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To: quality@epamail.epa.gov
cc:

Subject:

**REQUEST FOR CORRECTION UNDER the
INFORMATION QUALITY GUIDELINES of the U.S.
ENVIRONMENTAL PROTECTION AGENCY**

Julia Govis, January 10, 2005

I am filing this request for corrections and have followed the guidelines put forth by the EPA on their web-site located at <http://www.epa.gov/quality/informationguidleines/iqg-faqs.html>

Although the period for public comment on this subject has ended, this information has just been brought to my attention. It is stated in your EPA Information Quality Guidelines, that because I could not have submitted this information during that period of public comment, you will still consider a separate response to my request and I appreciate that consideration.

As per your submission request guidelines, I have listed the appropriate information below.

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Contact name, organization, phone number, physical address, and any other contact information (e.g., fax number or e-mail address if available).

[requestor's phone number and address removed by EPA for Web posting]

A description of the information you believe does not comply with the Office of Management of the Budget or EPA Information Quality Guidelines, including citations to the information and to the guidelines, if applicable.

I do not believe the process whereby, the chemical atrazine was re-resitered in this country, was conducted correctly under the EPA Information Quality Guidelines or the OMB regulations.

Furthermore, I believe the following guidelines explain why I believe that I have a right to file this request:

The OMB Guidelines state:

In section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554;H.R. 5658), Congress directed OMB to issue government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal Agencies..." The OMB guidelines direct agencies subject to the Paperwork Reduction Act (44 U.S.C. 3502(1)) to:

Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the OMB or agency guidelines

I believe the following specific guidelines have been violated

4.1 Quality System

To implement the Quality System, EPA organizations (1) assign a quality assurance manager, or person assigned to an equivalent position, who has sufficient technical and management expertise and authority to conduct independent oversight of the implementation of the organizations quality system:.....(4) use a systematic planning process to develop acceptance or performance criteria prior to the initiation of all projects that involve environmental information collection and/or use(6) conduct an assessment of existing data, when used to support Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and adequate quality for their intended use.

VIOLATION: Under Section Number 4.1

An EPA official charged with the duty of assuring that the EPA had the necessary data with which to examine a chemical's adverse effect had information that the chemical had adverse effects and chose not to pursue the issue.

4.2 Peer Review Policy

In addition to the Quality System, EPA's Peer Review Policy provides that major scientifically and technically based work products (including scientific, engineering, economic, or statistical documents) relating to Agency decisions should be peer-reviewed. Agency managers within Headquarters, Regionslaboratories, and field offices determine and are accountable for the decision whether to employ peer review in particular instances and, if so, its character, scope, and timing. These decisions are made consistent with program goals and priorities, resource constraints and statutory or court ordered deadlines. For those work products that are intended to support the most important decisions or that have special importance in their own right, external peer review is the procedure of choice.

VIOLATION: Under Section 4.2

An external peer review should have been conducted.

4.3 Integrated Error Correction Process

The Agency's Integrated Error Correction Process for Environmental Data (IECP) is a process by which members of the public can notify EPA of a potential data error in information EPA distributes or disseminates.

NOTE:

I believe this further validates my ability to notify your office of a data error.

5.1 What is "Quality" According to the Guidelines?

"Objectivity" focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and, as a matter of substance, is accurate, reliable, and unbiased. "Integrity" refers to security, such as the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.

VIOLATION: Under Section 5.1

The majority of the studies presented for this review came directly from the manufacturer. For all practical purposes, that would appear as "biased."

5.2 What is the Purpose of these Guidelines?

Information about the environment and human health underlies all environmental management decisions. These Guidelines describe EPA's policy and procedures for reviewing and substantiating the quality of information before EPA disseminates it. They describe our administrative mechanisms for enabling affected persons to seek and obtain, where appropriate, corrections of information disseminated by EPA that they believe does not comply with EPA or OMB guidelines

VIOLATION: Under Section 5.2

The EPA has very clear policy and procedures for reviewing and substantiating the quality of information before the EPA disseminates it. They obviously were not followed when reviewing the data submitted. The studies submitted were seriously flawed and did not meet EPA Good Laboratory Standards.

5.3 When Do these Guidelines Apply?

EPA initiates a distribution of information if EPA prepares the information and distributes it to support or represent EPA's viewpoint, or to formulate or support a regulation, guidance, or other Agency decision or position.

EPA initiates a distribution of information if EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it; if EPA indicates in its distribution that the information supports or represents EPA's viewpoint; or if EPA in its distribution proposes to use or uses the information to formulate or support a regulation, guidance, policy, or other Agency decision or position.

Agency-sponsored distribution includes instances where EPA reviews and comments on information distributed by an outside party in a manner that indicates EPA is endorsing it, directs the outside party to disseminate it on EPA's behalf, or otherwise adopts or endorses it.

VIOLATION: Under 5.3

This faulty information was used to support a regulation.

5.6 How does EPA Ensure the Objectivity, Utility, and Integrity of information that is not covered by these Guidelines?

Other information distributed by EPA that is not covered by these Guidelines is still subject to all applicable EPA policies, quality review processes, and correction procedure.

VIOLATION: Under Section 5.5

The EPA adopted this faulty information to allow the chemical re-regulation as well as listed it as not carcinogenic or as an endocrine disrupter on its web-site.

6.1 How does EPA Ensure and Maximize the Quality of Disseminated Information?

Beyond our internal quality management system, EPA also ensures the quality of information we disseminate by seeking input from experts and the general public. EPA consults with groups such as the Science Advisory Board and the Science Advisory Panel, in addition to seeking public input through public comment periods and by hosting public meeting.

For the purposes of the Guidelines, EPA recognizes that if data and analytic results are subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption of objectivity is rebuttable, The Agency uses a graded approach and uses tools to establish the appropriate quality, objectivity, utility, and integrity of information products based on the intended use of the information and the resources available. As part of this graded approach, EPA recognizes that some of the information it disseminates includes scientific, financial, or statistical information, and that this category should meet a higher standard of quality.

VIOLATION: Under Section 6.1

The Scientific Advisory Board and Panel had a direct conflict of interest, being financially involved with the manufacturer involved. This is in direct conflict with the ideas put forth in this particular section, as it clearly states this situation should meet a higher standard of quality (for review)

6.2 How Does EPA Define Influential Information for these Guidelines?

For the purpose of the EPA's Information Quality Guidelines, EPA will generally consider the following classes of information to be influential, and, to the extent that they contain scientific, financial, or statistical information that information should adhere to a rigorous standard of quality.

This category may also include precedent-setting or controversial scientific or economic issues.

Described in the Scientific Policy Council Peer Review Handbook, the EPA Peer Review Policy regards major scientific and technical work products as those that have a major impact, involve precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review. These major work products are typically subjected to external review.

VIOLATION: Under Section 6.2

This work should have been subjected to external peer review, aside from any individuals with biased considerations

6.3 How does EPA Ensure and Maximize the Quality of "Influential" Information?

EPA recognizes that influential scientific, financial, or statistical information should be subject to a higher degree of quality (for example, transparency about data methods) than information that may not have a clear and substantial impact on important public policies or private sector decisions. A higher degree of transparency about data and methods will facilitate the reproducibility of such information by qualified third parties, to an acceptable degree of imprecision. For disseminated influential original and supporting data, EPA intends to ensure reproducibility according to commonly accepted scientific, financial, or statistical standards. IT is important that analytic results for influential information have a higher degree of transparency regarding (1) the source of the data used, (2) the various assumptions employed, (3) the analytic methods applied, and (4) the statistical procedures employed. IT is also important that the degree of rigor with which each of these factors is presented and dis

VIOLATION: Under Section 6.3

Not only does this section call for a higher degree of quality, but for transparency about data and methods. After the fact (of reregistration) the studies were made public. It would be hard to find anyone to objectively review this data and not conclude that was seriously misrepresented

6.4 How Does EPA Ensure and Maximize the Quality of "Influential" Scientific Risk Assessment Information?

EPA conducts and disseminates a variety of risk assessments, When evaluating environmental problems or establishing standards, EPA must comply with statutory requirements and mandates set by Congress based on media (air, water, and hazardous waste) or other environmental interest (pesticides and chemicals). Consistent with EPA's current practices, application of these

principles involves "weight of evidence" approach that considers all relevant information and its quality, consistent with the level of effort and complexity of detail appropriate to a particular risk assessment. In our dissemination of influential scientific information regarding human health, safety or environmental risk assessments, EPA will ensure, to the extent practicable and consistent with Agency statutes and existing legislative regulations, the objectivity of such information disseminated by the Agency by applying the following adaptation of the quality principles found in the Safe Drinking Water Act (SDWA) Amendments of 1996:

A The substance of the information is accurate, reliable and unbiased. This involves the use of;

the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and

2 data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data).

B The presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable. In a document made available to the public, EPA specifies:

1 each population addressed by any estimate of applicable human health risk or each risk assessment endpoint, including populations if applicable, addressed by any estimate of applicable ecological risk,

the expected risk or central estimate of human health risk for the specific assessment

VIOLATION: Under Section 6.4

When the studies are analyzed correctly, the "weight –of-evidence" very clearly holds the harmful nature of the chemical.

The substance of the information was NOT accurate, reliable or unbiased, as set forth in this section.

6.5 Does EPA Ensure and Maximize the Quality of Information from External

Sources?

For information that is either voluntarily submitted to EPA in hopes of influencing a decision or that EPA obtains for use in developing a policy, regulatory or other decision, EPA will continue to work with States and other governments, the scientific and technical community, and other interested information providers to develop and publish factors that EPA would use to assess the quality of this type of information.

VIOLATION: Under Section 6.5

I know that the EPA will reassess their stance on the reregulation of atrazine based on this new information I have brought to them today, because under this section, it clearly spells out the fact that; For information that is either voluntarily submitted to EPA in hopes of influencing a decision or that EPA obtains for use in developing a policy, regulatory, or other decisions, EPA will continue to work with.... and other interested information providers to develop and publish factors that EPA would use to assess the quality of this type of information.

Since it has now been brought to the attention of the EPA, that in fact the quality of the information used to determine the reregulation of atrazine was indeed faulty, I know this organization will proceed by rectifying this situation.

A recommendation for corrective action

I personally would recommend that the EPA reevaluate the data submitted, adhering to their very high standard of regulations. I feel very confident that they also will conclude that the data submitted was very flawed and biased and that it is time to ban this product.

An explanation of how the alleged error affects or how a correction would benefit you

I would prefer not to be subjected to the exposure of this very toxic chemical, nor allow my family members to be either. We are all exposed to this chemical through air and water contamination. We have no choice in this matter. This is very undemocratic. The very company

that manufacturers it does not allow its use in their own country. What should that tell us? So, by helping the EPA understand the unfortunate mistake made in this situation, and being the patriotic citizen that I am, I will benefit by reaffirming my belief in the strength, truth and beauty that is the United States of America.

Thank you for your time.

Julia Govis