AdvaMedDx
Vital Insights | Transforming Care

September 20, 2013

European Chemicals Agency (ECHA)
Annankatu 18
P.O. Box 400
FI-00121 Helsinki, Finland

For Electronic Submission to ECHA Website

Re: Comments on the Draft Recommendation of Substances for Inclusion in Annex XIV including the Prioritisation of the Substance Name: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) Includes the Triton X-100 family

Dear Sir or Madame:

On behalf of AdvaMedDx, a Division of the Advanced Medical Technology Association (AdvaMed), we provide these comments on the ***Draft Recommendation of Substances for Inclusion in Annex XIV of Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH).*** Our comments are specific to the 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) substance, which includes the Triton X-100 family.

AdvaMedDx member companies produce advanced, *in vitro* diagnostic (IVD) tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and reduce overall health care costs. Functioning as an association within AdvaMed, AdvaMedDx is the only multi-faceted, policy organization that deals exclusively with issues facing IVD companies in the United States and abroad. Our membership includes manufacturers engaged in the development of innovative technologies supporting the advancement of public health, including manufacturers of IVD products for which the Triton X-100 family is commonly used in reagents and wash solutions.

We write to echo strong support for the comments submitted on this topic by the European Diagnostic Manufacturers Association (EDMA). Similarly, AdvaMedDx asks that ECHA recommend against prioritising 4-tert-OPnEO for inclusion in Annex XIV. There is lack of data regarding these substances in the dossier. Furthermore, we are very concerned that the impact would be substantial and disproportionate to the IVD medical device sector with wide-ranging impact on the global supply chain. Patient and health provider access to these critical IVD technologies is fundamental to global health care.

AdvaMedDx members have identified that some substances in the family of 4-tert-OPnEO are likely to be used under the trademark of Triton (primarly those in the Triton "X" family although not exclusively). Additionally, there are potentially multiple manufacturers using other trade names. Tritons are very commonly used in the production of IVD medical devices that are produced and marketed worldwide. They have a number of significant uses in the IVD industry including:

- As an effective surfactant/wetting agent, it reduces unspecific reactions, prevents protein binding on surfaces, and prevents aggregation of proteins or microparticles.

- Promotes solubility and stabilizing hydrophilic proteins allowing their detection.

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- Lyses cells and inactivates plasma products which are essential in blood diagnostics.

- In wash solutions, it is used in one or more of the steps for processing samples taken from patients to remove unbound material from process solutions like proteins that could interfere with the way the test works.

By preventing unwanted reactions with components of the assay, they play an important role in assuring accuracy and overall test performance for entire portfolios of diagnostic products. To find replacements for these surfactants will not only be challenging, but it would entail significant studies including validation and reregistration on a product-by-product basis in Europe and internationally for minute amounts of substances that directly impact the safety and performance of IVD products. Uses such as the purification of blood plasma products and use in *in vitro* diagnostic medical devices represent a very low percentage (estimated at less than 1%) of the use in the EU. This annual usage for IVDs imported into the EU is orders of magnitude below other uses within the scope of Authorisation cited by ECHA in the Annex XV report. At the same, the impact would be profound and wide-ranging with respect to patient care and future access to these innovative technologies and investment in other new IVD product development.

Thank you for the opportunity to provide comments. We respectfully request that ECHA not prioritise 4-tert-OPnEO for inclusion in the Annex XIV. A careful consideration should be made to assure that these innovative technologies are available globally without interruption to the public and the medical community.

Sincerely,

/s/

Khatereh Calleja, JD
Vice President
Technology and Regulatory Affairs