



ORGALIME

WORKING DOCUMENT:

COMPARISON ON RESTRICTION PROCESS AND CRITERIA under REACH and under RoHS

Last update: Brussels, 5 November 2008

	Directive 2002/95/EC on RoHS	Regulation N° 1906/2007 REACH
ISSUE:	Who can initiate a restriction procedure?	
	<ul style="list-style-type: none"> • European Commission 	<ul style="list-style-type: none"> • European Commission • A member state
ISSUE:	What can be restricted?	
	<ul style="list-style-type: none"> • Use of certain hazardous substances in electrical and electronic equipment that falls within the scope of the directive 	<ul style="list-style-type: none"> • Use of any substance in its own, in a preparation and/or in an article (also beyond EEE industry)
ISSUE:	What legal format would a restriction take?	
	<ul style="list-style-type: none"> • Directive based upon art. 95 of the EC Treaty (to be adopted under co-decision procedure) • National transposition by member states required 	<ul style="list-style-type: none"> • Any restriction will take form of an amendment of REACH annex XVII according to comitology procedure • REACH restriction procedures themselves are established in a regulation based upon art. 95 of the EC Treaty (no national transposition necessary)
ISSUE:	What criteria have to be considered for restricting the use of a substance?	
	<ul style="list-style-type: none"> • Environmental criteria 	<ul style="list-style-type: none"> • Environmental criteria • Socio economic criteria • Risk (hazard and exposure)

ISSUE:	What procedure applies for the <u>preparation</u> of a restriction dossier?	
	<ul style="list-style-type: none"> • No particular procedure foreseen 	<ul style="list-style-type: none"> • See annex: Guideline 11 of ORGALIME REACH GUIDE concerning restriction procedure under REACH
ISSUE:	Does a risk assessment have take place before restricting the use of a substance?	
	<ul style="list-style-type: none"> • No, not foreseen in the directive 	<ul style="list-style-type: none"> • Yes, foreseen in REACH restrictions chapter
ISSUE:	What is the average timeline for adoption of a restriction?	
	<ul style="list-style-type: none"> • No time schedule for internal COM preparations • Restrictions require COM proposal to be adopted by the European and Council according to co-decision procedure (average time line: 2 to 3 years) • Deadline for member states' national transposition granted in existing RoHS directive is 19 months (has to be added to timeline needed for co-decision) 	<ul style="list-style-type: none"> • Less than 20 months as of publication of an annex XV Dossier at European Chemicals Agency (ECHA) website • COM proposal to be adopted via comitology
ISSUE:	Are exemptions possible?	
	<ul style="list-style-type: none"> • Principle of the directive is the ban of a substance • Exemptions can be sought as adaptations to technical and scientific progress (so far according to comitology procedure; as from now onwards according to comitology with scrutiny procedure, i.e.: further on veto right for the European Parliament) 	<ul style="list-style-type: none"> • Restriction shall not apply to the manufacture, placing on the market or use of a substance: <ul style="list-style-type: none"> ○ In scientific research and development. ○ In PPOD if Annex XVII mentions it, as well as the quantities exempted. ○ For the use of substances in cosmetic products, as defined by Directive 76/768/EEC, regarding restrictions addressing the risks to human health. • Possibility of exemptions (of a use of restricted substance in a certain application) to particular restrictions in future amendments of REACH to be checked • For substances that have been restricted, no use can be authorised if the authorisation would mean a relaxation of that restriction (Article 60.6 REACH)

ISSUE:	Are Maximum Concentration Values established for compliance? What do they refer to?	
	<ul style="list-style-type: none"> • MCVs established in COM Decision 2005/618/EC • Homogeneous material defined in COM Guidance document 	<ul style="list-style-type: none"> • REACH <u>Notification and Registration Requirements</u> (art. 7) are based on presence of a substance above 0.1% of the weight of the whole article. However: • REACH <u>Restrictions</u> Chapter open for any reference – implementation of Directive 76/769 specifies concentration values and their references on a case by case basis (e.g.: for plastics, 0.1% of the weight of the plastic material, or for toys, weight of the toy or part of the toy); <p>IMPORTANT NOTES:</p> <ul style="list-style-type: none"> • Interpretation of article 7 REACH does not automatically apply for future restrictions • Inclusion of a substance in candidate list triggers authorisation procedure and information requirements. Inclusion of a substance in candidate list, however, is not a pre-condition for establishing REACH restrictions (other substances than those listed in the candidate list could be restricted) • In areas where restriction exists, the Commission cannot grant an authorisation for a restricted use, if the authorisation would mean a relaxation of that restriction (Article 60.6 REACH). • As soon as a substance has been included in Annex XIV REACH, it cannot be subject to new restrictions on their own or in preparations (Article 58.5 REACH). <i>However, after the inclusion of a substance in Annex XIV REACH, substances <u>in articles</u> can be subject to a restriction if ECHA considers that the use of the substance in article causes a risk for human health or the environment which is not adequately controlled (Article 69.2 REACH).</i>
ISSUE:	Do stakeholders have to be consulted?	
	<ul style="list-style-type: none"> • No formal consultation process foreseen for co decision procedure on adoption of a restriction • For exemptions, stakeholder consultation is foreseen in art. 	<ul style="list-style-type: none"> • Yes, formal consultation mechanism foreseen after publication of an annex XV dossier at ECHA website (commenting on risk assessment and socio economic

	5 (written consultation)	assessment possible for interested parties)
ISSUE:	Is there room for national derogations?	
	<ul style="list-style-type: none"> In principle no, however, national transposition process has shown relevant divergences being introduced in different member states; also, member states diverge from granted exemptions at EU level 	<ul style="list-style-type: none"> Derogation period included in REACH regulation, which provides that stricter national restrictions are allowed until 1.6.2013 “only” Otherwise, REACH as a regulation does not require transposition by member states
ISSUE:	Is a review clause foreseen?	
	<ul style="list-style-type: none"> Any exemption has to be reviewed at least every 4 years after it has been added to the annex 	<ul style="list-style-type: none"> Yes
	Are details foreseen on market surveillance?	
	<ul style="list-style-type: none"> No 	Yes, member states are required to establish a network of cooperation
ISSUE:	Other differences	
Scope	<ul style="list-style-type: none"> Electrical and electronic equipment falling under the categories 1, 2, 3, 4, 5, 6, 7 and 10 set out in Annex IA to Directive No 2002/96/EC (WEEE) and to electric light bulbs, and luminaires in households. RoHS does not apply to spare parts for the repair, or to the reuse, of electrical and electronic equipment put on the market before 1 July 2006. 	<ul style="list-style-type: none"> All substances on their own, in preparations and in articles (also beyond EEE sector) Few exemptions to scope (see Orgalime REACH guideline 2)

ANNEX: Guideline 11 of ORGALIME REACH GUIDE concerning the restriction procedure in REACH

5.11. Guideline 11: Restriction procedure

Title VIII of the REACH Regulation foresees a restriction procedure for the manufacture, placing on the market and use of substances on their own, in preparations or in articles, which represent too high a risk for human health or the environment and which needs to be addressed on a Community-wide basis.

If a DU uses a substance either on its own, in preparations or in articles, which is subject to a restriction, he is allowed to continue using it, only if he complies with the conditions of the restriction.

Restrictions are listed in Annex XVII REACH. Annex XVII initially includes the current marketing and use restrictions of Directive 76/769/EEC. As of 1 June 2009, Directive 76/769/EEC will be repealed.

Restrictions, whether new or amending an Annex XVII entry, take the shape of a Commission's decision, which is adopted according to comitology procedure. Decisions must take into account the socio economic impact of the restriction, including the availability of alternatives.

Exemptions to the restriction procedure (Article 67 REACH)

Restriction shall not apply to the manufacture, placing on the market or use of a substance:

- In scientific research and development.
- In PPORD if Annex XVII mentions it, as well as the quantities exempted.
- For the use of substances in cosmetic products, as defined by Directive 76/768/EEC, regarding restrictions addressing the risks to human health.

Preparation of a proposal for restriction (Article 69 REACH)

ECHA (at the request of the Commission) or any Member State may initiate a restriction procedure by compiling a so-called "Annex XV" dossier.

Member States have 12 months to prepare the dossier, from the date of notification to ECHA of their intention to prepare such dossier. ECHA will suggest a restriction within 12 months of the receipt of the request by the Commission.

ECHA has the duty to publish the Commission or Member State's intention to launch a restriction procedure for a substance and has to inform those who submitted a registration dossier for that substance. ECHA will further maintain a list of substances for which an "Annex XV" dossier is underway or planned. No other restriction dossier on the same substance present on the list may be introduced.

Before suggesting a restriction, it has to be demonstrated in the dossier that the risk is not adequately controlled and requests action on a Community-wide basis, beyond measures already in place.

The dossiers conforming with Annex XV and suggested restrictions must further be made publicly available on the ECHA website (without prejudice to Article 118 and 119 REACH, that is protection

of confidential business information). Interested parties are invited to submit within 6 months of the publication:

- a) Comments on dossiers and suggested restrictions.
- b) A socio economic analysis or information contributing to the suggested restrictions, providing input on the advantages and drawbacks of proposal. It must conform to the requirements in Annex XVI.

ECHA committees' opinions (Articles 70 and 71 REACH)

The Committee for Risk Assessment, within 9 months of the publication of the suggested restriction, has to provide an opinion as to whether the suggested restriction will appropriately reduce the risk to human health and the environment. In its opinion, the committee must take into account the Annex XV dossier and the views of interested parties.

Within 12 months of the publication of the suggested restriction, the Committee for Socio Economic Analysis also has to formulate an opinion on it, based on the socio economic impact and socio economic analysis or information provided by interested parties. ECHA must publish the draft opinion of the Socio Economic Analysis Committee on its website and invite interested parties to submit comments no later than 60 days from the publication of the draft opinion.

If the opinion of the Risk Assessment Committee diverges significantly from the suggested restriction, ECHA has the possibility to postpone the deadline for the opinion of the Committee for Socio Economic Analysis by a maximum of 90 days.

Once finalised, ECHA will publish the opinion of the two committees (without prejudice to Article 118 and 119 REACH) on its website without delay.

Commission's Decision

The Commission has the duty to prepare a draft amendment to Annex XVII in the form of a Commission's Decision within three months of the reception of the opinion of the Committee of Socio Economic Analysis or by the end of the deadline established in Article 71 if that committee does not form an opinion. A final Decision will be taken according to the procedure described in Article 133.4 REACH (comitology procedure). The draft amendment must be sent to Member States at least 45 days before voting. The Commission must provide explanation if the draft amendment diverges from the original proposal or does not take the opinions of the committees into account.

Restriction procedure in summary

WHO	WHAT	WHEN
MS	Preparation of Annex XV dossier (to be completed within 12 months of date of notification to ECHA)	From 1 June 2009
ECHA on request of COM	Preparation of Annex XV dossier (within 12 months of request of COM)	From 1 June 2009
ECHA	To maintain a register of Annex XV dossiers planned or underway	

ECHA	To publish on ECHA website Annex XV dossier and proposed restriction	
Interested parties	To submit comments on dossier or socio economic analysis	Within 6 months of publication on ECHA website
Committee for Risk Assessment (RAC)	To provide an opinion	Within 9 months of publication on ECHA website
Committee for Socio Economic Analysis (SEAC)	To provide an opinion	Within 12 months of publication on ECHA website
ECHA	To publish the draft opinion of SEAC	
Interested parties	To submit comments on draft SEAC opinion (upon invitation by ECHA)	No later than 60 days from the publication of draft opinion
ECHA	To possibly postpone deadline for opinion of SEAC	Maximum of 90 days
ECHA	To publish on ECHA website final opinion of RAC and SEAC	Without delay
COM	Preparation of amendment to Annex XVII	Within 3 months of reception of SEAC opinion or by the end of deadline set in Article 71.

NOTE:

- The Commission cannot grant an authorisation for a restricted use, if the authorisation would mean a relaxation of that restriction (Article 60.6 REACH).
- As soon as a substance has been included in Annex XIV REACH, it cannot be subject to new restrictions (Article 58.5 REACH).
- However, after the inclusion of a substance in Annex XIV REACH, substances in articles can be subject to a restriction if ECHA considers that the use of the substance in article causes a risk for human health or the environment which is not adequately controlled (Article 69.2 REACH).
- CMR substances category 1 and 2 for which a restriction to consumer use has been proposed by the Commission, do not require the compilation of an “Annex XV” dossier. Restriction of these substances for that specific use will be directly subject to comitology procedure (Article 68.2).
- Member States may keep existing restrictions which are more stringent until 1 June 2013. The Commission will compile and publish an inventory of these restrictions by 1 June 2009 (Article 67.3 REACH).

For further details, please check

ECHA Guidance for the Preparation of an Annex XV Dossier for Restrictions (June 2007)

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