ORGALIME

ORGALIME Comments 26-03-2004

On "LVD_04_I_24.doc"

Commission draft specifications for an extended impact assessment of the LVD

Orgalime represents the mechanical, electrical, electronic and metal working industries of 23 European countries. Its 34 member federations represent over 130 000 companies of all sizes. With production valued at 1200 billion euros in 2002, and employing 7.3 million people, the engineering industry is the largest industrial sector.

If we agree with the Commission that sufficient background information and the most important features of the planned update of the Low Voltage Directive (LVD) have been defined at this stage (with the draft "LVD Update.5"), **we believe that it is essential that the Commission states clearly its policy objectives with regard to the revision of the directive** in a more consistent manner than just a "bullet list". **The questionnaire should provide sufficient background information in clear and concise language to facilitate responses**. We welcome the Commission attempt with the second column of the draft questionnaire, although we believe it is not always reflecting all arguments that were discussed during the meetings of the LVD Update working group. Orgalime will come back to the Commission on these.

As part of an impact assessment, the Commission should always consider whether the revision is first of all necessary, cost effective and, if so, in what form it should be enacted, so as to choose the least onerous approach compatible with achieving a defined objective. Therefore, we believe that while Commission policy objectives are quite clearly reflected in the set of **questions and their corresponding policy options, the way they are raised should remain neutral**: questions and answers should not only mention benefits but also possible drawbacks (including costs) of the intended revision.

At the time when the **consultant** will be selected and will start its consultation of companies (among other stakeholders) with the help of such a questionnaire, we believe that he **should get advise and support from trade associations**: impact assessments stand or fall on the quality of data. Consultants often perform their task without having the necessary technical expertise on all relevant aspects for companies (from design to marketing), nor have the network of contacts to perform adequate research. **Companies, and especially SMEs, usually consider inadequate enquiries as an administrative burden without immediate benefit for their business**. The best questionnaire will not be answered, because SMEs lack the necessary time, expertise and confidence in the overall usefulness of such a process. As a consequence response rates are usually poor. These can however be substantially improved if representative associations, such as Orgalime members, are involved in the process since they generally have reference groups who are prepared to spend some time in participating in enquiries whose outcome may impact their businesses.

Orgalime considers that for such a complex issue which involves almost all SMEs in the manufacturing field, the enclosed questionnaire is inappropriate to be transposed into a Web based inquiry, where simple yes-or-no answers are limiting and would not ensure that the appropriate target has been reached nor that the questions have been properly understood.

We trust that the Commission will consider both our general remarks and the enclosed detailed comments when drafting the terms of reference for a consultant to perform an impact assessment of the revision of the Low Voltage Directive.

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Extended impact assessment on the revision of the LVD

ORGALIME Comments 26-03-2004

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
1. Changes to the Scope of the Directive		
1.1 Extension of the scope Equipment under 50 Volts		
1.1.1 What are the economic and social benefits of including electrical equipment related to the consumer area with supply voltage under 50 V in the scope of the LVD?	1.1.1 What are the economic and social benefits ***and drawbacks, e.g. costs*** of including electrical equipment related to the consumer area with supply voltage under 50 V in the scope of the LVD?	The text only focuses on the benefits, without any reference to the drawbacks. These drawbacks could not only be costs but could also mean other negative impact, like added administrative burden.
1. Include electrical equipment with supply voltage under 50 V in the scope of the LVD	Editorial: In the Commission's comments (second column of the specification table), change "1000V (DC)" and "1500V (AC)" into respectively "1000V (AC)" and "1500V (DC)" The Commission's comments make mention of options 2 and 3, which are equal in practice, if not, option 3 is missing.	
2. Do nothing, rely on mechanisms under the GPSD to set standards and on horizontal consumer protection and liability legislation		
1.1.2 What are the benefits of including professional equipment with supply voltage under 50 V in the scope of the LVD?	1.1.2 What are the benefits ***and drawbacks, e.g. costs*** of including professional equipment with supply voltage under 50 V in the scope of the LVD?	

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
1. Include electrical equipment for professional use with supply voltage under 50 V in the scope of the LVD.		
2. Do not harmonise technical regulation for electrical equipment for professional use with supply voltage under 50 V, rely solely on workers protection laws and liability legislation.		
1.1.3 If the scope of the LVD were extended to electrical products with a supply voltage under 50 V a big variety of benign products are concerned. How should one ensure that the regime to these products is proportional?	1.1.3 If the scope of the LVD were extended to electrical products with a supply voltage under 50 V a big variety of benign products are concerned. How should one ensure that the regime to these products is proportional? ***What are the benefits and costs of the proposed regimes?***	The new question is appropriate as the questionnaire is intended to be used for impact assessment
1. Introduce a simple procedure for benign electrical products in the new LVD by which the manufacturer only have to declare that their products are benign on which basis they then CE-mark the product.		
2. Exclude benign products from the scope of the LVD by introducing in the new directive a list of products that are not covered.		
3. Exclude benign electrical products from the scope of the LVD by a general exclusion.		

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
4. Treat benign products like other electrical products.		
1.2 Interface to other directives		
1.2.1 How to design the interface with other Directives in a way, which minimises duplication?		
1. Introduce a specificity clause as already commonly known in other NA directives.	1. Introduce a specificity clause as already commonly known in other NA directives ***as far as health and safety risks of products are covered by these directives.***	The specificity clause is valid as far as the special directive covers the health and safety as the LVD does.
2. Do not introduce a specificity clause. Assume that declaration against LVD can easily be made on the basis of the assessment of the more stringent requirements.		
3. Do not introduce a specificity clause but specify the interface with all relevant policy areas.		
	4. ***Introduce a specificity clause, and specify the interface in certain policy areas.***	To be complete, the suggested combination should also be included into the impact assessment.
2. Align Directive with horizontal New Approach principles		

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
2.1 Improve the definition of a harmonised standard. What is the impact when changing the definition?		
1. Align the definition of harmonised standards with other New Approach directives.		
2. Maintain current status quo.		
2.2 Is it proportionate from the economic point of view to delete the reference to purely national standards regarding presumption of conformity?		
1. Delete the reference to purely national standards. 2.		
2. Delete the reference to purely national standards but mention that the use of technical specifications mentioned in purely national standards could be helpful in fulfilling the requirements of the LVD. The technical specifications have to be mentioned in the technical documentation.		
3. Do not change current provision of the LVD regarding status of national standards and await replacement by	3. Do not change current provision of the LVD regarding status of national standards and await replacement by	Only in the countries, which have implemented, the respective national standards need the presumption of conformity

In the Commission's comments (second column of the specification table), the term "Notified Bodies" is used. That should be replaced by "National **Standardisation** Bodies" or "Notified **Standardisation** Bodies" (which exist on LVD), in order to avoid any confusion with the "Notified Certification Bodies".

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
European standards: "Purely national standards in areas where there are no European standards existing can give presumption of conformity with the ESRs of the directive."	European standards: "Purely national standards in areas where there are no European standards existing can give presumption of conformity with the ESRs of the directive ***in those countries***."	in their countries, as this standard is appropriate to a national context for safety. If a country B want to gives the presumption of conformity to a standard belonging to country A, it can implement this standard in its country, in following the usual rules
2.3 Is it proportionate from the economic point of view to delete the reference to international standards regarding presumption of conformity?		
1. Delete the reference to international standards.		
2. Delete the reference to international standards. However, mention - that the international standards serve as a basis for European harmonised standards and in most cases are identical. - that the use of technical specifications mentioned in international standards could be helpful in fulfilling the requirements of the LVD. The technical specifications have to be mentioned in the technical documentation.		
3. Do not change the current directive with regard to status of international standards		
	~~***2.4 What is the benefit or drawback e.g.***~~	~~Add a question on elements of other New~~

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
	~~***costs, of making use of a consultant or of including a cross-reference table of requirements (Annex Z)?***~~	~~Approach Directives, which do have an impact.~~
3. Annex I		
3.1 Is it necessary that manufacturers of electrical equipment can more easily apply the ESR's of the Directive? Would this facilitate the innovation? Is there a social and/or economic benefit of making the ESR's more clear?	3.~~1 Is it necessary that manufacturers of electrical equipment can more easily apply the ESR's of the Directive?~~ ***Would a more detailed list of ESR's assist manufacturers in applying the LVD.*** Would this facilitate ***or hamper*** the innovation? ~~Is there a social and/or economic benefit of making the ESR's more clear?~~	We note a false assumption in the explanatory statement of the EC. There are only a few cases in practice where companies complain about the lack of legal certainty. The LVD with its well-balanced reference to the set of harmonised standards has worked adequately for more than 30 years. Therefore ORGALIME proposes to replace the first sentence. Further, innovation can easier be hampered by more details than be facilitated. The last question should be deleted.
1. Increase the level of detail of the ESRs as far as reasonably necessary, included those points already mentioned in the guidelines if necessary and include the principles of safety integration		
2. Do not change level of detail. Voluntary European standards and legally non-binding LVD guidelines are sufficient.		
3.2 What are the benefits to introduce the	3.2 What are the benefits ***and costs*** to	See 1.1.1

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
principles of safety integration in the amended LVD?	introduce the principles of safety integration in the amended LVD?	
1.Introduce the principles of safety integration in the amended LVD.	1.Introduce the principles of safety integration in the amended LVD ***for all health and safety hazards***	This formulation of the question (and the added proposed policy option) would address an issue that ORGALIME believes important with regard to the scope of liability of manufacturers.
	2. Introduce the principles of safety integration in the amended LVD only for "reasonably foreseeable" hazards	
2. Do not introduce the principles of safety integration in the amended LVD	***3***. Do not introduce the principles of safety integration in the amended LVD	
3.3 Is it necessary to mention explicitly that people with special needs are covered by the Directive?	~~3.3 Is it necessary to mention explicitly that people with special needs are covered by the Directive~~ **3.3 Is there a benefit to be more specific in the new Directive than in the existing version about people with special needs (e. g. elderly people and children) or is it preferable to continue to leave it to the standards**	The questions and options are far too complicated. We are not dealing with handicapped people, because then assistive products come into focus. The Commission expects proper answers to the questions, but ORGALIME is of the opinion that this type of putting questions will not result into realistic answers. The real question is much easier to formulate and consequently to answer.
1. Specify explicitly certain groups of people that have to be considered by the manufacturer in the risk assessment for the product.	~~1. Specify explicitly certain groups of people that have to be considered by the manufacturer in the risk assessment for the product.~~	
2. Introduce a "whereas" point making clear that people with special needs also have to be considered in the risk assessment, where relevant.	~~2. Introduce a "whereas" point making clear that people with special needs also have to be considered in the risk assessment, where relevant.~~	

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
3. It is not necessary to further specify "persons". People with special needs (e. g. elderly people and children) already have to be considered in conditions that are reasonably foreseeable. This can also be further clarified in the guideline for the amended directive.	~~3. It is not necessary to further specify "persons".~~ ~~People with special needs (e. g. elderly people and children) already have to be considered in conditions that are reasonably foreseeable.~~ ~~This can also be further clarified in the guideline for the amended directive.~~	
4. People with special needs (e.g. Children and elderly people) are excluded from the scope of the existing directive	~~4. People with special needs (e.g. Children and elderly people) are excluded from the scope of the existing directive~~	
	3.4 Are there any other significant benefits or serious drawbacks incl. costs resulting from other modified ~~or new~~ essential requirements?	We believe that it is necessary to add an open question on possible drawbacks or costs that other changes or additions to the existing directive may occur.
4. Is there a need for Notified Bodies under the amended directive? **What are the benefits?**		
1. Delete reference to these bodies.		
2. Call these bodies "competent bodies".	2. Call these bodies "***designated*** ~~competent~~ bodies".	"Competent" has a specific meaning with regard to the EMC in force. The expression "competent bodies" is questioned in the future EMCD. It seems not appropriate to reintroduce it in the new LVD
3. Introduce a new module that	3. ~~Introduce a new module that~~	We see no reason to add such a question. It

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
involves a Notified Body	~~involves a Notified Body.~~	has never been the intention to include compulsory certification because it will only introduce extra costs and no safer equipment.
	3. Maintain the reference to Notified Bodies in case of a challenge in the use of self-declaration of conformity (module A)	We see no reason not to ask to maintain the existing situation.
5. Market surveillance **Traceability –Information requirements**		
1. Improve information requirements in the sense that it is easier to trace back the electrical equipment	1. Improve information requirements ~~in the sense that it is easier to trace~~ ***as far as necessary for an easier tracing*** back the electrical equipment	We prefer a more precise formulation
2. Do not change information requirements		
	~~***3. Introduce information requirements identical to those in the GPSD***~~	
6. How to handle fence controllers under the amended LVD? What are the benefits of including fence controller in the LVD? Will fence controller become unsafe?	6. How to handle fence controller**s** under the amended LVD? What are the benefits ***or the draw backs*** of including fence controller**s** in the LVD? Will fence controller**s** become unsafe ***if they will be brought under the LVD***?	- See 1.1.1 - Extra “s”: Editorial

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
1. Include fence controllers under the amended LVD.		
2. Include fence controllers, but introduce a specific conformity assessment procedure requiring third party certification		
3. Exclude fence controllers	3. Exclude fence controllers ***because the main danger (High Voltage) is not covered by the scope of the LVD***	
7. What are the benefits of explicitly referencing **ergonomic** principles in the essential requirements of the directive both health and safety? Is it necessary to address both health and safety related aspects as regards ergonomic principles? Is it necessary to further specify the technical requirements as regards ergonomic principles or can this be left to standardisation?	7. What are the benefits ***or drawbacks*** of explicitly referencing ergonomic principles in the essential requirements of the directive both health and safety? Is it necessary to address both health and safety related aspects as regards ergonomic principles ***for the operation of the product***. Is it necessary to further specify the technical requirements as regards ergonomic principles or can this be left to standardisation?	See 1.1.1
1. Ergonomic principles will be addressed in the amended directive.	1. Ergonomic principles ***as regards health and safety ~~will~~ should*** be ***specifically*** addressed in the amended directive.	In order to align the wording of this phrase with option 2.
2. Ergonomic principles as regards health and safety related aspects do not have to be addressed in the amended directive.	2. Ergonomic principles as regards health and safety related aspects do not have to be addressed in the amended directive.	The accompanying explanation should indicate that ergonomic principles “do not have to be addressed” because they are already covered by the existing health and safety requirements

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
		of the directive, according to the normal condition of operation of the equipment according to its "intended use" (e.g. under parental surveillance or not, or for an occasional consumer use vs. for an extensive professional use).
	8 . The spread of fire in the essential requirements of the directive	
8. What are the benefits of explicitly referencing the spread of fire in the essential Requirements of the directive?	8.1 What are the benefits ***and drawbacks*** of explicitly referencing the spread of fire in the essential requirements of the directive?	See 1.1.1
1. Addressed spread of fire in the amended directive explicitly.		
2. It is not necessary to explicitly address spread of fire in the amended directive, but to specify this in the new guidelines.		
	8.2. Is it necessary to include the protection against fire ignition sources, which are external to the equipment in the amended directive or is this risk sufficiently covered by the general requirement for safe operation and taken into account during the risk assessment (and standards making)?	There are only a few external sources, which have proven to cause fires through electrical equipment. ORGALIME suggests solving those problems in standardisation and other means such as voluntary agreements from manufacturers involved. A general formulation on prevention against external fire sources in the LVD will cause many unwanted side effects and unnecessary drawbacks.
	1. It is not necessary to include the	

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
	protection against fire ignition sources, which are external to the equipment and spread of fire in the amended directive.	
	2. Protection against fire ignition sources which are external to the equipment have to be included in the amended directive.	
	3. It is not necessary to explicitly address protection against fire ignition sources, which are external to the equipment and spread of fire in the amended directive, but to specify this in the standards, if required.	
	9. What is the benefit and the cost of the extra requirements on Technical Documentation in the LVD compared to the requirements in Technical Documentation in the new EMCD?	ORGALIME wonders what are the reasons to introduce a discrepancy between two new "New Approach" directives;
	10. Do you believe that the revision is appropriate, so that the expected benefits of the updated directive outweigh the drawbacks?	This is the most interesting "summing-up" question and it should be stated at the end of the Impact Analysis.
	1. Continue with the revision process	

EC Proposed Policy Changes	ORGALIME proposals	ORGALIME rationale
	2. Limit the revision to Annex I and the scope	
	3. Keep the existing directive and raise the issues by other means ~~such as the revision of the LVD Guidelines.~~	