

Comments on The Netherlands Annex XV dossier on acrylamide

- The Netherlands has submitted an Annex XV SVHC dossier on acrylamide for the identification of acrylamide as carcinogenic and mutagenic according to Article 57(a) and (b) REACH.
- Acrylamide is **manufactured or imported in the EU for uses as an intermediate exclusively** (either as a monomer to form a polymer or as a starting material for monomers). **There are no non-intermediate uses.**
- All uses of acrylamide described in the Annex XV SVHC dossier (including uses as grouting agent) meet the definition of on-site or transported isolated intermediates under Article 3(15) REACH.
- Since acrylamide is an intermediate as defined in REACH, Title VII REACH and its Article 57(a) and (b) cannot apply to acrylamide as described in the Annex XV dossier
- Consequently, **the Annex XV dossier cannot be used for purposes of the procedures laid down in Title VII**, and it cannot be used for the identification of acrylamide as carcinogenic and mutagenic under Article 57(a) and (b) REACH.
- Accordingly, **the Annex XV dossier submitted by the Netherlands lacks legal basis, should not have been submitted and must be withdrawn.**

1. INTRODUCTION

- 1.1 In August 2009, the Netherlands submitted a dossier under Article 59(3) and Annex XV REACH¹ for the substance acrylamide.² The dossier proposes to identify acrylamide as a carcinogenic and mutagenic substance according to Article 57(a) and (b) REACH.
- 1.2 The dossier was posted on the website of the European Chemicals Agency (“ECHA”) on 31 August 2009 and the deadline for submitting comments is 15 October 2009.
- 1.3 This position paper presents the comments of the Polyelectrolyte Producers Group EEIG (“PPG”) on the Annex XV SVHC dossier for acrylamide drafted and submitted to ECHA by the Netherlands under Article 59(3) REACH (hereinafter the “dossier”).

2. COMMENTS ON THE ANNEX XV SVHC DOSSIER

- 2.1 The dossier states the following in respect to the uses of acrylamide in the European Union (“EU”): “[...] *it is estimated that up to 99.9% of acrylamide in the EU (estimated at ~100.000 tonnes per annum) is used as an intermediate in the production of polyacrylamides for a number of applications. Other uses are as on-site preparation of polyacrylamide gels (~0.1% of the acrylamide produced in the EU) and as grouting agents.*”³
- 2.2 The crucial point is that all uses of acrylamide, including on-site production of polyacrylamide gels (more accurately referred to as electrophoresis gels used in scientific/medical research) and as a grouting agent, fall under the definition of intermediates under REACH.

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ [2006] L 396/1.

² EC number: 201-173-7, CAS number: 79-06-1.

³ Annex XV SVHC dossier on acrylamide (2009), p. 27.

2.3 The wording in the dossier suggests that the use of acrylamide for on-site production of polyacrylamide gels and as a grouting agent is not a use of acrylamide as an intermediate. However, these uses clearly also meet the definition of on-site and transported intermediates as defined under REACH, as explained below:

- Article 3(15) REACH defines **intermediate** as “*a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis")*”:
 - (a) (...);
 - (b) *on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;*
 - (c) *transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.”*
- The dossier indicates that “[w]hen the acrylamide grout **polymerises** or “gels”, it solidifies into a stiff gel that is impervious to water”⁴ (emphasis added). The reference to the polymerisation process confirms that, when used in grouting, acrylamide reacts to form a polymer – a polymer is defined as “**a substance consisting of [...]**” (Article 3(5) REACH)). Since, when used in grouting applications, acrylamide is transformed into a different substance (a polymer), it meets the definition of a transported intermediate since it is “*manufactured for and consumed in or used for chemical processing in order to be transformed into another substance [the grouting polymer]*” and it is “*transported between or supplied to other sites.*”

⁴ Annex XV SVHC dossier on acrylamide (2009), p. 27.

- The same rationale applies to the use of acrylamide in polyacrylamide gels (electrophoresis gels used in scientific/medical research) – polyacrylamides are polymers, hence acrylamide is necessarily and exclusively an intermediate because it reacts to form another substance, *i.e.*, a polymer (polyacrylamide).

3. AS AN INTERMEDIATE, ACRYLAMIDE CANNOT BE COVERED BY TITLE VII AND THE IDENTIFICATION PROCEDURES PROVIDED THEREIN (INCLUDING IN ARTICLE 57) ARE NOT APPLICABLE

- 3.1 According to Article 2(8) REACH, on-site isolated intermediates and transported isolated intermediates are exempt from Title VII REACH. This means that, because it is always used as an on-site or transported intermediate, acrylamide cannot be subject to any identification or other procedure laid down in Title VII, including listing in the candidate list or in Annex XIV to REACH.
- 3.2 The Annex XV dossier submitted by the Netherlands covers uses of acrylamide as an intermediate exclusively. As a result, the dossier cannot serve for the application of Article 57, or any other provision in Title VII, and the submission of the dossier on acrylamide therefore lacks support in a legal provision.

4. CONCLUSION

The Annex XV SVHC dossier on acrylamide submitted by the Netherlands in August 2009 covers, exclusively, uses of acrylamide as an on-site or transported isolated intermediate (as defined in Article 3(15) REACH). All such uses of the substance acrylamide are exempt from title VII REACH according to Article 2(8)(b) REACH.

Consequently, the dossier cannot be used for the purposes of the procedures laid down in Title VII, and cannot be used for the identification of acrylamide as carcinogenic and mutagenic under Article 57(a) and (b) REACH.

Accordingly, the Annex XV dossier submitted by the Netherlands lacks legal basis, should not have been submitted and must be withdrawn. Furthermore, acrylamide should be removed from the list of dossiers submitted for identification of substances of very high concern (SVHC).

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