The CLP Regulation – Opportunity for Global Standardization of Substance Classifications or Threat to Innovation from Regulatory Overreach?

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Around the globe, there is a huge effort underway to globally harmonize the classification of chemical substances known as GHS, or the Globally Harmonized System of Classification and Labelling of Chemicals. The European version of this effort is reflected in the Classification, Labelling, and Packaging Regulation (CLP). In this paper, the Gallium Arsenide Industry Team (GAIT) discusses its experiences with CLP, and its implementation under the European Chemicals Agency (ECHA).

The GAIT is composed of a group of companies that manufacture or use gallium arsenide in their products and of trade organizations whose members are affected by this classification, and has members from the EU, North America, and Asia. The GAIT formally came together in September 2010, in response to the Opinion of May 25, 2010 of the Risk Assessment Committee (RAC) regarding the classification of gallium arsenide as a Carcinogen 1A, Reproductive Toxin 1B, and Specific Target Organ Toxic – Repeated Exposure 1. Prior to September 2010, informal teams in both the EU and United States were operating on their own. Coming together as the GAIT allowed coordination of activities, and the ability to keep everyone involved informed.

The GAIT members reviewed all of the comments and scientific data cited by the RAC in its opinion and not surprisingly came to a completely different conclusion. The RAC did not follow the regulatory requirements for public comments on the dossier, and it used a faulty "read across" method to classify gallium arsenide the same as other arsenic compounds that are chemically very different from gallium arsenide. It should be said that the GAIT members are not opposed to globally harmonizing the classifications of substances, but are in fact very supportive of this process. However, as the impacts of these classifications can be very onerous, the processes for these classifications must be completely transparent and must use the most recent, robust scientific data.

After deliberation, the GAIT members worked diligently gallium arsenide toxicological experts around the world to learn more about the toxicological effects of gallium arsenide. They also

engaged with EU legal experts to investigate the requirements in the CLP Regulation, and whether these requirements were followed by the RAC in its opinion-making.

Why go through this expensive, laborious process? After all, it's just a classification, not a ban on the use of the substance. Many other substances used in the gallium arsenide industry are already classified.

The GAIT decided that the procedural and scientific errors by the RAC endangered the validity and integrity of the classification process. These erroneous classifications would ripple around the globe as more countries are writing their own new regulations that incorporate any classifications by any "authoritative body". The latest draft of the proposed Safer Consumer Products regulations in California specifically cite the EU CLP regulation as an authoritative body, whose classifications will be incorporated into the California regulation.

Not only will the classifications ripple around the world, but the consequences of those classifications would also. In the EU, the erroneous classification by the RAC would give gallium arsenide a high priority for being classified as a Substance of Very High Concern (SVHC). Since the classification of SVHCs is based solely on hazard traits (not risk), there would be very few legal grounds to oppose the SVHC classification.

What has the GAIT accomplished with these efforts? The GAIT members have engaged with the Director Generals of Enterprise (DG-ENT) and the Environment (DG-ENV) to explain industry concerns about the RAC processes. Through these efforts, a second public consultation on the carcinogenicity of gallium arsenide was opened, and it is expected that the reproductive toxicity classification will be subject to a second public consultation soon.

The extended abstract and presentation will cover the entire scope of GAIT's efforts in dealing with the aforementioned challenges as well as updates to the accomplishments reached.

Note: If your product relies on wireless communication, (*e.g.* through the mobile phone system) photonics-based communications or other forms of opto-electronic application, you are affected by the classification of gallium arsenide. If you would like to join the GAIT's efforts, please contact the GAIT at: https://gallium-arsenide.groupsite.com/login and request to become a member.