Minority opinion of Member State Committee members from the Czech Republic, Greece, Hungary, Ireland, Italy, Poland, Slovenia, Spain and UK on proposal to identify Hexamethylene Diacrylate (HDDA) as a substance of very high concern because, due to its skin sensitising properties, it causes probable serious effects to human health which give rise to an equivalent level of concern to those of CMR and PBT/vPvB.

We agree that there is sufficient evidence from studies in experimental animals to indicate that HDDA is a potent sensitiser and there may be grounds for classification in category 1A. We also agree that the assessment of whether a substance is of equivalent level of concern to CMRs in accordance with article 57(f) should be done on a case by case basis, using the six factors as outlined in ECHA's paper, 2012 (Identification of substances as SVHCs due to equivalent level of concern to CMRs (Article 57(f)) – sensitisers as an example, ECHA, 2012). While we do not rule out the possibility that a skin sensitiser could be identified as an SVHC in accordance with article 57(f) of REACH, we are of the opinion that in this specific case, an equivalent level of concern has not been proven. We therefore do not agree that HDDA should be identified as a substance of equivalent level of concern to those of other substances listed in points (a) to (e) of article 57 of REACH, in accordance with article 57(f) of REACH.

The ECHA paper 2012 identifies six factors that need to be addressed in order to compare the level of concern that exists between CMRs and sensitising substances. In our opinion, four of these (derivation of a safe level of exposure, delay of health effects, quality of life and societal concern), as addressed in the support document, are relatively generic in nature and could in fact be applied to all skin sensitisers. Therefore, we question whether such a generic assessment is sufficient to complete this comparison between CMRs and skin sensitisers and contribute to the equivalent level of concern argument.

For the remaining 2 factors, irreversibility of health effects and type and severity of possible health effects, we have the following concerns:

- We are of the opinion that the severity factor has not been met. We note the definition of mild skin damage in the ECHA 2012 paper as being "*e.g. a rash that can heal quickly, when the exposure to the agent is stopped"* and the definition of severe damage as being "*e.g. blistering that can burst. Skin function is impaired, possibly leading to infection. On-going exposure can lead to chronic inflammation and scar formation. Minimal or a single small focus of scarring does not normally constitute 'severe organ damage or major permanent functional change' in the skin as an organ".* In our opinion, the information presented in the support document supports the view that HDDA is a skin sensitiser which may result in allergic contact dermatitis in previously sensitised individuals. However, from the information presented in the support document, it was apparent that symptoms varied from mild to severe and no evidence was presented to indicate permanent skin damage (e.g. scar formation or chronic inflammation) or life threatening outcomes. We also note that in many of the case studies, it could not be definitively concluded that HDDA was the causative agent of the effects observed.

- As regards the irreversibility of the effect, we are in agreement that the induction phase of skin sensitisation is considered to be an irreversible state. However, we are of the opinion that the effects in the elicitation phase are usually fully reversible. The information presented in this case indicates that the skin reactions were reversible following cessation of exposure. In the most severe case outlined in the support document (Toxic epidermal

necrolysis from UV-cured printing inks, Ido, Kiyohara *et al*, 2012), the patient's symptoms did not recur within the 6 month follow-up, indicating that even the most severe effects were shown to be reversible. The other 3 occupational cases reported in the support document also demonstrate that the effects are reversible and do not recur if subsequent exposure is prevented. In the support document, it is indicated that "*skin sensitisation represents an irreversible adverse health effect"*. While we accept that the induction phase of skin sensitisation is irreversible, we are of the opinion that it in itself is not an adverse effect. The adverse effect occurs when a person is subsequently exposed to the allergen. Therefore, we feel that the irreversibility factor should be considered in that context. While there is an assumption in the support document that prolonged exposure to HDDA may lead to permanent skin damage, from the case reports available, there is no evidence of permanent adverse skin effects or that the effects persist once contact with the sensitising agent is removed. Finally, we feel that the arguments outlined in the support document with respect to the judgement of the General Court, Case T-135/13 concerning a respiratory sensitiser are not relevant for this case due to the clear difference in clinical outcomes of skin sensitisation as compared to permanent lung damage.

In summary, we do not agree that HDDA should be identified as a substance of equivalent level of concern to those of other substances listed in points (a) to (e) of article 57 of REACH, in accordance with article 57(f) of REACH. In particular, we are of the opinion that HDDA cannot be considered to be comparable to CMRs in terms of severity and irreversibility.