



The Soap and Detergent Association

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Public Information and Records
Integrity Branch (PIRIB) (7502C),
Office of Pesticide Programs (OPP),
Environmental Protection Agency,
1200 Pennsylvania Ave., NW.
Washington, DC 20460-0001

Attention: Docket ID Number OPP-2004-0205

The Soap and Detergent Association (SDA) appreciates the opportunity to review and comment on the proposals and options that represent the Environmental Protection Agency's (EPA) current thoughts for implementation of the Globally Harmonized System (GHS) for Chemical Hazard Classification and Labeling, as cited in the *Federal Register* (69 FR 52262) notice "Pesticides; Implementation of Globally Harmonized System; Notice of Availability" (69 FR 52262; August 25, 2004; Docket Number OPP-2004-0305). Specifically, SDA is providing comments on the document entitled, "The Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Implementation Planning Issues for the Office of Pesticide Programs" (White Paper, draft July 7, 2004).

SDA members produce and market antimicrobial pesticide products for home, institutional, commercial and industrial use that are regulated under existing EPA pesticide regulations and, therefore, subject to registration with EPA. Therefore, SDA has a strong interest in EPA's proposals.

SDA recognizes EPA's extensive efforts over the years in support of development of the United Nation's Globally Harmonized System of Classification and Labeling (GHS). The Soap and Detergent Association has also played an active role in the development of the GHS, including direct involvement in the intergovernmental meetings of the OECD, ILO, UN Subcommittee of Experts on the GHS and the UN Committee of Experts on the Transportation of Dangerous Goods and GHS, as well as its leadership of the Coordinating Committee on International Harmonization. Through these interactions SDA has made significant contributions to the development of a GHS that has the flexibility needed to achieve the objectives of the GHS and meet the needs of chemical end users in the U.S., including consumers. SDA's comments in response to the *Federal Register* notice are intended to support development of a practical implementation strategy for the Agency and the consumer products it regulates.

General comments on GHS principles and components that should be addressed by EPA in its final rule are provided first, followed by specific comments on the Agency's implementation proposal.

General Comments on GHS Principles and Components

The following are comments on the application of GHS principles, components and options to the regulation of EPA-registered pesticide products, with a focus on antimicrobial products.

SDA endorses EPA's proposal to limit adoption of the GHS to those Building Blocks that correspond to the existing scope of its regulations.

EPA should adopt the options and building blocks of the GHS that are relevant to its current regulatory framework, while preserving the key principles and provisions embodied in the GHS document adopted by the UN in July 2003.

The GHS document states: "the GHS may thus be seen as a collection of building blocks [but] the full range does not have to be adopted." This approach provides the flexibility to adopt elements of the GHS that meet the needs of the various chemical users, which in many cases are reflected in existing hazard communication regulations. In the White Paper, the Agency states "EPA ... does not intend to expand the scope of its requirements to include all elements that are part of the GHS." SDA supports this EPA position on application of the building block approach for adoption of the GHS into EPA regulations.

For example, indoor residential-use products are exempted from environmental labeling due to the intended use pattern and minimal exposure to the environment that occurs as a result of their use. EPA should not extend its environmental labeling requirements to indoor residential use products and, thus, should not adopt the GHS environmental endpoints for this category of products.

EPA should focus on requiring information that meets the needs of antimicrobial product users to enhance comprehensibility and promote proper handling and use.

The GHS includes "special arrangements to take into account the information needs of different target audiences." EPA should recognize this concept in its implementation of the GHS.

Cluttered, difficult to read consumer product labels, containing warnings that are outside the experience of users of a product category erode consumer protection by reducing the likelihood that labels would be read, understood and followed. Cluttered, crowded labels would be contrary to the findings of EPA's Consumer Labeling Initiative, where "clear, concise, easy-to-read" labels were found to be desirable.

GHS labeling in combination with existing EPA labeling requirements would be particularly burdensome for antimicrobial products, due to the small label and package

sizes. Therefore, the Agency should take this opportunity to consider all existing FIFRA labeling requirements for antimicrobial cleaning products and prioritize those requirements in the context of additional requirements that could be imposed by implementation of the GHS in EPA regulations. For example, storage and disposal statements and the federal misuse statement should be streamlined, or even eliminated, for certain types of pesticides. Section 3(h) of FIFRA provides the Agency with the ability to streamline and consider the risks as well as the benefits of antimicrobial products when regulating these products.

The White Paper notes that under the GHS, “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.” SDA agrees with EPA’s assessment and believes that the present level of flexibility that EPA allows for these other label elements under the current regulations meets the GHS requirements and should be maintained.

The Agency should base hazard labeling of consumer products that it regulates on consideration of risk, particularly for hazard labeling associated with chronic endpoints.

The GHS document states “competent authorities may authorize consumer labelling systems providing information based on the likelihood of harm (risk-based labelling).” SDA urges EPA to implement this option. EPA requirements for product evaluation and labeling for potential chronic effects (e.g., cancer, reproductive toxicity, target organ toxicity) have been, and should continue to be, risk-based. This approach improves the likelihood that consumers would identify important hazard and precautionary information on a label and take necessary actions to properly handle and use the products.

The Agency should implement the GHS in a manner that allows maximum use of existing data without mandating test methods.

As noted above, one of the central objectives of the GHS is to “reduce the need for testing and evaluation of chemicals” and mixtures. Further, the GHS document states, “[T]he GHS is based on currently available data.” SDA encourages EPA to implement the GHS in a manner that maximizes the use of existing information for classification and labeling purposes. Such an approach is consistent with EPA’s commitment to use non-animal approaches in assuring public safety (e.g., FIFRA’s current project focusing on identification and potential use of non-animal eye and skin irritation approaches for registration of antimicrobial products). Further, implementation of the GHS provides the Agency with the opportunity to consider broadening the scope of acceptable sources of information for registration, classification and labeling purposes. When scientifically robust, non-animal test approaches (e.g., human experience, bridging data, *in vitro* tests, SAR/QSAR, *in silico* approaches) are available, information and data from these approaches should be used by EPA for classification and labeling. Use of these

approaches would be consistent with the GHS and should be incorporated into the Agency's regulations implementing the GHS.

Separately, in implementing the GHS, EPA should not require the submission of additional test data simply due to the shift in classification criteria for some endpoints or the adoption of new endpoints (if any). For further details on this issue and examples, please see the Appendix to these comments.

The Agency should incorporate changes in their regulations that accommodate the GHS principle that human experience takes precedence over other information.

The GHS document states "Generally, data of good quality and reliability in humans will have precedence over other data." This is a critical concept, especially in determining appropriate labeling for consumer products. We urge EPA to incorporate this concept in its GHS implementation approach.

The Agency should use a weight-of-evidence approach in classification decisions.

The GHS document states, "For some hazard classes, classification results directly when the data satisfy the criteria. For others, classification of a substance or a mixture is made on the basis of the total weight of evidence. This means that all available information bearing on the determination of toxicity is considered together, including the results of valid in vitro tests, relevant animal data, and human experience ..." SDA supports the Agency's plans to adhere to this principle, as stated in the White Paper: "Consistent with EPA/OPP policy, a weight of evidence approach is used in making classification determinations based on the best available data."

Protection of Confidential Business Information should continue to be a critical responsibility of the Agency.

The GHS document states, "The competent authority should protect the confidentiality of the information in accordance with applicable law and practice." The White Paper recognizes this critical responsibility by stating: "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, ... and therefore these OPP policies are also consistent with the GHS." SDA is pleased that the Agency recognizes its important responsibility to protect Confidential Business Information submitted by registrants.

The following are comments and recommendations related to the questions presented in the Agency's White Paper.

Implementation Options and Other Considerations

Of the two options EPA outlines in the White Paper, SDA recommends that the Agency follow Option 1 - "a separate review and approval process." Further, SDA encourages

the Agency to follow a process that is “phased in by chemical or class of chemicals,” as stated in the White Paper. A phased-in approach is practical from a resource standpoint and could help minimize or avoid potential anti-competitive aspects of the implementation transition period.

Specifically, SDA recommends that the Agency adopt an implementation process that results in competing products in the same category being labeled according to the same set of requirements, so that there would be no competitive advantage or disadvantage resulting only from the timing of label changes. In general, the GHS would lead to chemicals and products being classified more frequently or being classified into higher hazard categories than is case under current EPA regulations. Thus, similar product could have significantly different labeling under the GHS than those labeled according to the existing regulations. Users of these products would see different labels if implementation was not coordinated by product category, which could jeopardize comprehension and greatly complicate education and training. Implementation by product category would allow for practical education of product users and reduce confusion, making label warnings more actionable.

Similarly, new products entering the market should not be held to the new GHS labeling standards until changes in labeling requirements are imposed on products within that category that are already on the market. Otherwise, the sale of new products could be negatively impacted and similar problems with users could be encountered.

Recognizing that there are three major divisions within EPA that manage registrations, it could be feasible for each division to develop its own implementation approach and associated schedule to manage label changes across the product categories it regulates. The divisions could set a schedule for each product category that is prioritized by factors related to their risk. SDA would encourage the Agency to engage stakeholders in any prioritization process.

On a related matter, the Agency proposes to use the label amendment process as the review mechanism for GHS-related changes. SDA recommends that EPA implement GHS labeling changes through the notification process whenever the label changes are only related to GHS compliance. Notifications are less burdensome to both the Agency and industry. They also require a shorter review time. If EPA decides to pursue GHS implementation only by label amendment, then GHS-only label changes should be classified as fast track amendments and not subject to PRIA fees.

In addition, in the context of the sizeable number of labels that would need to be reviewed, SDA urges the Agency to consider implementation of an electronic review process. Such a process could expedite implementation of the GHS labels in the marketplace and be useful for saving resources and costs in the registration process going forward.

After approving GHS-related label changes, SDA recommends that EPA treat existing label stock as stated in the policy “Clarification of Pesticide Registration Notices 2001-1

and 2001-6.” Under 40 CFR §152.130(c), the registrant may distribute or sell under the previously approved labeling for a period of 18 months after approval of the revision. This is an important provision for mitigating the economic impacts of GHS implementation. EPA should not require any re-labeling or stickering of label stock or products already in the marketplace at the time of implementation or require the re-call of products in the marketplace that meet existing labeling requirements.

Voluntary Pilot Project

SDA supports the concept of an EPA pilot project before final rule changes implementing the GHS are in place. Further, SDA encourages EPA to consider conducting the pilot project(s) before formally proposing amended regulations. A pilot study could provide information on the feasibility of GHS labeling changes and realistic timelines for GHS implementation by the Agency. Such an exercise also could provide important information to both EPA and to registrants about the resource and economic impacts of any regulatory changes under consideration.

An open dialogue with stakeholders would be important during the design and conduct of a pilot project and could provide important direction to EPA in drafting proposed changes to the regulation. The scope of the voluntary project(s) and criteria for participation should be developed with stakeholder input. Importantly, participation in such a pilot project should be voluntary, as proposed by the Agency. To encourage registrants to participate in a pilot project, the Agency could consider a mock label exercise or, in cooperation with the States, allow the volunteers an extended period of time to implement new labels. Otherwise, volunteer registrants potentially could be held to new labeling standards years ahead of their competition, which would be inappropriate.

The Agency should also consider having each of the major divisions handling registrations manage a pilot project. This could expand the knowledge gained on the effectiveness and difficulty of complying with proposed GHS amendments by the various sectors of chemical users. This could also avoid attempts to extrapolate information from a pilot on one category of pesticide products to another (e.g., extrapolation from agricultural herbicides to household antimicrobial pesticides). It is critical that the needs of the various end users of pesticides have information that is comprehensible and actionable. Pilot projects focused on each type of user are needed to gain this critical information.

An economic impact assessment should be undertaken prior to implementation of any new regulatory requirements. It is not apparent from the White Paper that the economic impact of GHS implementation would be investigated during the pilot study. The pilot study(ies) should be designed to provide data that support an economic impact analysis.

Timeframe for Implementation

The White Paper recognizes that achieving the International Forum on Chemical Safety goal of full GHS implementation by 2008 “is a very ambitious goal.” Implementation of

the GHS would be quite complex, involving many stakeholders that are just now becoming aware of its existence. Therefore, implementation by 2008 would likely be very challenging, requiring significant resources from both the Agency and industry. Separately, the White Paper suggests that “[I]deally, rulemaking could be initiated in 2004 and completed in 2005.” However, the latter, ‘ideal’ timing is not realistic. Because of the broad scope of the task and the magnitude of its potential impact on all registrants, EPA should exercise great care in establishing its schedule.

The implementation process and transition to any new system for EPA-regulated products would benefit greatly by the Agency, industry and other stakeholders working closely together on an implementation strategy and its implementation. Therefore, SDA recommends that EPA engage in a dialogue with stakeholders leading to a conceptual framework for GHS implementation. Such a dialogue could take place during 2005. As a result of the dialogue, a pilot project could be undertaken prior to the formal proposal of a modified regulation. Information obtained from the pilot project could be used to establish a rational timetable, as well as better inform the drafters of the proposed regulation. Although such a plan may extend the time period between now and the formal proposal of a regulation, it could shorten the period between the proposed regulation and its final promulgation by improving the quality of that proposal.

Also, the timeframe should be amenable to the need to coordinate with NAFTA partners, the states and other Federal agencies, as described in the next section of comments.

Working with NAFTA Partners, States and other Agencies

EPA should work within the NAFTA Non-agricultural Working Group (NAWG) as a means for streamlining GHS implementation among NAFTA partners. In working with NAFTA NAWG, EPA should consider not only aligning the mandatory labeling requirements with other NAFTA partners, but also aspects of the label where a single language may be used, e.g., net contents, ingredient statements. Items such as precautionary language and first aid statements may need to remain in French and English, but EPA should recognize that many US-marketed pesticides include Spanish as the preferred second language.

EPA should engage their counterparts in state agencies to ensure a smooth transition of the rules so that states can make corresponding changes in their own rules for pesticide products.

As an extension of this concept, EPA should utilize its investigation of how to implement the GHS as an opportunity to align as closely as possible the labeling requirements of indoor residential-use antimicrobial cleaning products with CPSC requirements for other consumer cleaning products. Residential-use antimicrobial products are frequently used for the same tasks as non-FIFRA cleaning products. Therefore, where possible, EPA should coordinate their GHS implementation efforts with CPSC’s implementation efforts so that consumers can find relevant, consistent product information on labels.

Further, many antimicrobial cleaning products are intended for use in the workplace – in institutions, commercial businesses and industries. The MSDSs for these products are regulated by OSHA, which will also be implementing the GHS within its regulations. SDA urges EPA to similarly coordinate with OSHA in order to avoid worker confusion that could arise out of differences between labels regulated by EPA and MSDSs regulated by OSHA.

Aligning the Federal and state regulatory agencies prior to the issuance of the GHS regulatory amendments is important for making the implementation process more efficient. SDA hopes that these efforts would result in minimizing duplicative label reviews across multiple agencies and reduce confusion among chemical users.

Outreach and Education

In terms of outreach and education, SDA recommends that the Agency consider conducting stakeholder meetings and workshops for pesticide registrants in order to enhance awareness and understanding of the GHS and how its implementation could impact EPA registrations. These meetings and workshops should be held in regions throughout the U.S. to facilitate participation. As changes in labeling are brought into the market, SDA recommends that EPA collaborate with industry organizations to reach out to and educate their downstream chemical users.

Related to this, SDA recommends that EPA establish a stakeholder working group that would have meetings and/or conference calls on a regular basis to develop the strategy and approach for GHS implementation. As noted above, such a group could help in the design and implementation of a pilot project.

The Soap and Detergent Association appreciates the opportunity to comment on the Agency's concepts for GHS implementation. SDA would welcome the opportunity to work with the Agency as it develops its pilot programs and further defines proposed amendments to its regulations. We hope our comments will be useful in your deliberations. If you have any questions about these comments, please contact us.

Sincerely,

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APPENDIX

Detailed Comments on Test-related Concerns

In implementing the GHS, EPA will change the classification criteria, classification categories and labeling requirements (e.g. symbols, signal words) for some endpoints/classes and could adopt criteria for other endpoints/classes not previously addressed in OPPT regulations. Under these circumstances, registrants could find themselves in a position of not possessing the specific data required to avoid inappropriate classification and labeling of the substance or mixture. Specifically many of the tests conducted to address acute endpoints/classes (for animal welfare reasons) are limit tests conducted at specified high doses. These doses may not exceed the full range of GHS values for classification and, although no deaths are observed in the studies, it could be anticipated that the substance or mixture would be classified because the limit dose does not exceed the GHS cut-off value for "not classified". In such an event the manufacturer of the substance or mixture would need to consider testing at higher levels. This additional testing is not justified scientifically. Several examples are noted below. The Agency should not implement the GHS in a manner that imposes any new test requirements on a product (for the purposes of GHS compliance) that were not previously required.

Acute oral toxicity

EPA Health Effects Test Guidelines OPPTS 870.1100 Acute Oral Toxicity allows for limit testing at 2000 mg/kg. When only limit test data at 2000 mg/kg are available on the substance or mixture (or similar substances or similar mixtures) and no deaths are observed in the study, EPA should accept the assessment that the substance or the mixture should not be classified and, therefore, GHS labeling should not be required. This is consistent with the principle of being test method neutral and no specific test data are required for GHS classification. Testing beyond 2000 mg/kg would result in unnecessary testing in animals when the scientific community considers materials having an LD₅₀ of greater than 2000 mg/kg having minimal toxicity.

Acute inhalation toxicity

EPA Health Effects Test Guidelines OPPTS 870.1300 Acute Inhalation Toxicity allows for a limit testing at 2 mg/L. Consequently, many of the tests conducted for this endpoint are limit tests. When only limit test data at 2 mg/L are available on a substance or mixture (or similar substances or similar mixtures) and no deaths are observed in the study, EPA should accept the assessment that the substance or the mixture should not be classified and, therefore, GHS labeling should not be required. This is consistent with the GHS principle that no specific test data required for classification. Additionally, if the maximal attainable concentration is less than 2 mg/L due to the physical or chemical properties of the substance or the mixture and no deaths are observed, then the substance or the mixture should not be classified as toxic and GHS labeling should not be required.

Acute dermal toxicity

EPA Health Effects Test Guidelines OPPTS 870.1200 Acute Dermal Toxicity allows for limit testing at 2000 mg/kg. When only limit test data at 2000 mg/kg are available on the substance or mixture (or similar substances or similar mixtures) and no deaths are observed in the study, EPA should accept the assessment that the substance or the mixture should not be classified and, therefore, GHS labeling should not be required. This is consistent with the principle that no specific testing is required and that classification should be based on existing information. Toxicology reference books cite 2000 mg/kg as the appropriate limit dose for testing acute dermal toxicity. Further dosing of the substance or mixture above 2000 mg/kg is not considered necessary because additional test material will be applied on top of the test material already present. This layering may form a physical barrier to prevent further absorption of the test material from the application site (*Principles and Methods of Toxicology*, Third Edition (1994). A. Wallace Hayes, editor. Raven Press, pages 597-598).