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REACH AND DIRECTIVE 2011/65/EU (RoHS)

A COMMON UNDERSTANDING

INTRODUCTION

Directive 2011/65/EU (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) entered into force on 21 July 2011 and Member States were obliged to bring national implementing measures into effect by 2 January 2013.

Once a substance is included in Annex II to RoHS, EEE placed on the market may not contain that substance in a concentration that exceeds the maxima specified in Annex II; such concentration is expressed by weight in homogenous material. However, this prohibition does not apply to exempt applications listed in Annexes III and IV.

Article 1 of RoHS states that the aim of the Directive is to contribute "to the protection of human health and the environment, including the environmentally sound disposal of waste electrical and electronic equipment (EEE)". Like most product-specific harmonising legislation, it does so by prohibiting the placing on the market of products containing substances in certain concentrations (sometimes providing for exempt applications). Although it does not specifically regulate the manufacturing process itself, the methodology behind the listing of substances in Annex II to RoHS could address risks arising at that stage. This methodology is required by Article 6(1) of RoHS to be “coherent” with REACH and could even be fully aligned with REACH risk assessment provisions (which also include waste management measures to reduce human or environmental exposure during disposal and recycling).

Furthermore, in determining conditions for the placing on the market of EEE, RoHS takes into account the waste management and recycling of EEE, and the potential for exposure (of workers and the environment) during waste management and recycling is probably greater than during the manufacture of new EEE.

Horizontal legislation such as REACH and product-specific vertical Union legislation such as the RoHS Directive are complementary. REACH aims to ensure that the risks presented by substances are adequately controlled throughout their whole life cycle, including those

occurring in the waste stream. In addition, RoHS contributes to the sound management of waste EEE. The Commission and the co-legislator wanted both pieces of legislation to work together and decided they should apply without prejudice to each other.

Their scopes partially overlap since REACH applies to all substances as such, in mixtures or in articles, including substances in EEE within the scope of RoHS. This paper is based on the premise that as far as possible, RoHS should be given priority to regulate issues pertaining to the use of substances in EEE.

There is therefore a need to further explore the **common understanding** on how to manage future regulatory action on the same chemical substances under REACH and RoHS, in particular in cases where

- one instrument already regulates a substance and an initiative is launched under the other in relation to the same substance; and
- where neither instrument yet regulates the substance in question but action under one or both is contemplated.

This paper should be systematically taken into account, as far as is practical, in both REACH RMO procedures and in the framework of the 2020 SVHC roadmap.

A. RESTRICTIONS

The following scenarios should be examined:

1. a restriction is proposed under REACH for the placing on the market of articles containing a substance[1] (including EEE) and the substance is already listed in Annex II to RoHS;
2. a new substance is proposed for inclusion in Annex II to RoHS and a restriction relating to articles containing that substance (including EEE) is already in Annex XVII to REACH;
3. the placing on the market of articles containing a particular substance is not yet restricted at Union level under either instrument but a proposal for a restriction under REACH is imminent and so it has to be clarified how RoHS should be taken into account.

1. Restriction proposed under REACH for a substance already in RoHS

The simplest way to avoid duplications and/or inconsistencies for a given substance already included in RoHS is, to exclude EEE within the scope of RoHS from the scope of a proposed REACH restriction also covering EEE. This approach was adopted for Diphenylether, octabromo derivative (entry 45 of Annex XVII to REACH). It avoids the problem described

[1] In REACH parlance, "a substance in an article"

in the REACH review, relating to the use of cadmium in electrical contacts (entry 23.7.) where both instruments cover the same substance and applications – but slightly differently.

The restriction process is laid down in Article 69 of REACH and whether the Commission requests that ECHA prepare an Annex XV dossier or a Member State prepares one, the criteria are the same: there must be a risk to human health or the environment which is not adequately controlled and needs to be addressed. The Annex XV dossier must demonstrate that Union-wide action is necessary beyond any measures already in place.

The question therefore is whether RoHS can be considered to afford adequate control of the risks presented by the substance in EEE throughout the lifecycle of the product such that those risks do not need to be addressed under REACH.

The assessment provided for in Article 6 of RoHS should reflect the principle that a Union-wide restriction is the most appropriate means of regulating the use of a substance in EEE and that the objective of RoHS is to contribute to the protection of human health and the environment including the environmentally sound recovery and disposal of waste EEE.

The general restriction in Article 4(1) of RoHS focuses on conditions for the placing on the market of EEE and Article 6 of RoHS requires the Commission to take "special account" of risks presented during the disposal and recycling of EEE, The [Methodology for Identification and Assessment of Substances for Inclusion in Annex II to RoHS] [2] currently focuses on hazardous substances and concerns related to them during waste management. The manufacturing and use of the substance is not part of the current version. However the methodology leading to the inclusion of substances in Annex II to RoHS could be adapted to take account of risks to human health and to the environment during the manufacturing process and the use phase. This methodology is required by Article 6(1) of RoHS to be "coherent" with REACH and could even be fully aligned with REACH risk assessment provisions (which also include waste management measures to reduce human or environmental exposure during disposal and recycling).

Furthermore, in determining conditions for the placing on the market of EEE, RoHS takes into account the waste management and recycling of EEE, and the potential for exposure (of workers and the environment) during waste management and recycling is probably comparable or higher than during the manufacture of new EEE. Therefore, in those situations in which the RoHS restriction generally takes into account the protection of human health and the environment, at all stages, similarly to REACH restrictions, the latter should exclude EEE from their scope of application, indicating that the use of the substance in question in EEE is restricted by the RoHS Directive.

[2] http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/Manual_September_2013.pdf (see third bullet of section 4.1 on page 24)

2. Restriction in place under REACH when a new substance is proposed for inclusion in RoHS

The current draft of the methodology for identification of substances for inclusion in Annex II to RoHS states that a substance which is a candidate for inclusion in Annex II will be excluded from the identification exercise if it is listed in Annex XVII to REACH and the restriction covers EEE. Indeed, if REACH restricts the use of a substance (in all products, including EEE as finished products), RoHS may not need to look at this substance anymore as its use is already restricted by REACH. This approach follows the Commission responses provided during the legislative procedure for the RoHS recast, the aim of which was to avoid having restrictions of the same substance, applicable to EEE, both in REACH and RoHS.

However, it is conceivable that once a substance is subject to a restriction in Annex XVII to REACH, RoHS decides to take action in order to establish the same or more stringent measures for EEE. In that event, Annex XVII to REACH would need to be amended to remove EEE from the scope of the restriction in accordance with the reasoning described in section 1 above, and the entry in Annex XVII should indicate that the use of the substance in question in EEE is restricted by the RoHS Directive.

There are precedents for using Article 131 REACH as the legal basis for amending Annex XVII to delete restrictions where a similar restriction comes into being under the Stockholm Convention and subsequently in Regulation (EC) No 850/2004 on persistent organic pollutants). The same logic (avoiding double regulation) would apply to the amendment of a restriction in Annex XVII to exempt EEE from the scope of an existing restriction.

3. Annex XV proposal for a restriction under REACH for a substance used in EEE but not yet in RoHS

What of the case where the Commission (by requesting ECHA) or a Member State initiates the preparation of an Annex XV dossier for the placing on the market of articles containing a substance which is used in EEE?

The RoHS Directive and its national implementing measures themselves are not specific enough to constitute a “measure already in place”, justifying the exemption of EEE, where the substance in question does not yet appear in Annex II. Therefore, a restriction could be imposed under REACH and later amended to carve out EEE if/when the substance is added to Annex II to RoHS.

Alternatively, the REACH restriction procedure could be used to prepare an amendment of RoHS outside the periodic review (expected to be every 4 years): in fact, when the opinions from RAC and SEAC confirm that a restriction for a substance in EEE is justified and proportionate, the Commission could decide to implement it via an amendment of the RoHS Directive, rather than an amendment of Annex XVII to REACH. When a need to restrict a substance in EEE has already been identified at an earlier stage (e.g. the RMO analysis),

rather than initiating the restriction procedure under REACH, the Commission or a Member State could also decide to initiate a restriction directly under RoHS, outside the normal cycle.

The REACH and RoHS restrictions would then be synchronised so that the REACH restriction could exempt EEE from its scope under the premises described in section 1 above.

B. AUTHORISATION REQUIREMENT

The REACH authorisation requirement prohibits a manufacturer, importer or downstream user from placing a substance on the market for a use (or using it himself) unless the use is authorised or exempt from the authorisation requirement. “A use” covers the use of the substance on its own or in a mixture and the incorporation of the substance into an article. However all EEE imported from outside the EU is outside the authorisation requirement.

In keeping with the general principle that the focuses of REACH and RoHS are complementary, the objective is to avoid overlapping requirement on products containing EEEs whilst maintaining the possibility that REACH authorisation could be considered necessary when it comes to regulating the use of articles especially at the stage of incorporation of a substance into an article.

The following scenarios should be examined:

1. a substance which has already been included in Annex II to RoHS is proposed for inclusion in Annex XIV to REACH.

2. a new substance is proposed for inclusion in Annex II to RoHS and that substance has already been included in Annex XIV to REACH.

3. a substance is not yet included in Annex II to RoHS nor in Annex XIV to REACH but such risk management measures are contemplated;

1. Substance already in Annex II to RoHS is proposed for inclusion in Annex XIV to REACH

(a) Where RoHS has not provided for exempt applications, the placing on the market of EEE containing the banned substance is excluded, but in principle the use of the substance for the manufacturing of EEE is still allowed (as it is outside of the scope of RoHS). In the very unlikely scenario that a company continued the use of the banned substance to manufacture EEE, although it would not be able to place the EEE on the EU market, the authorisation requirement under REACH would apply.

(b) Where RoHS provides for exempt applications (so that certain EEE containing a given substance may be placed on the market in specified cases), the incorporation of that

substance in EEE by EU manufacturers would be subject to the authorisation procedure under REACH. However, the possibility is also open to exempt the uses covered by the RoHS restriction (including its exempted applications) from the authorisation process under REACH pursuant to Article 58(2) of REACH on the basis of the arguments described above.

An additional issue to be considered where RoHS provides for exempt applications is whether the pressure to substitute would be lost if the incorporation of substances in EEE was exempted from the REACH authorisation requirement. In this regard, it should be noted that decisions taken under Article 5 of RoHS to include materials in Annexes III and IV (exempt applications) must take into account the practicability, reliability or socioeconomic impact of substitution. Moreover, the exemptions are time limited and will only be renewed after submission of the information listed in Annex V to RoHS, including updated details of the practicability and reliability of substitution, an analysis of possible alternatives and a timetable for action to develop /apply possible alternatives. All of these requirements may be seen as mirroring the substitution objective of the REACH authorisation procedure.

While recognising the preference for RoHS to deal with all aspects of the incorporation of substances in EEE, a case-by-case analysis may conclude that the restriction of a substance under RoHS with exempted applications does not constitute "proper control" for the purposes of Article 58(2) of REACH. In this event it is worth underlining that subjecting the inclusion of a substance to REACH authorisation for manufacture of EEE for which an exemption has been granted under RoHS will only apply to EU manufacturers and not to imported EEE manufactured outside the EU. Consequently, there would be an additional burden for EU manufacturers until such time that the exemption under RoHS is terminated.

2. Substance already included in Annex XIV to REACH when it is proposed to be restricted under RoHS

In these circumstances, even though it appears that RoHS is capable of affording proper control of the risks associated with a substance for the purposes of Article 58(2) of REACH, it would not have been possible to exempt the incorporation of the substance in EEE from the authorisation requirement when the decision was taken to include the substance in Annex XIV (as there was no RoHS restriction).

(a) Where RoHS restricts without exemptions, the authorisation requirement would apply to companies using the substance in the manufacture of EEE but obviously companies intending to place such EEE on the market in the Union would not be expected to use the substance in its manufacture as such placing on the market would be banned by RoHS.

Having RoHS restrict the substance would ensure a higher level of protection of human health and the environment, as well as avoiding disruption of the internal market, as it would address at the same time articles produced in the EU and articles imported into the EU.[3]

When RoHS restricts without exemptions, any authorisations for that use already granted under REACH effectively become redundant. Without corresponding exemptions in Annexes III and IV to ROHS, companies authorised to incorporate a substance in EEE would find no demand for their activities. As the ultimate objective of REACH authorisation is the substitution of substances of very high concern, it is difficult to argue that there are legitimate expectations on the part of companies to continue using those substances in the long run. Hence a restriction in RoHS on the placing on the market of EEE containing such a substance, beginning on the expiry of the first authorisation period set by the review clause, would not be at odds with the authorisation process in REACH.

(b) Where RoHS restricts with exemptions, the situation differs from that described above in that there will be a need to consider whether there is added value in continuing the authorisation requirement under REACH for those exempted applications under RoHS.

The considerations in point 1(b) should be taken into account. The results as well as the information derived from the authorisation process in REACH could give very good indications whether to provide for exempt applications under RoHS,

3. Substance not yet included in Annex XIV to REACH and not yet in RoHS

The options are either

- to proceed with inclusion of the substance in Annex XIV to REACH and exempt the incorporation of the substance in EEE later (except if there are good reasons for maintaining the authorisation requirement), once RoHS affords proper control of the risk, or
- to delay the REACH procedure pending inclusion of the substance in Annex II to RoHS.

With regard to the latter option, if substances could be added to RoHS with reasonable frequency, the situation described in Part 2 above may be avoided. If the RoHS procedure is begun early enough (perhaps as soon as it seems likely that a substance used in EEE will be considered a priority for inclusion in for Annex XIV by ECHA or during the RMO analysis) and concluded in time, it will be possible to consider whether to exempt the use in EEE from the authorisation requirement when the substance is added to Annex XIV to REACH.

[3] In such circumstances, to achieve the same objective, REACH would have to enact a dual approach of an authorisation requirement coupled with a restriction under Article 69(2) regulating imported articles after the sunset date has passed.

Companies that are able to justify the continued use of a SVHC in specific EEE applications can apply for a general exemption under RoHS instead of having to apply for individual authorisations under REACH.