

# Client Alert

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## The REACH Safeguard Clause: First Use by France

Although the 2006 REACH Regulation is intended to harmonize chemical law in the European Union, it allows the member state to adopt urgent provisional measures that are more stringent than those imposed by the REACH Regulation. This provision is known as REACH's "safeguard clause."

Until recently, the safeguard clause had not been used. Now, however, France has invoked the clause to impose temporary restrictions on ammonium salts in insulation materials. Ammonium salts are used as flame retardants, and have prompted health concerns in residential applications. The French measures, however, raise questions with respect to the proper interpretation and applications of the safeguard clause.

### The Limits of EU-wide Harmonization

The REACH Regulation, which is directly effective in all member states, sets forth comprehensive regimes for the registration, evaluation, authorization and restriction of chemical substances. The idea is to create an EU-wide single market for chemicals and products containing chemicals.

That does not mean, however, that REACH is applied and enforced in an identical manner throughout the EU. Member state national authorities play a key role in implementing and enforcing the various REACH regimes. Diverging interpretations of REACH and enforcement practices among member states, however, may still result in some degree of market fragmentation. This has happened, for example, with respect to nano-forms of chemical substances: France and Norway require mandatory registration of nano-materials, and Belgium and Denmark also intend to move ahead with registries. Some member states do not exclude national measures, if they perceive that the European Union does not take sufficient measures to specifically address the potential risks associated with nano-materials.

Under the REACH Regulation, member states are not allowed to adopt measures that go beyond REACH, subject to two narrow exceptions.

- First, national restrictions pre-dating REACH were allowed to remain in force until June 1, 2013, provided that they were notified to the European Commission. Only two such measures were dutifully notified to the European Commission: the restrictions imposed by the Netherlands government on wood treated with creosote and on short-chain chlorinated paraffins.
- Second, member states may invoke REACH's safeguard clause.

### REACH's Safeguard Clause and Conditions

Under the REACH safeguard clause, member states may adopt provisional measures to address urgent issues. Their authority to do so, however, is subject to two conditions.

- First, a member state may adopt more restrictive measures only if there are "justifiable grounds for believing that urgent action" is required. REACH does not define further when such grounds are present, which implies that the member states are to interpret this condition.

- Second, upon the adoption of any such “safeguard” measures, the member state concerned must immediately notify the European Commission and the other member states and communicate to them the reasons for the provisional measure and the “scientific or technical information on which [it] is based.” Upon notification, the European Commission has 60 days to authorize the measure for a definite period of time or require the revocation of the national measure. If the measure is authorized, the member state must prepare a proposal for a EU-wide restriction within three months from the Commission decision.

To sum up, the safeguard clause accommodates national measures to address chemical risks that must urgently be addressed, and subjects such measures to EU discipline. As it uses a broad, general standard, however, it leaves considerable discretion to the member states and, in second order, the European Commission.

### France’s Application of the Safeguard Clause

On June 21, 2013, France adopted a ban on cellulose wadding insulation materials containing ammonium salts adjuvants. As required by REACH, this measure was notified to the European Commission on August 14, 2013, and authorized on October 14, 2013.

- **Justification of the French measure:** The French government provided the following justification for the safeguard measure. Until September 2011, boric salts were used as flame retardants (and biocides) in cellulose wadding insulation. Boric salts were restricted because they are toxic to reproduction. Following this restriction, boric salts were replaced, with respect to flame-retardant use, with ammonium salts. These ammonium salts, however, under certain environmental conditions, may emit ammonia, a gas classified as corrosive under chemical laws.

The switch to ammonium salts resulted in “several” incidents reported to poison centers and the trade association concerned; a total of some 150 complaints were submitted to the trade associations only. The French authorities measured ammonia levels in houses in which the insulation material had been used, and found levels higher than the reference toxicological values for safe long-term exposure. The French government did not provide any information, however, on the actual or potential duration and frequency of exposure, nor on the costs and benefits of this use of ammonium salts. It also did not provide any analysis of alternatives for ammonium salts that might be less hazardous.

- **Ongoing assessments:** A trade association is currently reviewing potential alternative substances. It expects to finalize its analysis by the end of 2014. In the meantime, most manufacturers will use boric salts as flame retardants in insulation materials in proportions allowed by EU law.

The French authorities are planning to review the health effects of all insulation materials currently available on the market. It is not clear, however, when the result of this assessment will be available.

- **Next steps:** The Commission has authorized the French measure on October 14, 2013. France now has three months to prepare a proposal for an EU-wide restriction. The Commission authorization is temporary and will expire on July 14, 2015, when an EU-wide restriction becomes applicable, or six months after the restriction procedure is finalized without EU action, whichever occurs earlier.

### Conclusion

The first application of the REACH safeguard clause confirms that member states and the European Commission enjoy discretion in determining when urgent national measures are justified. France banned ammonium salts from insulation materials based on a series of complaints. Prior to banning these compounds, however, France did not conduct an assessment of alternatives, nor did it do a cost-benefit analysis. These deficiencies may be remedied in the ongoing processes.

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## How Hunton & Williams Can Help

The regulatory team of Hunton & Williams has extensive experience in assisting clients with REACH and regulation of plant protection product, biocide and industrial facilities. They advise clients on all regulatory matters, including compliance management, liability assessment, product stewardship audits, product defense, specific compliance issues, consortium and SIEF management, data rights, contracts, inspections and enforcement, and legal remedies. We work closely with our clients and with regulatory and technical experts so that clients' interests are protected effectively by professionals best placed to assist.

Hunton & Williams is a global law firm with a strong focus in regulatory law and with qualified and experienced lawyers on both sides of the Atlantic, in its offices in Brussels, Raleigh and Washington, DC, and also in its Asian offices, including Beijing.

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