Title 40 of the Code of Federal Regulations, Part 156 (40 CFR 156). EPA intends to initiate rule-making to change current label requirements, to bring them into conformity with the GHS. In addition, we will review other regulations that may be based in whole or in part on current classification and labeling categories, to determine if changes are appropriate. As noted in earlier sections of this paper, GHS is based on hazard, not risk, and is not intended to harmonize risk assessment or risk management approaches. To the extent that current risk management measures may be linked to classification and labeling categories, it will be important to evaluate whether such links should be maintained or modified, or whether they should be "decoupled." State pesticide authorities may also need to review regulations that link regulatory consequences beyond labeling to classification categories and identify any appropriate changes.

Options for implementing the GHS

OPP is considering two basic approaches to the actual review and approval of label changes, in light of the goals of ensuring equity and efficiency in the implementation process.

Option 1: A separate review and approval process. Under this approach, which could be implemented with contractor support, EPA would request label changes be submitted as amendments to current labels. Submissions would be limited to GHS changes only. The dates for submission could be staggered, so that changes would be phased in by chemical or class of chemicals. All labels would be reviewed, and if contractor support is used for the review of labels, OPP staff would do a secondary review of some percentage of submissions. While this approach has the attraction of providing for more uniformity in the timing of label changes, it has the disadvantages of requiring a substantial new commitment of resources and creating a major new workload for OPP and for pesticide registrants.

Option 2: Integrating GHS changes into ongoing registration and re-registration actions and label changes that come in for OPP review. Under this approach, registrants who are making changes in their labels would incorporate the GHS revisions as part of their routine business. Consistent with the international GHS implementation goal of 2008, the policy could be that all label amendments submitted for review during the period 2006-2008 should include the GHS along with any other changes that are being proposed. OPP could set a final deadline (or staggered series of deadlines if necessary for workload management) by which all registrants who have not already revised their labels would be required to submit GHS amendments.

The major advantage of this approach is that it does not create a major new workload for OPP or registrants but allows the GHS changes to be made in the course of other routine label changes and reviews. While products with similar characteristics might have different labels for some period of time, due to the fact that the registrants did not choose to revise their labels at the same time, this would not persist for an undue length of time and is not materially different from

the situation that exists when other label changes are made: there are often different labels in the marketplace due to differences in the time it takes for existing label stocks to be exhausted.

In light of the relative advantages of the two approaches, OPP's current thinking is that the second option is preferable, since it allows for the GHS changes to be accomplished without creating new procedures or significantly disrupting ongoing work and business. In either approach, an upgraded acute toxicity database would facilitate efficient review of GHS label changes and the progress of implementation could be tracked through use of special codes for label amendments containing GHS revisions.

Other measures to promote more efficient, effective implementation

In preparation for GHS implementation and in the interest of improving the efficiency of OPP label review procedures generally, we are investigating the possibility of upgrading our database of acute toxicity data to reflect the GHS categories and therefore ease the burden of reviewing new labels when changes begin to be made. This will be a significant improvement regardless of the implementation mechanism(s) selected.

OPP is also considering the possibility of pilot project before final rule changes implementing the GHS are in place. A pilot project could allow for voluntary submissions of label amendments with GHS changes by registrants who wish to make the revisions at an earlier date. Experience gained in such a pilot could help OPP refine procedures for label review. Criteria for participation in the pilot project should be drawn to keep the workload manageable.

Another way in which the approach to label review could be piloted on a relatively small scale would be to call for voluntary GHS changes to be made in connection with label revisions required by Re-registration Eligibility Decisions.

Finally, as implementation planning proceeds, OPP wants to explore opportunities for work sharing with states and/or through the NAFTA TWG. This could reduce the workload for all parties and enhance efficiency.

Timing

At the international level, as noted above, the Intergovernmental Forum on Chemical Safety and the World Summit on Sustainable Development have called for implementation of the GHS to the extent possible by 2008. This is a very ambitious goal in terms of pesticide labels. In addition, OPP will need to coordinate with other agencies working toward GHS implementation in their programs, including the Department of Labor Occupational Safety and Health Administration, the Department of Transportation, and the Consumer Product Safety Commission. We also plan to work toward coordinated implementation under the NAFTA TWG.

It is difficult to predict time frames at this early stage of implementation planning. Ideally, rule-making could be initiated in 2004 and completed in 2005. After a proposal is published, a pilot project could be undertaken. Once regulations have been promulgated, OPP would expect to see label amendments incorporating the GHS changes.

It is likely that implementation activities at the State level will be needed after EPA approval is obtained. EPA intends to work with States to ensure a smooth follow-on process and reasonable time to obtain State approvals.

IV. OUTREACH ACTIVITIES AND PLANS, REQUEST FOR COMMENT

As described in Part I of this paper, U.S. and international negotiators made considerable efforts to involve stakeholders throughout the GHS development process. Representatives of regulated industry and groups who use or are otherwise exposed to chemicals participated in the negotiation and joined in the consensus approval of the GHS document. Despite these efforts, OPP recognizes that many concerned stakeholders are likely not to be aware of the GHS or its implications for pesticide labels, and that substantial outreach and education should be undertaken in connection with GHS implementation.

In recent months, we have participated in number of awareness-raising activities with OPP stakeholders, including presentations at meetings and workshops and briefings for outside groups and the Pesticide Program Dialogue Committee, OPP's principal, broadly-based advisory committee. We have consulted with pesticide educators who will be involved in updating manuals and training users in how to interpret revised labels and have encouraged stakeholder organizations to educate their members about the GHS. We will be continuing these activities and invite suggestions for how to expand and improve them to promote more effective stakeholder participation in implementation planning. We are also upgrading our website information on the GHS and will be developing educational materials for pesticide users in cooperation with interested stakeholders.

With this paper, OPP is opening a new phase of outreach, beyond GHS awareness-raising, to share our current thinking and solicit comment on the implementation issues under consideration. In particular, we are inviting comments on the following questions:

- What are your views on the options presented for GHS implementation mechanisms? Are there additional considerations you believe OPP should take into account?
- Do you have recommendations on additional regulations, in addition to 40 CFR 156, which you believe may warrant review and possible revision in connection with GHS implementation?

- Would you favor a voluntary pilot project to permit GHS label revisions before final rules are in place? If so, what criteria would you propose for participation in the pilot?
- What time frames would be reasonable for the various steps involved in implementation, consistent with international implementation goals?
- Do you have suggestions for work sharing with NAFTA TWG partners and/or states, or for other efficiencies that could be introduced to improve the process?
- What are the most effective steps that OPP can take in terms of outreach and education?