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

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Abstract

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 the classification of gallium arsenide using the CLP process, and its implementation under the European Chemicals Agency (ECHA).

INTRODUCTION

There is a global effort underway to globally harmonize the classification of chemical substances. This is known as the Globally Harmonized System of Classification and Labeling of Chemicals, or GHS. In the European Union, these efforts are reflected in the Classification, Labeling, and Packaging Regulation (CLP). The CLP Regulation incorporates the classifications previously made under the Dangerous Substances Directive (DSD).

CLASSIFICATION PROCESS

The process for classifying chemicals according to the CLP Regulation is shown in Figure 1. An EU Member State (MS) or ECHA can announce their intention to classify a substance, and those announcements are documented in the Registry of Intentions on the ECHA website. The proposing MS or ECHA also gives a deadline by which they will complete the Annex XV dossier, also known as the Background Document (BD). When completed, the BD is submitted for review by ECHA. If compliant, a 45-day public consultation is held for input into the classification of the substance of interest. After the public consultation closes, the Risk Assessment Committee (RAC) of ECHA reviews the comments and then formulates an Opinion as to how the substance should be classified. During this review, only scientific, toxicological comments are considered. Those comments relating to socio-economic considerations are dismissed. This Opinion is sent to the EU Commission for adoption, modification, or rejection. Assuming the EU Commission adopts the Opinion, the classification will be entered into the CLP Regulation at the next Adaptation to Technical Progress (ATP).

Figure 1. Classification of substances in CLP Regulation

The classifications made under the CLP Regulation serve as the basis for further classifications of substances as Substances of Very High Concern (SVHCs) under the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) Regulation. Classification of a substance as an SVHC can lead to the ban or restriction of the use of that substance. This paper discusses the events occurring during the classification of gallium arsenide by the RAC from 2009 until today, and the lessons learned from participation in this process.

DISCUSSION

In June of 2009, France proposed to classify gallium arsenide under the CLP Regulation criteria as a Carcinogen 2, Reproductive Toxin 1B, and Specific Target Organ Toxic – Repeated Exposure 1 (See Table 1 for meanings of

carcinogenicity and reproductive toxicity classifications). Several companies in the United States joined together with IPC, a global trade organization for the electronics industry, and submitted comments regarding these proposed classifications, as well as interested parties in Europe. During during the public consultation, the Swedish Chemicals Agency proposed that the carcinogenicity classification should be harmonized with the opinion of the International Agency for Research on Cancer (IARC). The IARC had classified gallium arsenide as a Group 1 Carcinogen in 2006 [1], even though their evaluation was that there was *inadequate evidence* in humans and *limited evidence* in experimental animals for the carcinogenicity of gallium arsenide. Although France reproposed the carcinogenicity classification of 2 (CLP), the RAC and the RAC rapporteurs revised the Background Document (BD) and its classification proposal to reflect a Carcinogenicity classification of 1A (CLP). In May of 2010 the RAC released its Opinion for the classification of gallium arsenide as a Carcinogen 1A, Reproductive Toxin 1B, and Specific Target Organ Toxic – Repeated Exposure 1 (all CLP).

TABLE 1
HAZARD CLASSIFICATIONS

Carcinogenicity **acc. to CLP** / *acc. to DSD*	
1A[a] / *1*	Known to have carcinogenic potential for humans, largely based on human evidence
1B[a] / *2*	Presumed to have carcinogenic potential for humans, largely based on animal evidence
2 / *3*	Suspected human carcinogen, based on studies not sufficiently convincing to place in Categories 1A or 1B, such as limited evidence of carcinogenicity in humans or limited evidence of carcinogenicity in animal studies.
Reproductive Toxicity **acc. to CLP** / *acc. to DSD*	
1A[a] / *1*	Known human reproductive toxicant, largely based on human evidence
1B[a] / *2*	Presumed human reproductive toxicant, largely based on animal evidence if the adverse effect is not considered to be a secondary non-specific consequence of other toxic effects.
2 / *3*	Suspected human reproductive toxicant, based on studies not sufficiently convincing to place in Categories 1A or 1B, if the adverse effect is not considered to be a secondary non-specific consequence of other toxic effects.

[a] Substances classified at these levels are subject to future classification at SVHCs (REACH article 57)

GAIT formally came together in September 2010, in response to the RAC's May 2010 Opinion. Prior to September 2010, informal independent teams were operating in both the EU and United States. 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. GAIT members decided to investigate the scientific basis of the RAC Opinion to determine if proper procedures and the most recent, relevant scientific data were used. 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, relevant scientific data.

RAC PROCEDURAL ERRORS

GAIT found that the RAC did not follow the regulatory requirements for public comments on the dossier. The CLP Regulation states in Article 37:

> 4. The Committee for Risk Assessment of the Agency set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 shall adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment. The Agency shall forward this opinion and any comments to the Commission.

The RAC did not adopt an opinion on the original French proposal, but instead directed the rapporteurs to modify the BD to reflect a higher carcinogenicity classification proposal. The revised BD was not submitted for public consultation, which resulted in interested parties not being able to comment on the revised BD. This is a direct violation of the CLP Regulation.

The RAC also used a faulty "read across" method to classify gallium arsenide the same as other arsenic compounds that are chemically very different from gallium arsenide, such as diarsenic pentaoxide and diarsenic trioxide. The Organization for Economic Cooperation and Development (OECD) has issued guidance on the best method for "reading across" a trait from one chemical substance or group of chemical substances to the substance under consideration [2].

The RAC did not follow this recommended procedure, but instead incorporated data from other arsenic compounds that are very different from gallium arsenide both chemically and physically.

USE OF THE MOST RECENT, RELEVANT SCIENTIFIC DATA

GAIT members also worked diligently with gallium arsenide toxicological experts around the world to learn more about the toxicological effects of gallium arsenide. GAIT members researched the latest scientific data, and also researched the toxicological papers cited in the RAC May 2010 Opinion. GAIT members found new toxicological studies that were not reviewed in the IARC opinion. GAIT members came to the conclusion that basing the classification opinion on the IARC opinion excluded the most recent decade of scientific work in this field. Also, GAIT members found that some of the papers cited by the IARC in their opinion did not support the IARC's opinion.

GAIT ACTIVITIES

GAIT members decided that the procedural and scientific errors by the RAC endangered the validity and integrity of the gallium arsenide 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 an 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.

Based on our conclusions from the research by our members, GAIT decided to reach out to other industry organizations and other authoritative agencies within the EU. We engaged with the European Commission, specifically the Director Generals of Enterprise (DG-ENT) and the Environment (DG-ENV), to explain our concerns about the RAC processes – the use of improper read-across method and not allowing interested parties to comment on the revised BD. We also began working with other trade organizations within the European Union such as Eurometaux. Through these efforts, a second public consultation on the carcinogenicity of gallium arsenide was opened in early 2011. GAIT members arranged for independent toxicology experts to submit comments during this consultation, and GAIT members also submitted comments. The RAC determined that GAIT had submitted "new and relevant" information, and agreed to reconsider their May 2010 opinion. A workshop on gallium arsenide classification was held in September 2011, at which GAIT was able to bring unbiased, outside toxicological experts.

In parallel, EU members of GAIT have also reached out to their respective agencies that are charged with fostering innovation and high technologies within their countries. These agencies were completely unaware of CLP and REACH processes and their potential impact on innovation. GAIT members are now working with these agencies to make them aware that these regulations will impact high tech innovation in their countries.

As a result of these efforts, the RAC has reconsidered its opinion that gallium arsenide is a Carcinogen 1A, and now recommends a classification of Carcinogen 1B – still more stringent than the original proposal by France. This Opinion now goes to the EU Commission for harmonization across the EU Community. GAIT members are still working with the EU Commissioners and with Member State Competent Authorities (MSCAs) to add an "inhalable particulate" qualifier to the carcinogenicity classification, to reflect that the symptoms shown by the experimental animals in toxicological studies were due to the inhalation of fine, particulate gallium arsenide which is not the form present in consumer products such as mobile phones. This would match the IARC recommendation to consider gallium arsenide as a "particulate toxicant" ([1] – page 48).

GAIT members are also still working to open a second public consultation on the Reproductive Toxicity classification of 1B. GAIT members have concluded that the reproductive effects noted during the toxicological studies were due more to decreased lung capacity from the inhalation of the particulate matter, rather than from any chemical effects of gallium arsenide. The GAIT conclusion is supported by the German toxicological association UAIII, who have classified the reproductive toxicity of gallium arsenide as a 2, based on their review of the same studies.

CONCLUSIONS

GAIT members have learned a tremendous amount by participating in this process. GAIT members started out in this process assuming that the most recent, relevant science and comments by toxicological experts would dictate how substances should be classified. However, we have learned that the classification of chemical substances by ECHA committees is not an entirely science-based process. It is subject to political pressures both at the EU community level, and at the various Member State levels. Member State Competent Authorities (MSCAs) appear to be using ECHA processes to further their own goals at the EU level.

Another lesson learned by GAIT is that classification of chemical substances is viewed by the RAC as strictly based on *hazard*, not *risk*. The RAC believes that risk and hazard can be separated, and that a determination of the carcinogenic or mutagenic potential of a substance can be made, independent of assessing the risk of those potentials occurring. Members of the RAC have made the statement many times that classification is about hazard, not risk. Any comments made during public consultations about "no exposure" will simply be dismissed by the RAC as not relevant to the assessment of the hazard of the chemical substance. GAIT members have tried to explain to RAC members that any hazard assessment necessarily includes some exposure pathway and exposure amount or concentration. The basis of hazard determination is based on exposure scenarios. However, this argument continues to be dismissed by the RAC as irrelevant.

It is a very time-consuming, expensive process to fight what you believe to be an erroneous classification of a

chemical substance. In fact, it is almost impossible to do, and GAIT members would not recommend attempting this process on a regular basis. However, there are several factors that will contribute to your chances of success:

1. The most recent, relevant scientific data must be in your favor. There must be recent studies that are not already considered in the Background Document, that show that the substance does not have the degree of hazard proposed.
2. If you are not an EU manufacturer or importer, you must have EU partners – the more and the larger – the better. There has to be someone in the EU that can interact with important agencies in real time and in the appropriate languages.
3. Do not assume that other government agencies whose mission is to support innovative technologies are aware of regulations like REACH or CLP and their impacts on manufacturing. Your group will need to reach out to these agencies to inform them of the consequences of these classifications.
4. Your group must be ready to spend money to engage with toxicological experts, whose cost is approximately $400 per hour. Be prepared to spend $500,000 or more on experts, including travel costs to Helsinki and Brussels for several meetings.
5. Your group must be ready to spend the time reading toxicological papers and developing comments and letters. It is estimated that GAIT members have read over 10,000 pages of toxicological information in preparation for its comments.
6. You will need organization – a website that you can share information that members are gathering and analyzing, and someone to organize the meetings, write up the minutes, and drive completion of the team's goals.

The most important lesson learned by GAIT is to try not to get into the position of having to fight what you believe to be an erroneous classification. ECHA is under tremendous pressure to push chemical substances through this classification process as quickly as possible, which does not leave a lot of time for them to reconsider opinions. Companies will have to monitor the ECHA Registry of Intentions closely, and begin to gather their toxicological experts prior to the public consultations. As the public consultations are only 45 days long, the toxicological research has to begin months before hand. Fortunately, the Registry of Intentions gives us a warning that something is going to be classified.

GAIT continues to monitor classification efforts in the European Union, as it is certain that other substances critical to our industry will be proposed for classification in the future. GAIT is very interested in adding new members. 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.

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ACRONYMS

ATP: Adaptation to Technical Progress
BD: Background Document, also known as the Annex XV dossier submitted by a Member State to begin the classification process
CLP: Classification, Labeling, and Packaging Regulation
CMR: Carcinogen, Mutagen, or Reproductive Toxin
DG-ENT: Directorate General of Enterprise
DG-ENV: Directorate General of the Environment
DSD: Dangerous Substances Directive, predecessor to CLP Regulation
ECHA: European Chemicals Agency
EU: European Union
GaAs: gallium arsenide
GAIT: Gallium Arsenide Industry Team
GHS: Globally Harmonized System of Classification and Labeling of Chemicals
IARC: International Agency for Research on Cancer
MSC: Member State Committee
MSCA: Member State Competent Authority
OECD: Organization for Economic Cooperation and Development
PBT: Persistent, Bioaccumulative, and Toxic
RAC: Risk Assessment Committee
REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals Regulation
RoI: Registry of Intentions
SVHCs: Substances of Very High Concern