REACTION FROM THE EUROPEAN UNION TO THE COMMENTS RECEIVED FROM THE UNITED STATES CONCERNING NOTIFICATION

G/TBT/N/EU/407

DRAFT COMMISSION REGULATION AMENDING ANNEX XIV TO REGULATION (EC) NO 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL CONCERNING THE REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH)[1]

The European Union (EU) would like to thank the United States (US) authorities for their comments of 16 November 2016 on the draft "*Commission Regulation amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*", in relation to use of 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated (Triton X-100) in the biopharmaceutical industry.

The EU is aware of the concerns of the biopharmaceutical sector with regards to the proposed inclusion of Triton X-100 in Annex XIV. As stated in the comments submitted by the US authorities, similar comments were submitted by several individual companies or industry associations to the public consultation on Annex XIV (public feedback mechanism). These submissions also included a request to the EU for conducting an impact assessment in relation to the use of Triton X-100 in the biopharmaceutical industry.

First, the EU would like to underline that the fact that a substance is subject to the authorisation requirement does not imply a ban on using the substance, but requires companies that cannot replace the substance to obtain an authorisation for continued use after the "*sunset date*".

With regard to the request that the EU carries out a benefit/risk management assessment in relation to the use of the substance in question in the biopharmaceutical industry, the EU would like to highlight that a socio-economic assessment is an integral part of the authorisation procedure. In concrete terms, the decisions on granting an authorisation take into account the opinions of the scientific committees of the European Chemicals Agency (ECHA), i.e. the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC). The socio-economic impacts are therefore thoroughly assessed on the basis of information contained in individual applications for authorisation, which includes comparison of costs and benefits associated with the continued use of the concerned substance and an assessment of economic and technical feasibility of potential alternatives.

Furthermore, when preparing the draft amendment of Annex XIV to REACH, the EU took into account the information on socio-economic aspects that had been made

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474543758075&uri=CELEX:02006R1907-20160714

available by the industry concerned, both in the context of the call for information conducted by ECHA on the draft 5th recommendation for prioritisation of substances to be included in Annex XIV and through numerous direct submissions to the EU. In that regard, the EU notes that both in the 45-day ECHA public consultation in 2012 on the identification of that group of substances as substances of very high concern under Article 57(f) of REACH, and in the 90-day ECHA public consultation on the draft recommendation for inclusion of those substances in Annex XIV, comments were submitted by companies active in the pharmaceutical sector. The EU would like to clarify that this group of substances was not identified by the CAS numbers because an exhaustive list of such numbers for all the substances covered by the group was not available, and therefore the substance group was identified by its chemical name.

The EU is also aware of the concerns of the pharmaceutical industry about the length of authorisation periods in relation to the long timelines that are required for development of innovative pharmaceutical products as well as for the necessary clinical trials and the regulatory approval of such products. In order to address such concerns, the EU has started a discussion with ECHA and the EU Member States on possible criteria for setting review periods longer than twelve years in authorisation decisions.

The EU would like to thank the US once again for providing comments on this draft and hopes that the responses conveyed sufficiently clarify the issue.

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