

Cellulose wadding: how toxicovigilance data led to a regulatory restriction

Cellulose wadding is used as sound or thermal insulation in housing. It is applied by blowing, spraying or flocking into the walls and attics of homes.

Until 2011, boron salts were added to cellulose wadding insulation materials for their antifungal and flame-retardant properties. However, under the former Biocides Directive (repealed in 2012 in favour of Regulation (EU No 528/2012)), boric acid and its salts were banned as antifungal agents because of their toxicity to reproduction (harmonised classification “Reprotoxic Category 1B” – substances presumed to be toxic to human reproduction). As a result, boric acid and its salts could no longer be used in concentrations higher than 5.5%.

In France, because the Commission responsible for formulating technical opinions (CCFAT) decided not to renew opinions extending the authorisation of boron salts, cellulose wadding manufacturers replaced these salts with ammonium salts, as of November 2011. These additives made up between 6 and 12% of the total mass of the insulation.

In 2012, the French Poison Control Centre (PCC) in Angers received a complaint from a family exposed to an irritating ammonia odour following the installation of cellulose wadding insulation. A health technician visiting the home in question confirmed indoor air pollution with ammonia.

At the same time, the Directorate for Housing, Urban Planning and Landscapes (DHUP) was informed by the European Cellulose Insulation Manufacturers Association (ECIMA) and the French Scientific and Technical Centre for Building (CSTB) of a growing number of complaints of ammonia odours in homes following the installation of cellulose wadding insulation. ECIMA had registered 115 complaints with indoor air measurements of the buildings indicating the presence of ammonia.

Testimonies collected on internet DIY forums also confirmed the high number of customer complaints due to the release of ammonia from this wadding.

In December 2012, the Directorate General for Health (DGS) requested a one-year retrospective analysis of cases registered by PCCs.

The retrospective study identified 10 dossiers involving 19 people exposed between February and November 2012: 14 adults and five children, almost all complaining of an odour in the home that had alerted them. In two cases, the exposed individuals had installed the cellulose wadding themselves. One case involved occupational exposure.

Fifteen exposure cases showed symptoms of irritation to the eyes, nose, throat (ENT) and airways, of mild to moderate severity. These symptoms were all accompanied by a characteristic smell. Indoor air measurements had been taken in only three homes and had indicated the presence of ammonia.

While in 2012, ECIMA estimated that 20,000 French homes were fitted with cellulose wadding insulation, the low number of cases identified by the PCCs and the few cases for which indoor air measurements had been taken, supported the need for a prospective survey. This was conducted with the support of the regional health agencies (ARSs), so that metrological analyses of indoor air could be carried out.

The ARSs were therefore asked to participate, together with the PCCs, in the collection of information on the environmental circumstances of the building concerned and the clinical manifestations of the cases identified. This led to 14 dossiers involving 43 patients being registered between January and July 2013, corresponding to 19 children and 24 adults. Symptoms included upper airway irritation, coughing and bronchospasm. Only four indoor air measurements were performed in the suspect dwellings, which indicated low levels of ammonia contamination. In five cases, the cellulose wadding was removed completely. In three cases, it was partially removed, which is possibly not enough to avoid potential recurrences of ammonia releases.

Alongside this prospective study, the National Network for the Monitoring and Prevention of Occupational Diseases (RNV3P) identified five cases of occupational exposure, for which signs of minimal ENT irritation were observed, including one case of *de novo* asthma.

An analysis of the exposure circumstances of the cases identified by the PCCs and the RNV3P concluded that humidity (e.g. wet weather) or contact of the cellulose wadding with

On the basis of these clinical observations, France prohibited the marketing, import, sale or distribution and manufacture of cellulose wadding insulation containing ammonium salts (Ministerial Order of 21 June 2013). These materials have therefore been recalled and withdrawn from the French market.

Following this regulatory action, France informed the European Commission, the European Chemicals Agency (ECHA) and the Member States that urgent action was needed at the European level to protect against ammonia emissions from ammonium salts incorporated in cellulose wadding.

Then, following Commission Implementing Decision of 14 October 2013 authorising the provisional measure taken by the France in accordance with Article 129(3) of Regulation (EC) No 1907/2006 (REACH), a restriction dossier was prepared within three months of the date of the Commission Decision. ANSES was mandated to prepare this dossier.

As part of this process, many industry stakeholders, all the Member States and the European PCCs were consulted, which revealed an absence of complaints and cases outside France, weakening the restriction proposal.

A third investigation was then conducted by the French PCCs between July and December 2013, which identified new cases of exposure (12 dossiers). This also supplemented the information from the previously identified cases, showing that in the vast majority of cases, no indoor air measurements for ammonia had been carried out. In clinical terms, the exposure aggravated symptoms in two children, one of whom – a known asthmatic – had a new asthma attack at the time of exposure. This third investigation also showed that the corrective measures taken in seven of the 12 dossiers (removal of the cellulose wadding) had led to the rapid disappearance of the odour and recovery from the symptoms.

Considering this new clinical evidence, considering the assays carried out by the CSTB to test the stability of ammonium salts in cellulose wadding under experimental conditions (emission test chamber, high relative humidity), and considering the modelling of exposure to ammonia in housing, ANSES concluded in June 2014 that there was a risk to the population's health related to the ammonia released by cellulose wadding containing ammonium salts. The restriction proposed by ANSES involved prohibiting the marketing in Europe of cellulose wadding containing ammonium salts unless the ammonia emissions of such materials were less than 3 ppm according to the CEN/TS 16516 technical specification with some adaptations (test duration of 14 days with a moisture content of 90%).

This restriction was adopted by the European Commission in June 2016, prohibiting the placing on the market and use of cellulose wadding containing ammonium salts after 14 July 2018, unless it complies with the emission limits proposed by ANSES.

Research and development work has been then undertaken, in particular by ECIMA, to identify new additive formulations for cellulose wadding.

In France, in late 2012, the CCFAT issued new technical opinions authorising the use of boron salts as cellulose wadding additives at concentrations of less than 5.5%. The CCFAT extended the validity of these opinions until less hazardous alternatives to ammonium salts were identified.

This example illustrates the role and importance of toxicovigilance data in a European public health context, allowing the implementation of binding, harmonised regulatory measures at EU level. This situation also illustrates the possible pitfalls of attempts at substitution, which require constant vigilance.

Cécilia SOLAL (Anses)

TO FIND OUT MORE, VISIT:

European restriction dossier

https://echa.europa.eu/documents/10162/ceea529c-8aed_471a-9010-b465ac833b38

ANSES Opinion:

<https://www.anses.fr/fr/system/files/REACH2014re0001.pdf>

CCTV reports:

http://www.centres-antipoison.net/cctv/Rapport_CCTV_Ouate_de_cellulose_VF_Fevrier_2013.pdf

<http://www.centres-antipoison.net/cctv/>

[Rapport CCTV Ouate de cellulose VF Septembre 2013.PDF](#)