

T&D Europe Position Paper concerning the listing of anhydrides as REACH candidate

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Executive summary

T&D Europe¹ welcomes and supports the overall strategy of the REACH Regulation EG 1907/2006 in ensuring a high level of protection of human health and the environment and in encouraging the replacement of substances of high concern by less dangerous substances or technologies where suitable and economically available. However, the REACH process must ensure that decisions to take substances under surveillance are based on sound scientific arguments and eventually imposed risk management measures are proportionate to the risks involved.

T&D Europe is concerned about the latest development in the EU concerning the European Chemicals Agency' (ECHA) and Member States' application of the REACH Regulation in defining the anhydrides - MHHPA and HHPA - as Substances of Very High Concern (SVHC) and including them in the Candidate List. Before listing substances on the Candidate List, Member States and the ECHA must take full account of available hazard information and risk assessments, anticipated socio-economic consequences, suitability and availability of possible substitutes, and the introduction of additional risk management measures to reduce the exposure of these substances.

T&D Europe calls that ECHA has gone too far in their latest decision to list the two anhydrides MHHPA and HHPA - mostly applied as hardeners of epoxy material for solid insulation parts and for winding insulation - in the Candidate List of SVHC (decision ED/169/2012). In our opinion this decision is based on an incorrect interpretation of Article 57(f) of the REACH Regulation that respiratory sensitizers give rise to an equivalent level of concern as other SVHC substances, inter alia, carcinogenic, mutagenic or toxic for reproduction (CMRs). In the last 15 years, the industry members of T&D Europe have intensified their risk management measures in handling chemical substances and in taking care of workers.

T&D Europe proposes to stop the process of inclusion of these anhydrides in Annex XIV and asks for stronger industry involvement in the Risk Management Option Analysis during the preparation of future Annex XV dossiers.

Background information

¹ T&D Europe is the European Association of the Electricity Transmission & Distribution Equipment and Services Industry, which members are the European National Associations representing the interests of the electricity transmission and distribution equipments manufacturing and derived solutions. The companies represented by T&D Europe account for a production worth over € 25 billion EUR, and employ over 200,000 people in Europe. Further information on T&D Europe can be found here: <http://www.tdeurope.org>

The Netherlands as member state submitted a dossier with the proposal that MHHPA and HHPA should be identified as SVHCs due to a high prevalence of respiratory sensitization among exposed workers at low workplace exposure levels. The evaluation was based on examinations of workers published in different journals and collected by the World Health Organisation (WHO) in 2009 (ISBN 978 92 4 158075 0). The Member States and the European Chemicals Agency (ECHA) found that this information provides sufficient evidence for these substances being strong sensitizers. A decision was adopted by ECHA in December 2012.

MHHPA and HHPA are classified as respiratory sensitizers according to the CLP (Classification, Labelling and Packaging) regulation (EC) No 1272/2008. This sensitization might induce occupational asthma and inflammation of conjunctiva. These symptoms vanish after removal of workers from environments with exposure to anhydrides. Persistent symptoms of respiratory hypersensitivity were not reported.

Following the inclusion of these anhydrides in the Candidate List based on the submitted Annex XV dossier, there is a risk that these anhydrides will soon become subject to authorisation and/or EU-wide supply and use restrictions.

Application of anhydrides in T&D products

The members of T&D Europe are the global leaders in power and automation technologies for the transmission and distribution of electrical energy. They are significantly contributing to the creation of growth, jobs and well-being in Europe and in the world.

The anhydrides are used as epoxy hardeners in the casting of solid-insulating parts required for high voltage equipment. Typical examples are cast-resin distribution transformers, transformer bushings, wall bushings, instrument transformers, cable terminations and other insulating components of electrical switchgear for transmission or distribution networks. In addition to that, anhydrides are part of adhesive formulations widely used in bonded connections.

Anhydride risk management in the manufacturing process

The risk of sensitization by anhydrides is limited today in European factories due to compliance of the industry with risk management procedures as prescribed in the material safety data sheets of chemical substances and local occupational health and safety regulations. Modern and automated equipment is used more and more with closed vessel systems for the mixture of anhydrides, resin and filler material. The emission of free anhydrides into the environment is avoided thanks to, for example, injection processes in closed casting systems. Furthermore there are safety detection systems installed, if tubes or pipelines are damaged. During the processing of thermosetting moulding material, the worker has little contact with the pure anhydride. The production area and number of employees handling anhydrides are limited.

After more than 30 years of epoxy production with anhydrides there has not been any case of persistent lowered respiratory functionality related to workers exposed to anhydrides. Observations have been made that some exposed workers showed an increased risk to get allergic reactions, which resulted in diagnosed work based illness in severe cases. Employees

have then been re-located into other operations of the same factory, where all symptoms vanished.

Workers wear proper personal protective equipment. Together with ventilation and local exhaust systems this contributes to a safer working environment. Employees are trained for their work including emergencies and incidents. Employees working in exposed environments have regular medical checks to monitor their health status. They are informed about the risks and may require medical checks in case of allergic reactions.

Socio-economic considerations

Members of T&D Europe are globally known for their extensive research and optimisation of the manufacture of energy efficient, safe and reliable products. Anhydrides are the key substances used in the manufacturing of such products and systems.

The anhydrides are used only for professional applications and not in consumer articles. No secondary exposure exists as they are only used in industrial work environment. Final finished products do not contain any free anhydrides.

The high voltage and moisture withstand quality of today's solid insulation parts made of epoxy and anhydrides ensure long life, high reliability and safe conditions for personnel. If the anhydrides are out-phased the risk of significantly worse quality and reduced service life could increase. This may even result in a reduced stability and increased outage times of the electrical network.

There is a risk for manufacturing to be moved to non-EU countries, including the most valuable parts of the value chain like research and development, since the finished products can be sold to and used in European countries. Even a health impact on non-European countries might arise, if the production is moved to countries with less developed risk management of chemical substances. The European Union would merely export occupational health problems while importing unemployment and trade deficit. T&D estimates that approximately 1000 working places would disappear if the complete epoxy production leaves Europe and of course multiplied if also sub suppliers are considered.

The European electrical switchgear sector invested and is continuously investing in the research of substitutes to the anhydrides. So far, no substitutes fulfilling all the requirements have been identified. If a substitute is found, technology must be duly proven before being put on the market. I.e. the complete development process for each of the T&D products has to be initiated till final product implementation. Expenses will arise to cover the R&D costs, qualifications for special customers and other certifications Heavy investments will be necessary to adapt the manufacturing process.

It should be noted that anhydrides are also used in the production of energy efficient rotating machines, wind generators and LED lamps, which are promoted to be an energy efficient alternative to light bulbs. A ban of anhydrides would have a negative effect on the European energy consumption.

Detailed response to ECHA's decision

The approach of the REACH Regulation in reducing the risks associated with worker exposure and the environmental impact of dangerous substances in the EU is consistent with T&D Europe's global efforts to improve and enhance the working conditions in its factories and contribution to ensure a high level of protection of health and environment.

However, T&D Europe is against the definition of the anhydrides MHPA and HHPA as SVHC and their inclusion in the Candidate list, since operators of factories applying these anhydrides appropriately assess and manage the risks associated with their applications and use.

For the following reasons, T&D Europe claims that respiratory sensitizers should not be covered by Article 57(f) of the REACH Regulation and ECHA did not provide sufficient justification and evidence to demonstrate that these anhydrides are of "equal concern" to substances in hazard class CMRs, category 1:

1. The anhydrides do not qualify as SVHC substances having an equivalent level of concern as substances with CMR properties (carcinogenic, mutagenic or toxic for reproduction). These anhydrides do not have these health impacts but possess a high prevalence for respiratory sensitization for workers. In the rare case of an employee showing clinical manifestations, this person is moved into another work environment, where all symptoms vanish. Symptoms are not persistent. ECHA has by that gone too far in their interpretation of article 57(f) in REACH.
2. There are a limited number of employees exposed to concerned anhydrides in working environments. The exposure area is confined. The anhydrides have been safely used in the manufacturing of electricity transmission and distribution products for decades. Thus there is no need for any additional legislative control of risks through the REACH authorisation process.
3. The definition of anhydrides as SVHC is based on cases dating back to the period 1986-2002. More recent cases related to T&D Europe products have not been found in literature. Working conditions and diagnostic possibilities have improved tremendously in the last 10 years. European factories comply with EHS (environment, health and safety) routines such as ventilation of work places, skilled workers, or closed casting systems.
4. For the anhydrides no secondary exposure exists as they only are used in industry and no consumer uses exist. Final products do not contain any free anhydrides.
5. Substitution of anhydrides by alternative substances in T&D products need long development to satisfy the expectations of customers regarding safety, reliability and availability. For several applications there are no identified alternatives to the anhydrides.
6. There is a risk associated with the substitution to alternative substances since long-term human health hazard and environmental hazard is much less documented than for the anhydrides.
7. There is a risk for outsourcing products into non-EU countries where anhydrides are not restricted in use and less risk management measures are implemented in production. The European Union would merely export the use of anhydrides and occupational health problems outside EU, while importing more unemployment and trade deficit.

T&D Europe wishes to substantiate the deficiencies in the assessment conducted by the Member States and the ECHA, in particular with regards to current industry practice in controlling and managing the risks in the industrial context. It seems that the dossier submitted by the Netherlands is based on data submitted by a selected group of companies with an inadequate level of risk management implemented. ECHA's decision is incoherent with other EU policy areas promoting products with reduced energy consumption. Such disregard to socio-economic considerations and incoherence with other policy areas suggest that these anhydrides are insufficiently assessed.

Finally, T&D Europe wishes to highlight that on 28 February 2013, several legal actions were brought against ECHA on the decision ED/169/2012. The partial annulation of this decision based on similar arguments as presented in this position paper was requested (see Cases T-134/13, *Polynt and Sitre vs. ECHA* and T-135/13, *Hitachi Chemical Europe and Others vs. ECHA*).

Appendix 1 SUPPORTING ARGUMENTS with respect to the Dossier

The Netherlands made the proposal of defining the anhydrides MHHPA and HHPA as equivalent to SVHC according to article 57(f) of the REACH regulation. A public consultation was conducted between 2012-09-03 – 2012-10-18. After the public consultation period the two anhydrides were added to the REACH Candidate List on 19 December 2012. This is the first step in the authorisation process. The next step could be the inclusion of the anhydrides in Annex XIV, the Authorisation List, requiring an expensive authorisation of the use of anhydrides in any manufacturing process. In the end anhydrides may be forbidden and no longer available on the EU market.

The decision to add the anhydrides to the REACH Candidate list is based on several incorrect conclusions (in italic, Reference: ANNEX XV – SVHC DOSSIER MHHPA – CAS NO. 25550-51-0):

- *Case reports and epidemiology studies in worker populations have shown that health effects such as rhinitis, conjunctivitis and occupational asthma can result from MHHPA exposure. Effects have been so severe that subjects were forced to leave their current job. It is noted that most cases date back to the period 1990-2006, cases that are more recent have not been found in literature.*

T&D Europe's statement: The conclusion is indeed based on old data. Since then, much work has been done in order to reduce or eliminate the risks imposed by the use of anhydrides. The risk on human health in European factories is limited due to implemented risk measures and high compliance with risk management routines. Consequently, the anhydrides have been used for decades, and recent health impacts on workers are not reported.

- *Exposure to MHHPA has the potential to induce irreversible sensitisation to the substance. Sensitisation in itself is irreversible but not an adverse effect per se. It is only when the sensitized individual is exposed to MHHPA again, that signs of e.g. asthma, rhinitis and/or conjunctivitis will occur.*

T&D Europe's statement: In those cases, where workers show manifestations of symptoms, they would be re-located into other operations. Symptoms are not persistent, and therefore vanish. Since these persons will never have contact with anhydrides again – cured epoxy parts contain no anhydrides - they will be no longer affected by the sensitization to anhydrides for their whole life.

- *In most cases, the need to eliminate exposure means that the person cannot work in their chosen profession any longer. Re-training of affected individuals in the workplace can also impair that person's quality of life.*

T&D Europe's statement: Based on extensive experience with anhydrides, this aspect is not an issue of concern, considering workers are re-located to other assignments within the factory. The fact that a worker is re-located or re-assigned does not impair the person's quality of life.

- *For these chemicals, it is not possible to derive a “safe” no effect level. A “zero risk” can only be derived if there is no exposure. In the case of the respiratory sensitizer it is difficult to establish what the threshold dose is for the induction and elicitation phases of response.*

T&D Europe’s statement: The dossier claims that the only possibility of setting a safe concentration limit is no exposure. However, the WHO report dated 2009 provides in Table 5 critical limits of exposure for different anhydrides. T&D Europe requests reasonable exposure limits for discussion rather than an unspecified general non exposure demand.”