

October 19, 2004

Public Information and Records Integrity Branch (PIRIB)
Information Resources and Services Division (7502C),
Office of Pesticide Programs
Environmental Protection Agency
Rm. 119, Crystal Mall #2
1801 South Bell St
Arlington, VA 22202

**Subject: Comments: Draft GHS Implementation Planning Issues
 69 FR 52262 Docket Control No. OPP-2004-0205**

Dear Sir or Madam:

Monsanto is pleased to offer comments on “The Globally Harmonized System of Classification and Labeling of Chemicals: Implementation Planning Issues for the Office of Pesticide Programs”.

Monsanto supports the EPA’s efforts to harmonize the classification and labeling of pesticide products in worldwide markets. This effort has the potential to benefit both the producers and consumers of these products. Our comments are intended to be constructive and seek to aid in a smooth implementation of the system as well as request guidance regarding some test-specific implementation issues. Our comments include a discussion of the importance of the precautionary statements to U.S. consumers followed by comments on the general GHS implementation and finally a request for guidance on test-specific GHS implementation issues.

Monsanto’s chief areas of concern are the following:

1. EPA should avoid reducing precautionary labeling clarity and utility through integration of GHS information into already cluttered labels. Both a reconsideration / reprioritization of necessary front panel information and user education are important elements.

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2. EPA should finalize necessary changes in the regulations in the 40 CFR and define any GHS-specific procedures for amending registrations before requiring registrants to amend product labels.
3. GHS label amendments, including any relevant data reviews, should be exempt from PRIA fees.
4. Monsanto prefers EPA's Option 1 in order to maintain a level playing field in the market and avoid implementation delays that are inherent in Option 2.
5. The GHS acute inhalation implementation into the existing US framework appears likely to lead to over labeling of hazard and prompt registrants to undertake additional testing.

We have provided more detailed information on these and other points in the attachment.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider (202-383-2866) or by direct phone (314-694-1582), fax (314-694-4028), or electronic mail at stephen.j.wratten@monsanto.com.

Sincerely,

Stephen J. Wratten
Manager, Registrations

Attachment – Monsanto’s Detailed Comments on the GHS Implementation Plan.

1. Label Clarity.

Over the years, pesticide labels have become a familiar icon to pesticide applicators in the U.S. throughout all sectors of pesticide use. The signal word and precautionary statements on the front panel of the pesticide label allow users to quickly recognize the potential hazard of a product and the appropriate level of care that must be taken during handling, transportation, and use. Detailed information on the potential hazards of a pesticide product and proper use instructions that minimize exposure and environmental effects are contained in the complete Directions for Use portion of the product label. A pesticide applicator is required to read these directions before applying the product. However, the pesticide handler needs the brief, relevant information on the product’s potential hazards before he reads the entire booklet, such as at the time of purchase, transport from the retail outlet and storage before use. This is the relevance of the prominently displayed signal word and precautionary statements on the front of every pesticide package sold in the U.S.

When given a choice, most pesticide users would prefer to use the least toxic alternative that will control the target pest. This is especially true of homeowners. Pesticide consumers recognize the advantage of using a product that is labeled with the word CAUTION over one that is labeled with the word DANGER, or one that contains skull-and-cross bones on the label. The information contained on the front panel of the pesticide label gives the consumer the information they need to make an informed decision at the time of purchase, as well as to protect them before they have the opportunity to read the complete directions for use.

The EPA should be cautious and not sacrifice the significance and importance of this section of the pesticide label to the U.S. consumer for the sake of international harmonization alone. We are concerned that the GHS has already started us down that path, as it appears that many of the pesticide products sold in the U.S. today would carry essentially the same precautionary text and pictograms under the new GHS. We fear that this situation has the potential to lead to a dilution of the intended message and consumer indifference to labeled warnings. It is all too obvious in the world today that, although international trade is of growing importance and scope, significant cultural differences between peoples of different countries still exist. A system that works very well in one country, or amongst one culture, may not necessarily work as well in all.

2. Front Panel Crowding.

We caution the EPA to avoid putting too much precautionary information on the front panel of the label. This only serves to dilute the message. This is a critical point since one of the major purposes of the front panel of the label is to present relevant information

of immediate importance to the pesticide applicator prior to reading the directions for use. US labeling requirements specify the lengthiest textual information of any country, and many detailed elements are required to be included on the container label, often the front panel. In contrast, newer pesticides are evolving toward higher unit activity, allowing reduced application rates and smaller container sizes. As a result, labels have no remaining space for the addition of the pictograms. Monsanto requests that in conjunction with the revised regulation on the precautionary text, EPA also reconsider what information absolutely must appear on container labels, and develop a prioritized list of the label elements that may be relocated to supplemental labeling Direction For Use pamphlets. Also, the size requirements for the pictograms need to be specified, possibly as a function of label size?

3. Establish Regulations and Procedures First.

There are several issues regarding the GHS implementation other than the strategy to provide an avenue for companies to begin making submissions under the GHS. EPA has stated that the 40 CFR Regulations need to be updated to reflect the new GHS parameters and text. Monsanto believes that no registrants should be required to submit GHS label amendments for approval until the final rules have been established. This prevents compulsory label changing under interim guidance, which may differ from finalized requirements, leading to the need to amend again to achieve compliance. “GHS-like” amendments undertaken voluntarily by registrants, possibly as a pilot program, are acceptable and approvable, but may not be final. The idea of a voluntary pilot program is attractive, however, we cannot imagine which registrant would volunteer to worsen its products signal word before their competitors. What advantage is there to participate?

4. Additional Testing.

The proposal states that implementation is guideline and testing neutral – i.e., no changes in testing methods or additional testing study data will be required. Monsanto believes this is not completely accurate, because:

- GHS has different break points between categories than the current EPA system. Present data on file include certain specific testing levels, often limit test levels, which were chosen based on EPA’s categorization scheme. Recategorization under GHS will often place the product into a less favorable category than it might warrant had different dose levels been chosen. Many companies will likely repeat tests taking into account the new framework in order to obtain optimum categorization. Both animal usage and review time will be impacted.
- The “harmonized” element in GHS implies that a product sold in two jurisdictions will have the same precautionary words and pictograms. However, different underlying data requirements today may still lead to different labeling. For instance, many formulations in the EU do not require specific inhalation testing

data, but do require ecotoxicity testing in aquatic species. In contrast, the US always requires inhalation testing but does not routinely require aquatic ecotoxicity testing on the formulation, reverting to active ingredient data. Therefore, it seems likely that the labeling aspects derived from the different datasets will not be harmonized. Monsanto anticipates that there will ultimately need to be harmonization on the underlying data requirements, which will likely increase overall testing needs in the long term.

- The GHS categories for toxicity are more numerous (6 vs. 4) essentially increasing the resolution of the system by 50%. It will thus be more critical to numerically define the LD₅₀ or LC₅₀ more often, as compared to the use of limit test data. In practice, this will result in more dosed groups, increased animal use and increased costs.

5. Coordinating with Other Regulations.

Other labeling and handling considerations are tied to certain toxicity triggers. It is helpful when such triggers match category breakpoints. For instance, the Child Resistance Packaging criteria (40CFR 157.22) are largely triggered at toxicity levels that match with category breakpoints. That is, the inhalation trigger point (2 mg/L) matched the Category III / IV boundary. Such a paradigm is convenient and conservative of animals when limit tests are used. In the GHS scheme, the corresponding inhalation category boundaries are at 1 or 5 mg/L. Monsanto requests that EPA search the pesticide CFR Parts 150 to 189 for occurrences of toxicity triggers and revise them to appropriately match the GHS category transitions.

6. No PRIA Fees.

Amendments to implement GHS labeling, including the review of any additional testing data that may become needed, should not be subject to PRIA fees. These are clearly label changes that EPA is requiring rather than registrant-initiated changes.

7. Aquatic Toxicity.

Today, the US EPA aquatic toxicity labeling requirements focus on fish and invertebrates, but are not generally triggered by effects on algae or aquatic plants. However, the GHS guidance incorporates fish, invertebrates, and aquatic plant criteria. Herbicides are likely to have potent effects on the algae and plants, and receive the 'dead fish / dead tree symbol'. This is misleading because (a) these plants may be target species for control and (b) the symbol implies fish toxicity. Monsanto requests that herbicides be exempt from pictogram labeling when due solely to aquatic plant toxicity.

8. Mutual Acceptance in NAFTA.

For NAFTA, mutual acceptance of GHS labeling decision should apply. Since the H represents 'harmonized', it should not matter whether EPA or PMRA reviewed a given formulation first, the same precautionary labeling should result. Therefore, either country should accept the other's labeling decision without duplicative review.

9. Only Applicable to Labeling of Newly Manufactured Product Containers.

There should be no stickering or modification required for product containers already manufactured and released for shipment. Labeling under the present scheme has been sufficiently protective to users for decades, and there is no need to spend resources to change it on existing containers.

10. Prefer Option 1.

Regarding the Options 1 and 2, EPA suggests for implementation, Monsanto favors Option 1, because:

- All like products can be reviewed and changed synchronously. Under Option 2, registrants will wait until the last possible minute, preferring to postpone label changes in favor of maintaining marketing advantages of better signal word as long as possible. Those that may be forced to amend earlier for other reasons will be placed at marketing disadvantage, creating an unlevel playing field.
- Because of the need to defer PRIA fees on EPA-mandated label changes, e.g., this program, having a separate process will facilitate this fee segmentation.
- Option 2 will make it very difficult for inspectors to know when GHS labels should be in the marketplace, since each and every formulation will be on a different schedule. Option 1 would allow that all products with ai's in a given group / class must implement by a common date.

11. Study Specific Technical Issues.

There are several issues related to implementation that are specific to individual tests and categories. EPA needs to develop specific new guidance for both registrants and reviewers to ensure uniform practices. These issues are presented below:

- Section V. of the OPP/GHS Classification Criteria and Labeling Comparison document regarding Serious Eye Damage / Irritation is in need of clarification. The GHS criteria in the comparison do not use the mean irritation scores to aid in classification as described in the GHS document. In this way the system described in the OPP comparison ignores the degree of irritation in the GHS

classification. Additionally, there is no opportunity for a pesticide to be “not classified” as described in the GHS document. Also, is “fully reversible” defined as the absence of all irritation (scores of 0 for everything) or the absence of all positive irritation scores (scores of 1 for conjunctival redness and chemosis are not considered positive according to the guideline OPPTS 870.2400)?

- Chapters 3.2 and 3.3 of the GHS document address eye and skin irritation. The classification guidance refers only to irritation studies conducted using three animals. EPA needs to provide interpretive guidance on the translation for older irritation studies that used six or more animals. The EEC labeling criteria, which is very similar to the GHS, used the overall mean value of 24, 48, and 72 hour scores for all of the animals as the basis for classification. Please provide clarification.
- The biggest test-specific issue for pesticide producers lies in the GHS classification scheme of acute inhalation hazard, especially for dusts and mists. It is extremely difficult to consistently generate a respirable aerosol at atmospheric concentrations of 5 mg/L. This issue was settled long ago in the U.S. by reducing the limit concentration for 4-hour acute inhalation testing to 2 mg/L. However, consider a product that has been tested at the prevailing U.S. limit concentration with no mortality or overt toxicity and currently has a CAUTION signal word with no precaution language. Under GHS, it will carry the following language on its label: WARNING! Harmful if inhaled. The Agency has long advocated against unnecessary hazard labeling (“over labeling”), but this situation appears to promote it. Along the same lines, a product which used bracketing to establish that the LC₅₀ was between 0.5 mg/L and 2.0 mg/L (EPA Category III) would go from a label of “CAUTION Harmful if inhaled” to “DANGER Toxic if inhaled” with a skull and crossbones. To correct this over labeling, the company will be forced to conduct additional inhalation exposures to establish that the inhalation LC₅₀ is greater than 1.0 mg/L. Additionally, a material would have to be tested at or above the 5 mg/L limit with no mortality or toxicity in order to achieve “non-classification”. It is very difficult to produce a high aerosol concentration with most concentrated liquid pesticide formulations using artificial means. Since these products are not sprayed without prior dilution, there is a miniscule chance that an aerosol of the concentrated liquid will be produced, and it is over labeling to use a skull and crossbones on the label to protect against this theoretical “hazard”. Monsanto requests that EPA develop guidance on the application of the GHS classification criteria for inhalation toxicity and create a system by which registrants can apply for the inhalation toxicity classification of products based on attainable data and the physical characteristics of the product. In this way the real inhalation hazard could be evaluated and the product labeled based on the hazard.
- OPP should determine whether or not it intends to apply bridging principles as defined in section 3.1.3.5 of the UN/GHS document for acute toxicity classification. Under the current paradigm used by OPP in determining classification for acute toxicity, if a pesticide product of a lesser concentration

relies on acute toxicity data of a similar product of higher concentration, OPP would assign the toxicity endpoints of the more concentrated product to the less concentrated product without consideration of the dilution factor. The GHS procedure describes mathematically adjusting the LD₅₀ / LC₅₀ by the dilution factor prior to arriving at a category determination. In section 3.1.3.5.2 of the UN/ GHS document, an example is given where a linear relationship is assumed for the toxicity of a product that is diluted with water or another totally non-toxic material. Will OPP adopt this GHS approach, which is both scientifically sensible and conservative of test animals, testing costs, and review time?

In summary, Monsanto understands that OPP has decided to adopt the Globally Harmonized System of Classification and Labeling of Chemicals, put forth by the UN Economic and Social Council. We acknowledge the advantages such a harmonized system can provide in a global economy. However, we urge the Office of Pesticide Programs to not lose sight of the importance of the pesticide label, and the information that it contains, to pesticide users in the U.S. We urge you to continue to resist the apparent trend of the GHS to add additional classification information to the label, as you have already done, which would only serve to dilute the overall importance of the precautionary statements. Monsanto supports the creation of a separate review and approval process in which label changes would be submitted as amendments to current labels. We feel that this approach would have the least impact on registrants and provide a level playing field for competitive products in the marketplace.