France proposes a restriction on inorganic ammonium salts that are used in cellulose insulation materials [1]

SUMMARY

France has submitted a report proposing a restriction on the placing on the market of inorganic ammonium salts in cellulose insulation materials unless emission of ammonia gas of such materials is below 3 ppm according to the horizontal measurement/test methods of Technical Specification CEN/TS 16516.

Until 2011 boron salts were widely used as additives for these applications but due to their classification as toxic to reproduction (mainly Repr. 1B) they have been replaced in the French market by inorganic ammonium salts. These ammonium salts, which account for 6% to 12% of the total mass of the products, can lead under certain conditions (e.g. high humidity) to emissions of ammonia, a gas which is irritant to the mucous membranes and respiratory tract. French 'toxic vigilance data' in 2012 and in the first half of 2013 identified about 40 people showing various types of irritation on the upper airways and more than 100 relevant complains in the internet forums.

The restriction proposal is targerted to apply a complete reduction of the identified risks for EU citizens (i.e. eye and respiratory irritation) from the release of ammonia from cellulose insulation materials containing inorganic ammonium salts and the consequent exposure to the population at large. The main cost elements of the proposed restriction for economic operators concern the testing of ammonia emmission and the R&D to find new formulations, while the benefits are estimated on the basis of re-insulation and re-housing costs.

ECHA launches today the public consultation on this restriction report, which will end on 18 December 2014. However, the rapporteurs of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) would welcome any comments, in particular on the availability of alternatives and socio-economic information, by 1 September 2014 to assist them in the first discussions of the restriction proposal.

GENERAL REMARKS

The Annex XV restriction report, prepared by France, has been published on ECHA's website. It is open to public consultation for a period of six months[2], to allow stakeholders[3] to submit their comments, as well as additional information relevant to the proposal. Comments are welcomed from the EU or beyond.

At a later stage in the RAC's and SEAC's opinion making process, a 60 days public consultation will be held specifically on the draft SEAC opinion.

The opinions of RAC and SEAC will take into account the comments received in the public consultation. ECHA will publish the responses of the dossier submitter and the Committees' rapporteurs to these comments on its website.

[1] The information note has been prepared based on the Annex XV report prepared by France.
[2] The duration of the public consultation is six months according to Article 69(6) of REACH.
[3] Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities.

SUGGESTED RESTRICTION (SCOPE)

Following the measure taken by France (prohibition of manufacture, placing on the market, import, sale and distribution of cellulose insulation materials with inorganic ammonium salts adjuvants), the European Commission has granted a provisional authorisation via its Implementing Decision of 14th of October 2013. Subsequently, according to Article 129(3) of REACH Regulation, France has prepared an Annex XV report proposing a restriction of the placing on the market of inorganic ammonium salts in cellulose insulation materials unless:

- Emission of ammonia gas of such materials is below 3 ppm according to the horizontal measurement/test methods of Technical Specification CEN/TS 16516 and
- Specific test parameters are applied in terms of duration (14 days), relative humidity (90 +/- 5), "Attic insulation" area specific emission rate (1.25 $m^3.m^{-2}.h^{-1}$), and "Wall insulation" area specific emission rate (0.5 $m^3.m^{-2}.h^{-1}$). Cellulose insulation thickness and density are adapted to the foreseen use.

The proposed restriction would apply 12 months after the amendment of the REACH Annex XVII comes into force.

No derogations are proposed by France. It should be noted that the proposed restriction concerns only cellulose based products, therefore other types of insulation materials (even if treated with ammonium salts) are not proposed to be restricted.

INORGANIC AMMONIUM SALTS IN CELLULOSE INSULATION

The products in question of the proposed restriction are cellulose insulation materials with ammonium salts adjuvants. About 250,000 tonnes of cellulose insulation are yearly placed on the EU market, out of which about 15,000 tonnes (around 5%, both produced and imported) contain inorganic ammonium salts as flame retarding additives. Under certain conditions (e.g. high moisture, alkaline pH etc.) ammonium salts decompose into ammonia gas.

Due to acute and chronic toxicity properties of ammonia, exposure from this substance via the inhalation route can develop the irritating effects in the airway or ocular mucosa. Based on the different selected human health risk values (HRV) found in the literature and REACH registration dossier, the French Authorities have established a sub-acute inhalation DNEL of 1.3 $mg.m^{-3}$ (1.7 ppm) based on this critical effect, and taking into account susceptible population sub-groups such as asthmatics. Since for most manufacturers, the exact composition of the additives is not publicly available, it was not possible to set up an exhaustive list of ammonium salts that are used as flame retardant by the cellulose insulation industry. This restriction proposal, therefore, addresses all inorganic ammonium salts when used in cellulose insulation materials.

REASONS FOR ACTION

The proposed restriction covers cellulose insulation materials containing ammonium salts, a market which although currently represents a minority part of the EU market for insulation, its growth is exponential (currently borate-based formulations dominate the EU market but the reprotoxicity classification (Repr. 1B) of borates may trigger their gradual substitution by ammonium based forumations). Under certain conditions (humidity, pH etc.) ammonium salts can easily decompose to emit ammonia, a substance with irritating properties to mucosa and respiratory tract.

Based on the analysis presented in this Annex XV report, it is concluded that a restriction based on ammonia emission under REACH Regulation is the most realistic, effective and proportionate option to manage the health risks at EU level related to ammonia emission from cellulose insulation.
Although no health cases due to emitted ammonia were found in other Member States than France up to date, given that similar formulations of cellulose insulation containing ammonium salts are used in various EU countries, it cannot be excluded that similar heath issues would be developed in the future.

CONSEQUENCES OF THE ACTION

The proposed restriction is expected to result to a complete risk reduction of ammonia emissions from cellulose insulation materials both for occupants and professionals as compared to the baseline situation. This is also claimed to be a fair option for the industry as it leaves a door open for the use of ammonium salts in stabilized blends if the manufacturer of cellulose insulation demonstrates that it does not emit more than the established limit.

The main costs of the proposed restriction are considered bearable for the users of insulation material, mainly concerning testing and reformulation process and considering also the lower price of the borates (the main currently available alternatives at EU level). The benefits estimations of the proposed restriction are based on the avoided costs of re-insulation and do not include health benefits, therefore they may be considered as an underestimation. It is estimated that by 2025, the benefits from this restriction will account for more than double than the associated costs (3.3. millions versus 1.4 millions).

SPECIFIC INFORMATION REQUESTED

A few specific elements have been addressed in the Public Consultation in order to gather relevant information, if available, from stakeholders. An indicative list is given below:

- Types/quantities of cellulose products in the EU market and which inorganic salts are used as additives for these applications (+ info on concentration/emissions)
- Information on alternative to ammonium-based formulation or alternative techniques.
- Reported cases of irritation/clinical cases for public or workers following exposure to ammonia emitted from ammonium based insulation material.
- Any specific economic or social impacts to economic operators due to a potential future restriction of ammonium salts in cellulose based materials.

COMMENTS PREFERABLY BY 18 AUGUST 2014

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 18 June 2014. Interested parties can comment on the proposed restriction report using the ECHA website. Although the public consultation concludes on 18 December 2014, the rapporteurs of RAC and SEAC would appreciate receiving comments by 1 September 2014 to assist them in the detailed discussion of the restriction proposal in September 2014.

The final opinions of both Committees are scheduled to be available by 18 June 2015. ECHA will send these two opinions to the European Commission, which will take the decision whether to include the proposed restriction in the Annex XVII of the REACH Regulation.