"Have there been any recent updates to the EU's RoHS Directive?"

On 14 March 2016, the Oeko-Insitut announced a news RoHS stakeholder consultation on two requests for new exemptions from the EU RoHS Directive. It is also worth a reminder that beginning July 22, in vitro diagnostic medical devices will come within the scope of RoHS for the first time.

Per the new exemption requests, one proposed exemption is for lead in bearings and bushes of professional-use non-road equipment engines meeting certain criteria, and the other is for lead in solders used in a specific in-vitro diagnostic application. Details on the exemption requests for this consultation are as follows:

- Request 2016-1 is for lead in bearings and bushes of professional-use non-road equipment engines that meet the following criteria: 15 litre and larger total displacement professional use; less than 15 litre engines for professional non-road equipment designed for use where the time between a signal to start and full load is required to be less than 10 seconds, for example in emergency, standby generators and peak shaving generators; less than 15 litre engines for professional non-road equipment designed for operation in harsh and dirty environments such as construction sites, quarries, mines, etc. for example, in drills, air compressors, rock crushers, irrigation pumps and tub grinders

- Request 2016-2 relates to lead in solders used to construct and connect to Peltier thermal cyclers used for in-vitro diagnostic analyzers that use polymerase chain reaction.

The consultation on these proposed exemptions is open until 9 May 2016. If exemptions are granted for these requests, they will be added to Annex IV of RoHS 2.

Under RoHS, exemptions from the established restrictions may be permitted in cases when substitution is not possible. If granted, exemptions are limited in scope and duration. They are provided for specific substances used in specified applications in specified products, and as such, the exemption does not apply to the whole product. In can be helpful to note that exemptions are not limited to the applying company; a producer of a product with an exempted application may utilize that exemption even if they were not the applying company.

The Oeko-Institut provides assistance to the European Commission on technological, socio-economic and cost-benefit assessments related to exemptions from the RoHS Directive, and it evaluates exemption requests in groups that it calls "packs". Each pack evaluates applications for granting, renewing or revoking exemptions, to be included in or deleted from Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS or RoHS 2).

Beginning July 22, 2016, in vitro diagnostic medical devices will come within the scope of RoHS for the first time. Industrial monitoring and control instruments (M&C) will come within the scope one year later, on July 22, 2017. And on July 22, 2019, four more substances – DEHP, BBP, DBP and DIBP – will become restricted from use in products regulated under RoHS. The new phthalate restrictions will apply after a transition period for in vitro diagnostic medical devices and industrial M&C.

How do you keep up with all of the regulatory and industry announcements affecting your organization's products, suppliers and markets? More importantly, are you able to quickly analyze their impact on your business? Regulatory Monitoring from 3E can help. To learn more, please click here.