15 December 2016

(Presented at MSC-51)

Concerns: **Annex XV proposal for identification of Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (Trimellitic anhydride, TMA) (EC No. 209-008-0) as a substance of very high concern under Article 57 (f) of the REACH Regulation**

Title: **Minority position of three MSC members who do not agree to the proposed identification of 4 Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (Trimellitic anhydride, TMA) (EC No. 209-008-0) as a substance of very high concern under Article 57 (f) of the REACH Regulation**

Minority position of MSC members from Italy, the Czech Republic and Malta on the proposal for identification of Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (Trimellitic anhydride or its abbreviation TMA), EC number: 209-008-0, CAS number: 552-30-7, as a substance of very high concern on the basis of the criteria set out in REACH article 57

Substance name:

In the ECHA document "Identification of substances as SVHCs due to equivalent level of concern to CMRs (Article 57(f)) – sensitisers as an example", it is stated that "classification of a substance as a sensitiser in itself is not enough in order to identify it as a SVHC under Article 57(f). The substance must also be of "equivalent level of concern to CMR substances" and it is clear that an assessment should be made on a case- by-case basis. To determine equivalent level of concern, ECHA has indicated that health effects, reversibility of effects, delay of health effects, societal concerns and threshold levels must be compared to CMRs substances.

Type and severity of possible health effects

Type and severity of the effects of the CMRs may be defined with the term "serious", according to Directive 2001/83/EC, cited on pg. 27 of the Annex XV proposal, serious means "a hazard that can result in death, could be life-threatening, could result in patient hospitalization or prolongation of existing hospitalization, could result in persistent or significant disability or incapacity or could be a congenital anomaly/birth defect or permanent or prolonged signs in exposed humans".

The effects of the CMR on the human health can be easily recognized in this definition, while TMA effects do not show the same effects on health of expose individual. The severity of health effects of respiratory sensitisers vary based on the individual that is sensitized, but they are not equivalent to CMRs that can cause disability, incapacity or death. Respiratory sensitisers may cause symptoms if exposure continues without intervention, but not in the same manner as CMRs (eg. workers that exhibit effects of sensitisation would be immediately removed from further exposure). There is no history of deaths associated with exposure to TMA. There are no recorded incidents of serious or permanent organ dysfunction. There are no recorded incidents of permanent impairment of lung function.

Irreversibility of health effects

Health effects of TMA sensitisation (allergic effects) are reversible if a person is no longer exposed to TMA and full recovery is likely to occour, referenced on page 21 of Annex XV dossier (Grammer et al., 2000). Any allergic effects such as persistent sneezing, blocked nose/sinus congestion, watery eyes/runny nose, breathing difficulties and coughing are other than in rare cases, temporary and disappear once exposure ceases. The symptoms are reversible as referenced on page 21 of Annex XV dossier (Grammer et al., 2000). Authors reported that in 35/42 individuals on disease status transferred to different job, symptoms disappeared, pulmonary function improved and specific IgG and IgE levels decreased. In practice it is highly unlikely that any worker could be exposed long enough for the elicitation phase to occur. If the individual is removed from the source of TMA exposure, the symptoms do disappear. There is no evidence of current or former TMA workers that have on-going health effects due to TMA when exposures stop.

Delay of health effects

If an individual is exposed to a cancer-causing chemical and years later, cancer develops the effects cannot be reversed. If the individuals exhibit acute effects to TMA, they can be removed from potential exposure; and without continued exposure the response will not be triggered. Because exposure to TMA can only occur at

industrial setting, it is impossible for someone to be inadvertently exposed and to have long-term exposure that would lead to severe health effects.

Derivation of a safe level of exposure

There are no doubt that, in common with all other forms of allergy, chemical respiratory sensitisation is a threshold phenomenon, in both sensitization and elicitation phases. In a recent publication, Cochrane et al. (2015) showed that sensitisation is dose related and that a derived threshold value is possible. In case of chemical respiratory sensitisers the identification of its value can be difficult. In the case of a substance used only in an industrial setting, they consider it is possible to use occupational exposure data to derive a safe threshold value.

For TMA a threshold of safe exposure can be established. Occupational Exposure Limits (OEL's), to prevent sensitisation, have been determined for TMA in over 50 countries around the world. Countries in the EU have their own threshold limits. A recent paper by Grammer et al indicates that for 302 TMA workers studied, after one year there were no positive cases of IGE identified for individuals with exposures below <0.87 µg/m^3. In a 2014 publication ACGIH recommended a TLV-TWA of 0.0005 mg/m^3 and a TLV-STEL of 0.002 mg/m^3.

Quality of life impaired

In the rare cases where someone is sensitised to TMA, once the workers are removed from TMA exposure they no longer have allergy symptoms. The sensitised person can go on to work in another position and live a normal life. Just the fact that the person is relocated or re-assigned does not necessarily impair a person's quality of life. Typically, this does not trigger a change in profession, workers are assigned a job in another part of the same factory doing a similar role and would not significantly impact their life or cause extensive retraining of those employees.

The extremely low number of staff affected by TMA exposure can easily be accommodated to another role within the business. Workers potentially exposed to TMA are only 2.8% to 4% of the total workers involved in TMA using industries.

Social concern

TMA is not found outside of industrial settings and so it should not be seen as a concern for society.

It is also important to recognize that TMA readily hydrolyses to form trimellitic acid (TMLA). TMLA is not a respiratory sensitiser, so once this conversion occurs exposure to TMA is no longer possible. TMLA is readily biodegradable in atmospheric, aquatic and soil compartments and does not bioaccumulate.

For all these reasons we cannot support the proposal for identification of TMA as SVHC substance, because TMA does not meet the criteria set forth in Article 57f and ECHA guidance for equivalent level of concern when compared to CMRs.