

# EU chemical policy

## From dangerous substances to dangerous precedents

Regulations are all very well, but it's a matter of getting the balance right. *Dr Roger Doome*, Senior Scientific Officer of IMA-Europe, considers the case of EU proposals to classify borates, and raises concerns that could impact all industrial minerals producers

SOME REGULATION IS necessary in a fair and free society, and the European Commission can point to many successful initiatives that have raised safety standards and lowered environmental impacts. But the foundation of all effective policy lies in the careful and realistic consideration of both its benefits and its costs. By ignoring the checks and balances created to ensure that balance, policies that are intended to protect people from danger can develop into dangerous precedents in their own right. This article presents a case study on a proposal to classify borates that illustrates this concept.

Borates are naturally occurring minerals that can be found throughout the environment – and in all food – in trace amounts. They are essential for plants and nutritionally important for people. Borates are also key ingredients in a wide array of products that are essential to an acceptable standard of living, including agricultural micronutrients that increase crop quality and yield, wood preservatives that protect nature's most sustainable building material, insulation products that lower energy use and greenhouse gas emission and even medical treatments that show promise in preventing arthritis and prostate cancer.

The European Commission's Dangerous Substances Directive governs the classification and labelling of substances which may cause a risk to human health under normal handling and use. Borates have been proposed for classification as a Category 2 reproductive toxicant based on animal studies – despite the fact that feeding laboratory animals artificially high doses of borates over long periods of time does not reflect human exposure to borates during their manufacture and use. Even though borates have been used safely for hundreds of years in hundreds of applications, people's greatest exposure to borates is the one to three milligrams they eat every day as part of a healthy diet of fruits and vegetables, nuts and grains, and even wine and coffee.

In short, this regulatory proposal poses a bigger threat to society and the environment than the substances it seeks to regulate.

### Background

In the 1960s, the national chemical provisions of the six EC Member States differed widely and thus hindered trade and impeded market integration. In addition, there was a need to protect public health, including the health of workers handling dangerous substances. This need resulted in the adoption of Directive 67/548/EEC which outlines procedures for the classification, packaging and labelling of dangerous substances produced in or imported into the EU.

The goal of standardisation was to ensure a common market for chemical substances and a high level of public safety. In this regard, it is critical to remember that the legal basis for the Directive is Article 94 of the Treaty establishing the European Union rather than Article 152. In other words, the Directive is not a public health measure; rather, its purpose is to harmonise trade of chemical substances and preparations. It is also worth noting that environmental protection was only introduced in 1979 and that the requirement for the Safety Data Sheet (SDS) as a hazard communication tool for professional users dates from 1992.

Currently there are fifteen classes of hazard in Directive 67/548/EEC including "explosive", "very toxic", "carcinogenic", "irritant" and "dangerous for the environment". The Annexes to the Directive contain, among other things, a list of dangerous substances, their classification, labelling provisions, symbols related to each hazard, standard phrases defining these hazards and a series of phrases giving advice on safety precautions related to exposure.

Since the Directive's adoption in 1967, Community legislation has been updated regularly to take into account scientific and technical progress. This procedure is referred to as the adaptation to technical progress, and is designed to ensure the appropriate performance of the internal market, as well as a high level of public, worker and environmental safety. So far, the core legislative text has been amended nine times, while the annexes have been adapted to technical progress 29 times. Annex 1 contains approximately 2,700 existing and 1,100 new entries, covering approximately 8,000 substances.

Besides classification and labelling, Directive 67/548/EEC has also spawned some siblings, such as legislation dealing with various aspects of marketing and use. It has also been incorporated into an extensive list of Directives and regulation dealing with the environmental aspects of products and their storage and disposal such as the water framework Directive and eco-labelling. Comparable but distinct legislation also exists for cosmetics, detergents, pesticides and pharmaceuticals. These substances are excluded from the provisions of the dangerous substances legislation.

*Stricto sensu*, the Dangerous Substances Directive only provides downstream users and consumers with appropriate information regarding the substances' hazards. This is comparable to the warning labels established by the United States' Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard. The Directive and its subsequent amendments have given the classification system another strategic dimension. As an example, substances classified as carcinogenic, mutagenic or toxic to reproduction (Category 1 and 2) and listed in Annex 1 are prohibited from sale to the general public, subject to certain provisions relating to concentration limits. Under certain conditions, an exemption from Annex 1 may be granted. The use of hazard identification in a number of downstream regulations further restricts the use of substances regarded as dangerous.

### The route to EU classification

Due to its significant impact on substances on the EU internal market and the Directive's original intent, formal classification is an exclusive EU competence and Member States are therefore not allowed to unilaterally classify a substance. There are, however, provisions that allow Member States to temporarily classify substances or prohibit them from markets in light of new information that they might constitute a danger to people or environment. The Commission must be informed of any such action. Industry is also obliged to be aware of any relevant data on a chemical and provisionally classify and label accordingly.

When there are presumptions that a chemical warrants classification, a dossier is submitted for review to the EU Working Group for the Classification and Labelling of Dangerous Substances (CWG). Specialised Experts meetings may also be convened by the European Chemicals Bureau (ECB) to assess specific questions regarding carcinogenicity, mutagenicity or reproductive toxicity. In their evaluation, the CWG and the Specialised Experts are required to apply assessment criteria specifically set out in the Directive. These criteria impose a clear legal requirement to base the classification assessment on:

- the intrinsic properties of the substance;
- the risks that may arise in the normal handling and use of the substance; and,
- the potential risks of the substance to humans and the relevance of any available scientific data to humans

The CWG and the Specialised Experts have a strict legal requirement to make their classification assessment based on these criteria

The CWG's opinions are then compiled on a draft Adaptation to Technical Progress (ATP), which is passed on to the European Commission for internal review. One of the purposes of this review is to ensure that the legal criteria have been followed. The final ATP, which consists of the measures to be taken for classification and labelling of substances, is then submitted to the Technical Progress Committee (TPC) – composed of Member State representatives – for a formal vote. An adaptation to the technical progress of the Directive is then published and the provisions are transposed into the national law of each Member State.

### System failure: the case of borates

In 1999, borates – specifically boric acid and borax – were nominated for classification as reproductive toxicants based on data derived from experiments conducted with animal in which very high, chronic doses of borates were shown to cause reproductive and developmental effects. Borates were initially proposed for classification as Category 3 reproductive toxicants, but were removed from the 29th ATP in April 2004 due to concerns with that the internal review process had not been completed.

Animal studies clearly identify exposure levels below which no


reproductive toxic effects are observed. Although animal testing has yielded reproductive effects when artificially high doses of borates are administered orally, these studies are not relevant to humans. First, the dose levels simply cannot be replicated through exposure to borates in any existing application, even among people who work with borates every day. People's greatest exposure to borates is dietary, and we do not eat, drink, or inhale borates in sufficient amounts to produce these effects. The only exceptions would be very high oral doses which can be regarded as either accidental or abusive intakes. Even in these cases, however, very high doses would induce vomiting via an auto-reflex action before any reproductive effects would be possible, or before extremely high doses could be lethal.

In October 2004, the Commission convened a group of Specialised Experts to review borates' health effects. The group recommended that borates be assigned a Category 2 classification – a more restrictive classification than originally proposed, and one that requires products containing borate concentrations of 0.5 percent or more to be labelled with a skull and crossbones and a warning that these products "should be regarded as if they impair fertility or cause harm to the unborn child." This recommendation has been adopted on the draft 30th ATP and will follow the process outlined above.

Following detailed examination of the Summary Record of the Specialised Experts' meeting, it is clear that the legal requirement of the classification process – to consider substances based on their health effects under normal handling and use – continues to be disregarded. Accordingly, borates and boric acid should not be classified until and unless complete consideration of normal handling and use and the relevance of animal data to humans have been given. In short, classifying and labelling borates will not result in any benefits to public health and safety – but it will have a devastating economic impact on the very industries and markets the Directive was originally intended to support.

According to a 2000 study conducted by the Centre for Economics and Business Research Ltd., classifying borates would have a negative impact on EU businesses with sales totalling €89 billion per year. Moreover, borates are essential ingredients in many products and processes where they impart properties that would be either technically impossible to achieve, or require the use of more hazardous substances. Restricting borates' use would also restrict new product development, a critical factor in Europe maintaining a competitive position in the global marketplace.

This case study raises some key questions and concerns that have the potential to affect all industrial minerals producers:

- Clear evidence of a threshold toxic effect, as is the case for reproductive toxicity, makes the consideration of "normal handling and use" a critical criteria for classification. Failure to apply these criteria leads to safe products being wrongly labelled as dangerous and, under extreme circumstances, restricted in their use.
- The legislation does not permit the testing of products containing substances classified as toxic to reproduction so there is no way that industry can demonstrate their safety.
- The wide adoption of the hazard classification system in downstream legislation leads to disproportionate and inappropriate regulation.
- Cases will occur where a risk assessment clearly demonstrates no risk yet the product will be substituted purely on the basis of hazard. 



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