RoHS: „open scope“ takes effect and maximum concentration values for phthalates

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The scope of the Electrical Substances Ordinance (implementation of Directive 2011/65/EU into national law) was previously limited to the categories of devices mentioned in in § 1 No. 1 of the Ordinance, in Nos. 1-10. As of 22 July 2019, the "open scope" (No. 11) is applicable as well. Background: the Ordinance contains a transitional provision for other electrical and electronic equipment which did not fall within the scope of the Electrical and Electronic Equipment Act before the Ordinance took effect. Such electrical and electronic equipment was exempt from the restrictions if it was placed on the market prior to the passage of 21 July 2019. Since that date, even equipment which was previously not included is subject to the restrictions imposed by the Ordinance.

Additional restrictions on four new phthalates

In addition to the open scope which is now in effect, as of 22 July 2019, companies also need to observe maximum concentration values (0.1% by weight for each homogenous material) for the following phthalates:

- Di (2-ethylhexyl) phthalate (DEHP)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)

However, exceptions apply for medical devices, including in-vitro diagnostics, as well as monitoring and control instruments, including industrial monitoring and control instruments. Such devices may still be placed on the market until the passage of 21 July 2021.

Affected by the Ordinance? This is what companies can do

Companies are still finding themselves unprepared when the Ordinance is applied to their devices (despite the transitional period) since their devices formerly did not fall under Categories Nos. 1-10. As a result, they fail to take adequate internal precautions for eventual application of the Ordinance, or take no precautions at all.

Companies affected by the Ordinance should first conduct an analysis to determine which of their devices contain excessive concentrations of restricted substances. Then, the Ordinance's transitional provisions should be examined. If no transitional provisions apply, the next step is to examine Annexes III and IV if the RoHS Directive, which contain numerous exemptions from the restrictions. If it is ultimately determined that a device is subject to the Ordinance and that no exemption or transitional provision applies, it must be ensured that all substance restrictions are observed. In particular, it is important in this regard to ensure that parts purchased from suppliers conform to the restrictions. The duties which the Ordinance imposes on manufacturers must also be observed before the devices can be placed on the market (e.g. technical documentation, EU Declaration of Conformity and CE marking).

Conclusion

Companies should analyze their products for the substances cited in the Ordinance and take measures to rectify the situation if necessary. In particular, the exemptions specified in Annex III and IV of the RoHS Directive should be checked continuously in the future in order to avoid the negative economic consequences of non-conforming production processes (e.g. temporary suspension of production and fines of up to 100,000 Euros).

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