



ORGALIME Comments 06-10-2003 on

Commission "LVD UPDATE.4" Working Document dated 10-07-2003

Orgalime represents the mechanical, electrical, electronic and metal working industries of 21 European countries. Its 32 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.

We are pleased to forward our comments on Commission fifth working document on the LVD Update, further to the outcome of the last LVD Update Working Group meeting held on 5 June 2003. We thank the Commission for having provided stakeholders with a consultation period of at least 8 full working weeks.

However, we have concerns about the methodology chosen by the Commission during the last meeting, which has avoided discussing entire parts of the draft or has assumed that the discussion was settled.

With a view to achieve the most consistent and unambiguous wording as possible, ORGALIME considers that several points still deserve further consideration from the members of the working group. Therefore we have tabled once more comments that we believe are still relevant for the wording of the current tabled version "LVD Update.4".

We trust that the participants in the LVD Update Working Group will consider them during the next meeting, which we understand will be the last meeting with stakeholders.

1.	<p>Whereas the essential health and safety requirements must be observed in order to ensure that electrical equipment is safe; these requirements must be applied taking account of the general acknowledged state of the art based on technical, economic, social and environmental factors, experience <i>and</i> <u>relevant consolidated findings of science</u> at the time of design and manufacturing;</p>	<p>Comments received on the LVD update.3 document will be discussed in the next meeting</p>	<p>ORGALIME: The proposed text is the result of discussion of the June meeting.</p>
2.	<p>Whereas electrical equipment must be designed and manufactured in such a way that electric, magnetic, and electromagnetic fields generated by the equipment are limited to the extent necessary for its operation, and operate at a safe level in compliance with the generally acknowledged state of the art, taking due account of Council Recommendation 1999/519/EC on the limitation of exposure for the general public to electromagnetic fields (0 Hz to 300 GHz);</p>	<p>Comments received on the LVD update.3 document will be discussed in the next meeting</p>	<p>ORGALIME: The proposed text is the result of discussion of the June meeting.</p>
3.	<p>Whereas electrical equipment must be designed and manufactured in such a way that any emission of ionising radiation is limited to the extent necessary for its operation and that the effects on exposed persons are non-existent or reduced to non-dangerous</p>	<p>Will be amended in the light of the discussion with the relevant commission service dealing with the EURATOM directives.</p>	<p>ORGALIME: OK</p>

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	levels in compliance with the generally acknowledged state of the art taking due account of Council Directive 96/29/EURATOM "laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation";		
4.	Whereas electrical equipment includes only components intended to be incorporated into electrical equipment or installations and designed to fulfil a function in such a way that their compliance with the essential requirements can be assessed independently. Basic component such as transistors, diodes, capacitors, resistors and certain electromechanical components are not covered by this Directive. The definition includes also products, such as cable management systems.	Comments received on the LVD update.3 document will be discussed in the next meeting	ORGALIME: suggests the following amendments in relation with points n°15 and n°25: " Whereas <u>the definition of</u> electrical equipment includes only <u>those</u> components intended for incorporation into electrical equipment (such as operating switches and transformers) or installations (such as cable management systems), <u>the safety of which depends to a large extent on their intrinsic characteristics.</u> Other components, the safety of which mainly depends on the way they are incorporated into the final equipment, such as integrated circuits, capacitors and connectors are not covered by this Directive."
5.			ORGALIME: See our comments under article 7 in point number 60: Whereas the approach proposed by the previous version of the directive during a period of more than 30 years, has successfully made possible to publish a number of harmonized standards covering more than 90% of the subjects and has reduced in a same way the number of applicable national standards in each country, but knowing that some fields not yet harmonised or excluded for the moment from the Low Voltage Directive, such as electrical installations, require specific products entering the scope of the directive for which the presumption of conformity is significant for the manufacturers, considering in addition that the transparency must be ensured to limit any trade barrier.

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6.	Title of the directive		
7.	Directive xx/xx/EC of the European Parliament and of the Council relating to electrical equipment		<p>ORGALIME: We recall that the one but last LVD Update meeting (22&23 January 2003) adopted the following title:</p> <p><i>"Directive xx/xx/EC of the European Parliament and the Council relating to Low Voltage electrical equipment"</i></p>
8.	Article 1: Scope and definitions	Comments received on the LVD update.3 document will be discussed in the next meeting	
9.	This Directive regulates the health and safety requirements for electrical equipment. It aims at ensuring the proper functioning of the internal market of the European community by imposing a high level of health and safety.		<p>ORGALIME: Besides the words "low voltage", we recall that the one but last meeting agreed to add the word "protection" as follows:</p> <p><i>"This Directive regulates the health and safety requirements for low voltage electrical equipment. It aims at ensuring the proper functioning of the internal market of the European community by imposing while ensuring a high level of protection of health and safety."</i></p> <p>Rational: Health is a state of being that could not be enforced by law.</p>
10.	This directive shall not apply to the following equipment:		-
11.	(a) Electrical equipment as defined under Article 296 of the EC Treaty		-
12.	(c) Electrical equipment intended for human and veterinary medical purposes		-
13.	(d) Electrical parts specifically designed for incorporation into goods and passenger lifts		-

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14.	(e) Domestic plugs and sockets outlets for connection to the AC mains supply		-
15.	() Basic components intended to be incorporated into electrical equipment whose compliance with the essential requirements of this Directive cannot be assessed independently;		<p>ORGALIME: proposes the following amendments in conjunction with points n°4 and n°25:</p> <p>() Basic components intended to be incorporated into electrical equipment <u>or installations, the safety of which mainly depends on how they are incorporated</u> whose compliance with the essential requirements of this Directive cannot be assessed independently.</p>
16.	(f) Specialised electrical equipment, for use on ships, aircraft or railways, which complies with safety provisions including electrical safety drawn up by international bodies in which the Member State participate.		<p>ORGALIME: This clause is OK. We recall that the one but last LVD Update meeting agreed to introduce a clause in the preamble (whereas) in order to exclude the specialised electrical equipment already addressed by international agreements in the maritime field.</p>
17.			<p>ORGALIME: We see different terms for the person who places the product on the market: manufacturer, authorised representative, importer, and agent. It is not clear who has which responsibilities. We could use an ISO definition of "producer" but that is not entirely in line with the Blue Guide. We could use only the words 'manufacturer' and 'authorised representative' and derive other persons from these terms.</p> <p>Therefore, ORGALIME proposes to replace the various indications in items 70, 86, Annex I Section III.1(b), Annex III Section B, Annex IV items 1 and 2 1st box by "manufacturer or his authorised representative" and to introduce the following definitions:</p> <p>"Manufacturer" means any natural or legal person responsible for the conformity of electrical equipment with this directive in view of its placing on the market under its own name or trademark or for its own use.</p>

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			<p><i>"Authorised representative" means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts on his behalf and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this directive.</i></p> <p>Further, a new item should be introduced e.g. in Article 10: <i>"Where the manufacturer is not established within the Community and in the absence of an authorised representative, the obligation to ensure that electrical equipment placed on the market conforms with the requirements of the applicable implementing measure shall lie with the person placing the equipment on the market."</i></p> <p>Both definitions and the new item have been taken over from the Proposal for a directive for eco design requirements for energy using Products, COM(2003) 453 final dated 01.08.2003.</p>
17a.			<p>ORGALIME: After the last meeting we received comments from our sister organisation CLEPA – European Associations of Automotive Suppliers. They were not aware that their products might be affected by the LVD. They fully support the ORGALIME statement in Update.3. For this reason we would like to rediscuss the item in the presence of the representative of CLEPA.</p> <p>Comments: It is not good to include all equipment in cars into the LVD, because there is no reason for it. Some equipment is already covered by other legislation. Therefore ORGALIME proposes to include the following text in order to exclude it from the LVD:</p> <p>"() Equipment used in cars.</p> <p><i>Electrical equipment, which can only be used for incorporation into motor vehicles, such as motor management systems for cars, oil pressure and temperature contacts for incorporation into cars, ABS-systems, etc"</i></p>

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18.	(g) Equipment covered by the Directive 98/37/EC on the approximation of the laws of the Member States relating to Machinery		-
19.	(h) High-voltage step-down transformers for use in electricity distribution networks with an input voltage above 1000 Volts		-
20.	3. This Directive does not apply to electrical equipment covered by more specific Community legislation designed to achieve the same objectives as this Directive with regard to placing on the market, free movement of goods and to the protection of health and safety.		-
21.	4. For the purpose of this directive, the following definitions shall apply		-
22.			
23.	Electrical equipment		
24.	Any electrical equipment designed for use with a supply or output voltage not exceeding 1000 Volt for alternating current and 1500 Volt for direct current and intended for the purposes of generation, conversion, transmission, distribution or		-

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25.	<p>utilisation of electricity.</p> <p>Electrical components intended to be incorporated into electrical equipment or installations and designed to fulfil a function in such a way that their compliance with the essential requirements can be assessed independently, are deemed to be electrical equipment for the purposes of this Directive.</p>		<p>ORGALIME: The existing Directive does not address the status of components. However, the existing LVD Guidelines are very clear in this respect and their formulation works very well in practice, both for manufacturers and market surveillance authorities. Therefore, ORGALIME believes that the new LVD should follow the wording of the LVD Guidelines.</p> <p>LVD Guidelines, under 9.</p> <p><i>"In general, the scope of the Directive includes both electrical equipment intended for the incorporation into other equipment.....</i></p> <p><i>However, some types of electrical devices, designed and manufactured for being used as basic components to be incorporated into other electrical equipment, are such that their safety to a very large extent depends on how they are integrated into the final product and the overall characteristics of the final products. These basic components include electronic and certain other components."</i></p> <p><i>Note: This includes active components..... etc</i></p> <p>The examples of basic components in note 10 of clause 9 of the LVD Guidelines can be divided into three categories:</p> <ul style="list-style-type: none"> - <i>active electronic components: integrated circuits, transistors, diodes, rectifiers, triacs, GTO's, IGBT's, opto-semi-conductors;</i> - <i>passive electronic components: capacitors, inductances, resistors, filters;</i> - <i>electromechanical components: connectors, devices for mechanical protection which are part of equipment, relays with terminals for printed circuit boards, micro-switches</i> <p>In the previous meeting, it was agreed that the principle would not change. However, ORGALIME foresees many difficulties when applying the current formulation in practice.</p>

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			<p>The key issue is not how the component can be assessed, but <u>to what extent its safety depends on the way it has been incorporated into the final product.</u></p> <p>Therefore, ORGALIME proposes the following wording, which is consistent with the preamble (whereas), the definition and the exclusions.</p> <p>Preamble</p> <p>It was agreed that some examples of the exclusions will be mentioned in the preamble, one example from each category.</p> <p>ORGALIME proposal for a text in the preamble (see point n°4):</p> <p><i>"Whereas <u>the definition of</u> electrical equipment includes only <u>those</u> components intended for incorporation into electrical equipment (such as operating switches and transformers) or installations (such as cable management systems), <u>the safety of which depends to a large extent on their intrinsic characteristics</u>. Other components, the safety of which mainly depends on the way they are incorporated into the final equipment, such as integrated circuits, capacitors and connectors are not covered by this Directive."</i></p> <p>Definition</p> <p>Orgalime proposes the following to define components (see pt. 25):</p> <p><i>"Electrical components intended to be incorporated into electrical equipment or installations, <u>the safety of which depends to a large extent on the components' characteristics</u> and designed to fulfil a function in such a way that their compliance with the essential requirements can be assessed independently, are deemed to be electrical equipment for the purpose of this Directive."</i></p>

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			<p>Future LVD Guidelines</p> <p>The future LVD Guidelines should include a text such as:</p> <p>“Examples of these basic components can be divided into three categories:</p> <ul style="list-style-type: none"> - active electronic components: integrated circuits, transistors, diodes, rectifiers, triacs, GTO’s, IGBT’s, opto-semi-conductors; - passive electronic components: capacitors, inductances, resistors, filters; - electromechanical components: connectors, devices for mechanical protection which are part of equipment, relays with terminals for printed circuit boards, micro-switches.
26.	Products intended to be used in conjunction with electrical equipment and designed to contribute to its safe functioning, including cable management systems, are deemed to be electrical equipment for the purposes of this Directive.		-
27.			
28.	Harmonised Standards		
29.	"Harmonised standard" means a technical specification adopted by a recognised standards body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC for the purpose of establishing a European requirement, compliance with which		-

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	is not compulsory.		
30.			
31.	Intended purpose		<p>ORGALIME: "purpose" means "intended use": moreover the words "intended use" can be found in the Directive. Therefore we propose to substitute the expression "intended use" which is consistent with the standardisation practice to the proposed pleonastic wording:</p> <p>"Intended use purpose"</p>
32.	The use of the equipment according to the information supplied by the manufacturer on the labelling, in the instruction for use and/or promotion material or that can normally be expected from common and expected usage.		<p>ORGALIME: proposal to amend the text:</p> <p><i>"The use of electrical equipment according to the information supplied by the manufacturer on the labelling, in the instruction for use and/or promotion material or that can normally be expected from common and expected usage."</i></p> <p>because the word "expected" is already used as a verb.</p>
33.			
34.	Electric, magnetic, or electromagnetic fields Designate non-ionising low, medium and high frequency waves or radiations from 0 Hz to 300 GHz;		<p>ORGALIME: proposes to delete the "s" in "radiations", since "radiation" is already a plural noun (editorial):</p> <p><i>"Designate non-ionising low, medium and high frequency waves or radiations from 0 Hz to 300 GHz;"</i></p>
35.			
36.	Other non ionising radiations Designate optical radiations or infra-red, visible or ultra-violet electromagnetic waves from 300 GHz to 3×10^{15} Hz;		<p>ORGALIME: proposes to delete the "s" in "radiations", since "radiation" is already a plural noun (editorial):</p> <p>"Other non ionising radiations"</p> <p><i>Designate optical radiations or infra-red, visible or ultra-violet electromagnetic waves from 300 GHz to 3×10^{15} Hz;"</i></p>
37.			

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38.	<p>Ionising radiation Designate radiations above 3×10^{15} Hz.</p>		<p>ORGALIME: proposes to delete the "s" in "radiations", since "radiation" is already a plural noun (editorial): "Designate radiations above 3×10^{15} Hz."</p>
39.			
40.	<p><i>Article 2</i></p>	<p>Comments received on the LVD update.3 document will be discussed in the next meeting</p>	-
41.	<p>The Member States shall take all appropriate measures to ensure that electrical equipment may be placed on the market only if it is in conformity with the essential health and safety requirements at Annex I and its conformity has been assessed according to the provisions of this Directive.</p>		-
42.			
43.			
44.	<p><i>Article 3</i></p>	<p>Comments received on the LVD update.3 document will be discussed in the next meeting</p>	-
45.	<p>The Member States shall take all appropriate measures to ensure that if electrical equipment is of such a nature as to comply with the provisions of Article 2, subject to the conditions laid down in Articles 5, 6, 7 or 8, the free</p>		<p>ORGALIME proposes an editorial comment: "The Member States shall take all appropriate measures to ensure that if electrical equipment is of such a nature as to comply with the provisions of Article 2, subject to the conditions laid down in Articles 5, 6, 7 or and 8, the free movement thereof within the Community shall not be impeded for reasons of health and safety."</p>

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	movement thereof within the Community shall not be impeded for reasons of health and safety.		
46.			
47.	<i>Article 4</i>	Comments received on the LVD update.3 document will be discussed in the next meeting	-
48.	In relation to electrical equipment the Member States shall ensure that stricter health and safety requirements than those laid down in Article 2 are not imposed by electricity supply bodies for connection to the grid, or for the supply of electricity to users of electrical equipment.		-
49.			
50.	<i>Article 5</i>	Comments received on the LVD update.3 document will be discussed in the next meeting	
51.	1. Where equipment complies with the relevant harmonised standards whose references have been published in the Official Journal of the European Union, Member States shall presume compliance with the essential requirements referred to in Annex I, to		-

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	which such standards relate.		
52.	2. These standards shall be kept up to-date in the light of the generally acknowledged state of the art.	will be deleted	-
53.	<p>3. Where it is considered that a European harmonised standard, whose references have been published in the Official Journal of the European Union, does not fulfill the requirements of Annex I within its scope, the Commission or a Member State shall bring the matter before the Committee instituted by Directive 98/34/EC hereinafter referred to as "the Committee" giving the reasons thereof. The Committee shall deliver an opinion without delay.</p> <p>In light of the Committee's opinion, the Commission shall decide to maintain the listing, or to maintain the listing but note restrictions on the presumption of conformity offered by the standard concerned, or to withdraw the relevant references in the Official Journal of the European Union.</p>		-
54.	<i>Article 6</i>	<i>Not for discussion; will be modified</i>	ORGALIME: We recall that the previous meeting decided to delete the article and to put a clause in the Preamble
55.	1. Where European harmonised standards referred to in Article 5 do not exist, the Member States shall take all		

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	<p>appropriate measures to ensure that, for the purposes of placing on the market or free movement as referred to in Articles 2 and 3 respectively, their competent administrative authorities shall also regard, as complying with the provisions of Article 2, electrical equipment which complies with publicly available standards of the International Electrotechnical Commission (IEC) covering the essential health and safety requirements as set out in Annex I. The references of these standards have to be published by the Commission in the Official Journal of the European Union in accordance with the procedure laid down in paragraphs 2 and 3 has been applied</p>		
56.	<p>2. The Commission shall notify to the Member States and inform the European standards organisations CEN, CENELEC and ETSI of the standards referred to in paragraph 1. After consulting the above parties, the Commission shall state the provisions and in particular the variants which it recommends to be published.</p>		
57.	<p>3. In the case of objections presented by one or more Member States the Commission shall seek for an opinion of the 98/34/EC committee. After consultation of the 98/34/EC committee</p>		

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	the Commission will decide which of these provisions or their variants are to be published and will inform the Parties concerned. References for which no objections have been received shall automatically be published in the Official Journal of the European Union once the consultation is completed.		
58.			
59.	<i>Article 7</i>	Will be deleted	
60.	1. Member States shall presume the compliance of electrical equipment with the essential requirements referred to in Article 2 when it conforms to national standards applicable to them in so far as, in the areas covered by such standards, no harmonised standards or standards according to Article 6 exist.		<p>ORGALIME: We recall that there was only the intention of the Commission to delete it, but it was not decided. ORGALIME is not in favour to delete these items. As pointed out during the meeting, as long as national installation rules are not harmonised, manufacturers must adapt their products to the various local installation requirements. Therefore, manufacturers need article 7 in order to benefit of the presumption of conformity when they are placing their products on a local market.</p> <p>It is not necessary that conformity to the requirements of a national standard gives presumption of conformity to the national standards requirements of all EU countries, but only in the applicable country. Therefore ORGALIME proposes to replace Article 7 in the existing directive with:</p> <p><i>A Member State shall presume the compliance of electrical equipment with the essential requirements referred to in Article 2 when it conforms to national standards applicable in that Member State, if no harmonised standards or standards according to Article 6 exist.</i></p>

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61.	2. The Commission shall notify to the Member States and inform the European standards organisations CEN, CENELEC and ETSI of the standards referred to in paragraph 1. After consulting the above parties, the Commission shall state the provisions and in particular the variants which it recommends to be published.		<p>ORGALIME: suggests to replace "the above" with "these" (editorial):</p> <p>"2. The Commission shall notify to the Member States and inform the European standards organisations CEN, CENELEC and ETSI of the standards referred to in paragraph 1. After consulting the above these parties, the Commission shall state the provisions and in particular the variants which it recommends to be published."</p>
62.	3. In case of objections presented by one or more Member States the Commission shall seek for an opinion of the 98/34/EC committee. After consultation of 98/34 the Commission will decide which of these provisions or their variants are to be published and will inform the Parties concerned. References for which no objections have been received shall automatically be published in the Official Journal of the European Union once the consultation is completed.		<p>3. In case of objections presented by one or more Member States the Commission shall seek for an opinion of the 98/34/EC committee. After consultation of 98/34 the Commission will decide which of these provisions or their variants are to be published and will inform the Parties concerned. References for which no objections have been received shall automatically be published in the National Official Journal of the relevant countries and, for information, in the Official Journal of the European Union, stating for which countries the listed standards are applicable, once the consultation is completed.</p>
63.	4. The Commission may limit the period of application of the standards referred to in Article 7 to give compliance with the essential requirements referred to in Article 2.		(no comment, no change)
64.	5. The Commission may entrust a standardisation mandate to the European Standardisation Organisations in accordance with directive 98/34/EC		(no comment, no change)

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	with regards to national standards.		
65.	<p>6. Where it is considered that a European harmonised standard, an international standard or a national standard published according to the relevant procedure under this Directive, does not fulfill the requirements of Annex I within its scope, the Commission or a Member State shall bring the matter before the Committee instituted by Directive 98/34/EC hereinafter referred to as "the Committee" giving the reasons thereof. The Committee shall deliver an opinion without delay.</p> <p>In light of the Committee's opinion, the Commission shall decide to maintain the listing, or to maintain the listing but note restrictions on the presumption of conformity offered by the standard concerned, or to withdraw the relevant references in the Official Journal of the European Union.</p>		<i>(no comment, no change)</i>
66.			
67.			
68.	<i>Article 8</i>	Comments received on the LVD update.3 document will be discussed in the next	

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		meeting	
69.	1. Before being placed on the market, electrical equipment referred to in Article 1 must have affixed to it the CE marking provided for in Article 10 attesting to its conformity to the provisions of this Directive, including the conformity assessment procedure described in Annex IV.		<p>ORGALIME: This article requires the CE marking <u>on</u> the product. This is both superfluous and in contradiction with the provisions of Annex III, which allows under some conditions to affix the CE marking also elsewhere. Therefore, we suggest to merge articles 8 and 10. We suggest the following amendments:</p> <p><i>"1. Before being placed on the market, electrical equipment referred to in Article 1 must have affixed to it the CE marking provided for in Article 10 Annex III attesting to its conformity to the provisions of this Directive, including the conformity assessment procedure described in Annex IV."</i></p> <p>The other paragraphs in articles 8 and 10 of the Commission's proposal have to be combined as far as relevant.</p>
70.	2. In the event of a challenge, the manufacturer or importer may submit a report, drawn up by a body, which is notified in accordance with the procedure set out in Article 11, on the conformity of the electrical equipment with the provisions of Article 2.		<p>ORGALIME: proposes to make it consistent with our comment in point number 17 and with the EMC Directive:</p> <p><i>"2. In the event of a challenge, the manufacturer or importer, if he is not established in the EU the person who is responsible for the placing on the market, may submit a report, drawn up by a body, which is notified in accordance with the procedure set out in Article 11, on the conformity of the electrical equipment with the provisions of Article 2."</i></p>
71.	3. (a) Where electrical equipment is subject to other Directives concerning other aspects which also provide for the affixing of the CE marking, the latter shall indicate that the equipment also conforms to the provisions of those other Directives.		-

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	<p>(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the Official Journal of the European Union, must be given in the documents, notices or instructions required by the Directives and accompanying the electrical equipment.</p>		
72.	<u>b</u>		
73.	<i>Article 9</i>	Comments received on the LVD update.3 document will be discussed in the next meeting	
74.	1. If, for reasons of health and safety, a Member State prohibits the placing on the market of any electrical equipment or impedes its free movement, it shall immediately inform the other Member States and the Commission, indicating the grounds for its decision and stating in particular:		-
75.	- whether its non-conformity with Article 2 is attributable to a short-coming in the harmonised standards		-

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	referred to in Article 5, the international standards referred to in Article 6 or the national standards referred to in Article 7;		
76.	- whether its non-conformity is attributable to faulty application of such standards or publications or to failure to comply with good engineering practice as referred to in Article 2.		-
77.	2. If other Member States raise objections to the decision referred to in paragraph 1 the Commission shall immediately consult the Member States concerned.		ORGALIME: believes that a deadline should be inserted for the whole procedure. We propose 6 months as being realistic.
78.	3. If an agreement has not been reached within three months from the date of notification as laid down in paragraph 1, the Commission shall obtain the opinion of one of the bodies notified in accordance with the procedure laid down in Article 11, having its registered office outside the territory of the Member States concerned and which has not been involved in the procedure provided for in Article 8. The opinion shall state the extent to which the provisions of Article 2 have not been complied with.		-
79.	4. The Commission shall communicate the opinion of this body to all the		-

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	Member States which may, within a period of one month, make their observations known to the Commission. The Commission shall at the same time note any observations by the parties concerned on the above mentioned opinion.		
80.	5. Having taken note of these observations the Commission shall, if necessary, formulate the appropriate recommendations or opinions.		
81.			
82.	<i>Article 10</i>	Comments received on the LVD update.3 document will be discussed in the next meeting	
83.	1. The CE conformity marking referred to in Annex III shall be affixed by the manufacturer or his authorized representative established within the Community to the electrical equipment or, failing that, to the packaging, the introduction sheet or the guarantee certificate so as to be visible, easily legible and indelible.		<p>ORGALIME: See our comments on Article 8. We believe that the following wording, in line with the EMCD (article 8), is better:</p> <p><u>"1. The CE conformity marking referred to in Annex III shall be affixed by the manufacturer or his authorized representative established within the Community to the electrical equipment or, failing that to the packaging, the introduction sheet or the guarantee certificate so as to be visible, easily legible and indelible. Equipment whose compliance with this Directive has been established shall bear the CE marking which attests to that fact. The affixing of the CE marking shall be the responsibility of the manufacturer or his authorised representative established within the Community. The CE marking shall be affixed in accordance with the provisions set out in Annex III."</u></p>

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			Annex III should be made consistent accordingly.
84.	2. The affixing on electrical equipment of any markings liable to deceive third parties as to the meaning and form of the CE marking shall be prohibited. However, any other marking may be affixed to the electrical equipment, its packaging, the instruction sheet or the guarantee certificate provided that the visibility and legibility of the CE marking is not thereby reduced.		-
85.	3. Without prejudice to Article 9:		-
86.	a. Where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his agent established within the Community market shall be obliged to make the electrical equipment comply as regards the provisions concerning the CE marking and to end the infringement under conditions imposed by the Member State;		-
87.	b. Where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the electrical equipment in question or to ensure that it is withdrawn from the market.		-

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
88.			
89.	<i>Article 11: Notified bodies</i>	Not for discussion	
90.			

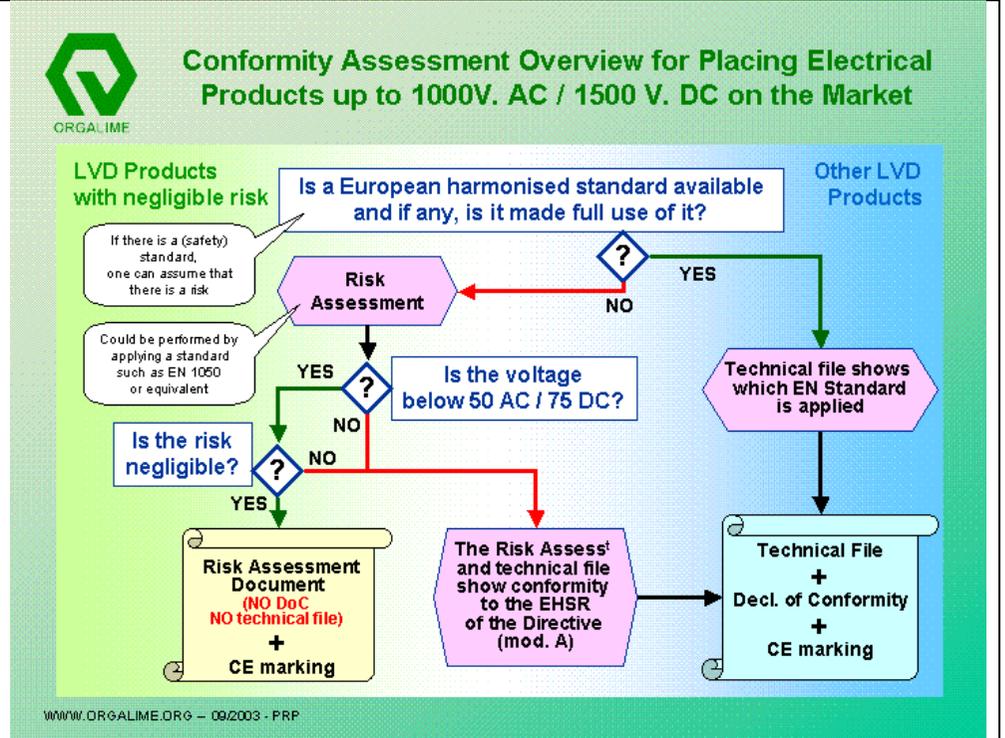
No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
91.	Annex I	The current wording of Annex I has been generally agreed by the LVD update group.	
92.	Essential health and safety requirements		
93.	Section I		
94.	General requirements		
95.	1. The manufacturer of equipment is under the obligation to perform a risk assessment referring to the essential health and safety requirements.		
96.		The Commission is currently discussing the proposal from ANEC to introduce the principles of the "Design for All" concept into the LVD.	<p>ORGALIME: Design-for-All is above all a matter of awareness-raising for which clarification of the concept of "All" or of "accessibility for All" is required. Like environmental aspects, it could be a matter of guidelines for standardisation makers but could in no way lead to a mandatory requirement in this Directive, for the following reasons:</p> <ul style="list-style-type: none"> - it would be in contradiction with the "fit for purpose" and the "intended use" principles and could lead even to increase risks for the safety of average users (e.g. some professional machines such as presses could not be triggered by single-handed users, in order to avoid that two-handed workers be harmed); - the "design for All principle" could lead to counterproductive results by reducing the range of choice, contradicting handiness for the average user (e.g. a mobile phone with a large key-pad would not fit anymore in one's hand); - there is a large variety of disabilities, some of them could be mutually exclusive in terms of ergonomics. Therefore there is a need to maintain some freedom of design in order to leave manufacturers bridge adequately each "usability gap"; Otherwise

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			<p>where would be the borderline between designed-for-All-products and assistive technology and prosthetics?</p> <ul style="list-style-type: none"> - if design-for-All could be justified for products used in public places, public services and activities, it is not acceptable for private customers and users, including elderly or disabled people, who are expecting customized products that fit as closely as possible their very own needs and expectations. - there is no sound reason to believe that the market will not meet the safety needs of the ageing European population. One product for each user is better than each need in one product. The greater the number of elderly people with impaired senses, the bigger investments in research and new technologies, the bigger the choice and the more affordable the products for all. - Design-for-all should be considered in the wider context of globalisation (with a harsh international competition, especially for SMEs), where a number of products entering the EU market are not compliant. How would companies be able to cope with all these requirements (health, safety, environment, ergonomics, crime-proofing, CSR, etc...) while other unfair manufacturers already place non compliant products on the EU market? How design-for-All requirements in a New Approach Directive such as the LVD could be adequately enforced, while in many Member states market surveillance is overwhelmed and not able to preserve competitiveness at a level-playing field? ; <p>Eventually, coherence of the EU policy and legal issues should be carefully looked at with regard to responsibility, which should be shared equitably between the manufacturer (design), intermediates in the value added chain (employers, retailers, public infrastructure managers, administrations, etc...) and the final user of a product, service, etc... (workers, consumers, including elderly and disabled people). This share of responsibility is well understood in some countries for the use of automotive vehicles, where the driving licences are not anymore granted for life and could conversely be withdrawn in case of faulty behaviour.</p>

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
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97.

The proposal for a simple procedure referring to benign products will be discussed as agreed by the LVD update group by a small group consisting of UK, DE, IR, ORGALIME and Commission. The outcome will be presented at the next meeting.



ORGALIME: agreed to delete the lower voltage limit of the Directive, which consequence is to extend the scope and requirements of the LVD to products below 50V AC / 75V DC.

Since most of these products are exposing the user to negligible risks, the LVD Update Working Group agreed on the principle of a simplified risk assessment procedure, which would still oblige manufacturers to undertake a risk assessment (or to apply an existing standard), but would avoid them the administrative burden occurred by the making of a technical file and a declaration of conformity.

It was agreed during the last meeting of the LVD Update Working Group that CENELEC will prepare a special easy to perform "simple conformity

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			<p>assessment procedure" for equipment identified by risk assessment as presenting negligible risks, along the lines illustrated in the enclosed flow chart.</p> <p>This procedure will result in additional costs for manufacturers of negligible risk products, because they will be required to keep the result of their risk assessment available to market surveillance authorities for 10 years into a simple A4-like "risk assessment document". In addition, they will be required to affix the CE marking on negligible risk products or the packaging or the instruction for use. However, we believe that this procedure has many advantages for products with negligible risk:</p> <ul style="list-style-type: none"> - it will align further the LVD on the New Approach and will avoid a double application of the technical requirements of both the LVD and the General Product Safety Directive; - it is not necessary to draw up an arbitrary borderline between products with negligible risks and others, thus this will consequently reduce interpretation and litigation problems. - the fact that the CE marking is often considered by consumers as a quality mark urges towards clearly indicating that the negligible risk product follows the EU requirements for its placing on the market. Otherwise there will be further confusion on its use, misuse and abuse, especially because many of these low risk products are imported in large batches from Southeast Asia as well as China are CE marked (many shops and brochures in these countries make use the "CE certification" as promotion for "high quality" product). - Many negligible risk LVD products should meet the requirements of the EMCD, which already include the CE marking <p>Therefore, ORGALIME supports the creation of a new article (or a new Annex):</p> <p><u>SIMPLE CONFORMITY ASSESSMENT PROCEDURE</u> <u>For equipment identified by risk assessment as presenting negligible risks the following procedure shall be applied:</u></p>

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			<p><u>(1) The risk assessment document shall be held at the disposal of the competent authorities of Member States for a period of ten years after the date of manufacture;</u></p> <p><u>(2) If neither the manufacturer nor his authorised representative is established within the Community, the obligation to hold the risk assessment document at the disposal of the competent authorities shall be the responsibility of the person who places the apparatus on the Community market.</u></p> <p><u>(3) The manufacturer shall affix the CE marking on the equipment in accordance with Article 6 Paragraph 2."</u></p>
98.	Applying Harmonised Standards covering all relevant essential health and safety requirements fulfils the obligation to perform a risk assessment.		-
99.	2. The obligations laid down by the essential health and safety requirements apply to equipment		-
100.	<ul style="list-style-type: none"> when properly installed and maintained according to the manufacturer's instructions, 		-
101.	<ul style="list-style-type: none"> taking due account of its intended use 		-

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
102.	throughout its anticipated lifetime.		<p>ORGALIME reminds the Commission that it was agreed in the 2nd WG Update meeting to follow ORGALIME's proposal to introduce the term "including duration" from paragraph 2b of the GPSD, instead of "throughout its anticipated lifetime".</p> <p>Therefore, ORGALIME propose the following wording:</p> <p>"2. The obligations laid down by the essential health and safety requirements apply to electrical equipment</p> <ul style="list-style-type: none"> - when properly installed and maintained according to the manufacturer's instructions, - taking due account of its intended use throughout its anticipated lifetime including duration." <p><u>Rationale:</u> Electrical equipment is requested to stay safe during the whole of its lifetime, which is well understood by the standardisation community, i.e. that a product has to be safe during its lifetime and that it should "die safely".</p> <p>When designing a product and writing its instruction of use, the manufacturer should take into consideration the "reasonably foreseeable conditions of use" of the product, including the level of education, training, experience and skills of the final user. This particularly true for consumer products that could be used by non proficient and inexperienced consumers. This why Article 2b of the GPSD stipulates:</p> <p><i>"Whereas a 'safe product' means any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, must not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons;"</i></p> <p>If sometime, the manufacturer could give some indication of time in the instruction for use (e.g. for battery operated products) he could not determine the expected lifetime of a given product because it could</p>

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
			<p>determine the expected lifetime of a given product, because it could vary greatly according to the conditions of use, maintenance and upgrade which are often not depending from him. After the transfer of property of a product to the end-user, the end-user bear the responsibility to use and maintain the product according to the manufacturer's instructions in order to keep it safe.</p> <p>The manufacturer could not bear the responsibility of a situation where the user put himself at risk due to a misuse of the product. For instance, if a consumer identifies a crack or a hole in the housing of his coffee machine that would have fallen on the ground, it should be his entire responsibility to sort out whether the situation is dangerous or not, and whether it requires either a careful disposal or to bring the product to proficient repair shop.</p> <p>Therefore the LVD, which regulates the placing on the internal market should not overlap with other civil or social regulations and should preserve as much as possible the freedom of contracts, where "condition of use", "maintenance", "repair" and "liabilities in case of defect" are fully agreed for a specified time span between professional parties. The manufacturer could not be required to fix arbitrarily the life-time of a product, which is already regulated at 2 years for consumer guaranties and limited to 10 years for product liability recourse. It may lead otherwise to litigations and commercial side effects, especially with regard to insurance policies.</p> <p>ORGALIME is therefore of the opinion that the expression "anticipated" should be deleted and "life-time" could be better replaced by "duration" as in the GPSD.</p>

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
103.	Conditions that can be reasonably foreseen by the manufacturer must also be taken into account.		
104.	I.1 Principals of safety integration		
105.	a) Equipment must be designed and manufactured so that it provides adequate protection for persons and, where appropriate, domestic animals and property.		
106.	This protection must be against all health and safety hazards arising from the use of the equipment, or such hazards caused by reasonably foreseeable external influences on the equipment itself taking into account its functionality.		<p>ORGALIME: We recall that the term “reasonably foreseeable” should be used in conjunction with “health and safety hazards” and not only for “external influences”. It is impossible that manufacturers have to take into account ALL health and safety hazards. Therefore we propose to move this term “reasonably foreseeable” to “health and safety hazards”.</p> <p>In addition, we suggest to be more specific by a reference to the health and safety hazards which are described in Annex I (EHSRs).</p> <p>The expression “taking into account its functionality” is right, but could be misunderstood. Therefore we propose to add an explanation with a direction to the use and working of the equipment. We propose the following changes:</p> <p><i>“This protection must be against all reasonably foreseeable health and safety hazards listed in annex I, arising from the use of the equipment, or such hazards caused by external influences on the equipment itself taking into account its functionality, i.e. the use and the working of the equipment.”</i></p>
107.	b) The solutions adopted by the manufacturer for the design and construction of the equipment must conform to safety principles, taking		

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
	into account the generally acknowledged state of the art.		
108.	In selecting the most appropriate solution, the manufacturer must apply as far as reasonably possible the following principles in the order given below:		
109.	– eliminate hazards or reduce risks by inherent design measures;		
110.	– take the necessary protective measures in relation to risks that cannot be reduced by inherent design measures;		
111.	– inform users and where appropriate other persons of the residual risks, indicate whether any particular training is required and specify any need to use personal protective equipment.		
112.	c) Equipment shall be		
113.	– designed and manufactured so that it can be safely and properly assembled, connected and maintained;		
114.	– supplied with the necessary accessories to permit safe connection and installation.		
115.	Section II		
116.	Requirements regarding design and		

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
	construction		
117.	II.1 Protection against electric shock and other electrical hazards		
118.	Equipment must be designed and manufactured in such a way that persons and/or domestic animals shall be protected under normal or single fault conditions against danger of excessive current passing through the body.		<p>ORGALIME: The expression "single fault conditions" will raise major application problems for the following reasons: In a limited number of cases in equipment of insulation class I (earthed), and class II (double insulated) in the application of reinforced insulation would no longer be allowed. Components like single insulated supply cords such as twin eight cords used on lighting products (negligible mechanical stress) and electric shavers (high flexibility required), appliance plugs and switches as well as similar constructions in equipment could no longer be manufactured because there are no alternatives. On the other hand, long lasting market experience has shown that these constructions are safe.</p> <p>Therefore, ORGALIME proposes to delete the reference to single fault conditions by rephrasing the text to:</p> <p><i>Equipment must be designed and manufactured in such a way that persons and/or domestic animals shall be protected under normal or single fault conditions against danger of excessive current passing through the body.</i></p>
119.	In particular, equipment must provide adequate protection against electrical hazards arising from:		
120.	- leakage current;		
121.	- energy supply;		
122.	- electro-static charges;		
123.	- arcs.		
124.	The protective measures shall take		

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
	into account electrical, mechanical, chemical and physical stresses.		
125.	II.2 Protection against fire hazards		
126.	II.2.1 Equipment must provide an adequate level of fire resistance to an external ignition source and must not contribute significantly to the spread of fire		<p>ORGALIME:</p> <ul style="list-style-type: none"> - It does not take into account the most important hazard: fire initiated by the equipment itself. The text in Update.3 did include that. - The request of some national representatives in the Working Group is to ensure that TV enclosures do not contribute to the spread of fire. This could be acceptable, provided that it is limited to the use of candles in household environments. - The word "significantly" is too vague. <p>Therefore, ORGALIME proposes to go back to the text of the version LVD Update.3:</p> <p><i>"Electrical equipment must provide, where appropriate, adequate protection against fire hazards initiated by the electrical equipment itself or by substances produced, emitted or used by electrical equipment."</i></p>
127.	II.3 Protection against mechanical hazards		
128.	Equipment must provide adequate protection against mechanical hazards, in particular, arising from:		
129.	- instability;		
130.	- ejected objects;		
131.	- rough surfaces, sharp edges or		

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
	corners;		
132.	- moving parts;		
133.	- vibration;		
134.	II.4 Protection against other hazards		
135.	Equipment must provide adequate protection against hazards arising from:		
136.	- explosion caused by the equipment itself or by substances which may be produced, emitted or used by the equipment;		
137.	- implosion;		
138.	- acoustic noise;		
139.	- excessive temperature of materials ejected or accessible non-working surfaces;		<p>ORGALIME: The manufacturers of electrical equipment with heating elements such as ironing machines, toasters and hobs do need the expression "likely to be touched", because the non-working surfaces which are immediately adjacent to the hot working surfaces are also hot but "not likely to be touched" by the user. Otherwise, electrical equipment with heating elements can not be manufactured anymore in the way as they are delivered now and will become much more complicated to design and to use and could not be proposed anymore at an affordable price. Therefore we urge to add the words "likely to be touched" after "surfaces".</p> <p>- excessive temperature of materials ejected or accessible non-working surfaces likely to be touched;</p>
140.	- biological and/ or chemical		

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
	phenomena;		
141.	- hygiene conditions for equipment intended to come into contact with the human body or with products or substances to be ingested by or administered to human beings;		
142.	- emissions, production and/or use of hazardous substances (e.g. gases, liquids, dusts, mists, vapour);		
143.	- ageing of materials;		
144.	- unattended operation;		
145.	- connection to and interruption from power supply;		
146.	- combination of equipment;		
147.	If equipment is intended for use in combination with other equipment, each equipment shall be designed and instructions shall be provided so that it is possible to combine the equipment without creating hazards.		
148.	- Energy supply other than electricity.		
149.	II.5 Protection against hazards arising from incorrect functioning		
150.	Equipment shall be designed and manufactured so as to provide		

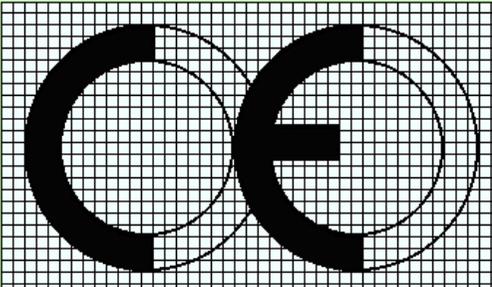
No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
	adequate protection against hazards arising from malfunctioning, due to:		
151.	- expected environmental conditions, including electric, magnetic and electromagnetic disturbances;		
152.	- logic errors in hardware or software		
153.	- interruptions or normally expected fluctuations in the power supply;		
154.	- unexpected starting or stopping operation;		
155.	- failure to stop.		
156.	II.6 Protection against hazards arising from electric, magnetic, and electromagnetic fields, other ionising and non ionising radiation		
157.	Equipment must be designed and manufactured in such a way that electric, magnetic, and electromagnetic fields and other non ionising radiations generated by the equipment are limited to the extent necessary for its operation, and operate at a safe level in compliance with the generally acknowledged state of the art, taking due account of specific community measures.		ORGALIME proposes to delete the "s" in "radiations", since "radiation" is already a plural noun (editorial).

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
158.	Equipment must be designed and manufactured in such a way that any emission of ionising radiation is limited to the extent necessary for its operation and that the effects on exposed persons are non-existent or reduced to non-dangerous levels.	The wording regarding ionising radiation is still under consideration with the responsible Commission service. It was proposed: Electrical equipment must be designed and manufactured in such a way that it complies in normal operating conditions with the basic safety standards established under Title II, Chapter 3 of the EURATOM Treaty.	
159.	II.7 Ergonomics		
160.	Equipment shall be designed and manufactured in accordance with ergonomic principles including the ability to be moved and handled safely.		<p>ORGALIME:</p> <ul style="list-style-type: none"> - It is not in the aim of the LVD to regulate the way products are designed and manufactured. The Directive should only include requirements relating to the product itself. Therefore we propose to delete the words "designed and manufactured". - The first ergonomic rule is that the product should be fit for its purpose. The LVD applies both to consumer and professional products or could be part of a construction where their destination excludes that they could be moved or handled by users (cables, cable management, luminaires, etc.). Therefore we suggest to replace the words "including the ability to be moved and handled" by the broader and less specific expression "operated safely" which recall that ergonomics principles which are not directly related to safety are not mandatory.

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
			<p>Therefore we propose the following changes:</p> <p><i>"Equipment shall be designed and manufactured in accordance with ergonomic principles <u>so that it can be operated including the ability to be moved and handled safely.</u>"</i></p>
161.	Section III		
162.	Information Requirements		
163.	III .1 General		
164.	(a) Equipment shall be identified either by means of type, batch, serial number or any other information allowing for the identification of the product and for the traceability of the manufacturer. This shall be marked legibly and indelibly on the equipment or, if this is not possible, in the accompanying instructions for use. The identification shall be amended if the equipment is altered in respect of the essential health and safety requirements of this Directive.		
165.	(b) Equipment shall be accompanied by the name and address of the manufacturer, and, if he is not established in the Community, the name and address of the person established in the Community responsible for placing the equipment on the market.		<p>ORGALIME: we are still of the opinion that it is not necessary to add the name and address of the manufacturer outside Europe and the address of the authorised representative. One address in Europe is enough. When we are going to require this extra information, special plates etc have to be made, so that the extra cost is not proportionate to the benefit. In some cases it will make the product significantly more expensive, because the housing has to be changed totally. Moreover, surveillance authorities have only benefit in some rare cases. We propose to replace the word "and, if" into ". If".</p>

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
166.	(c) Information provided with the equipment shall include instructions for safe installation, maintenance, cleaning, operation and storage.		
167.	(d) Where risks remain despite all the measures adopted or in the case of potential risks, which are not evident, appropriate warnings must be provided.		
168.	(e) The essential characteristics, the recognition and observance of which will ensure that equipment will be used safely and in applications for which it was intended and for which it can reasonably be foreseen, shall be marked legibly and indelibly on the equipment or, if this is not possible, in the accompanying instruction for use.		
169.	(f) Information provided either by marking or in the instructions for use, which is essential for the safe use of the equipment, shall be easily understandable for the intended user.		

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
170.	Annex III	The current wording of Annex III has been generally agreed by the LVD update group.	
171.	CE conformity marking and EC declaration of conformity		
172.	A. CE conformity marking		
	The CE conformity marking shall consist of the initials "CE" taking the following form:		<p>ORGALIME: to be consistent with our proposal under Article 8, we suggest to make the text consistent with the text in the EMC Directive:</p> <p><u>"The CE marking must be affixed to the equipment or its data plate. Where it is not possible or not warranted on account of the nature of the equipment, it must be affixed to the packaging, if any, and to the accompanying document"</u>.</p>

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
173.			
174.	<ul style="list-style-type: none"> If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected. 		
175.	<ul style="list-style-type: none"> The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. 		
176.	B. EC declaration of conformity		
	The EC declaration of conformity must contain the following elements:		
177.	<ul style="list-style-type: none"> reference to this Directive; 		
178.	<ul style="list-style-type: none"> date and place of issue of the declaration; 		
179.	<ul style="list-style-type: none"> name and address of the manufacturer or his authorised representative, established within the 		

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
	Community;		
180.	<ul style="list-style-type: none"> a description of the equipment, including type, batch, serial, model number or any other information allowing for the identification of the product and for the traceability of the manufacturer, etc.; 		
181.	<ul style="list-style-type: none"> reference to the harmonised standards, where these have been applied; 		
182.	<ul style="list-style-type: none"> where appropriate, references to the specifications with which conformity is declared, 		
183.	<ul style="list-style-type: none"> identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorised representative established within the Community. 		

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
184.	Annex IV	The current wording of Annex IV has been generally agreed by the LVD update group.	ORGALIME does not agree with this statement. In fact, Annex IV was never subject to discussion in any meeting of the LVD Update Working Group.
185.	Internal production control		
186.	1. Internal production control is the procedure whereby the manufacturer or his authorised representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the equipment satisfies the requirements of this Directive that apply to it. The manufacturer or his authorised representative established within the Community must affix the CE marking to each product and draw up a written declaration of conformity.		ORGALIME: suggests the following amendment: <i>"Internal production control is the procedure whereby the manufacturer or his authorized representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the electrical equipment satisfies the requirements of this Directive that apply to it. The manufacturer or his authorized representative established within the Community must affix the CE marking to each product according to annex III and draw up a written declaration of conformity."</i>
187.	2. The manufacturer must establish the technical documentation described in point 3 and he or his authorised representative		ORGALIME: suggests to delete "on Community territory" and to introduce a 3rd paragraph similar to the draft Proposal of a revised Machinery Safety Directive:

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
	<p>established within the Community must keep it on Community territory at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last product has been manufactured.</p>		<p>"2. The manufacturer must establish the technical documentation described in point 3 and he or his authorized representative established within the Community must keep it on Community territory at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last product has been manufactured.</p> <p>Further it might be more effective to add the requirement to write it in a language of the EU.</p> <p><u>The technical file does not have to be located in the territory of the European Union, nor does it have to be permanently available in material form. It must be capable of being assembled and made available with a period of time commensurate with its importance by the person designated in the EC declaration of conformity in one of the languages of the European Community.</u>"</p>
188.	<p>If neither the manufacturer nor his authorised representative is established within the Community, the obligation to hold the EC declaration of conformity and the technical documentation at the disposal of the competent authorities shall be the responsibility of the person who places the equipment on the Community market.</p>		

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
189.	3. Technical documentation must enable the conformity of the equipment to the requirements of this Directive to be assessed. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the equipment. It must include:		<p>ORGALIME: In the list of technical documentation there are some items, which are not relevant for the requirements of the Directive. Market surveillance authorities and inspectors are proficient people who should not need education to understand drawings and schemes. Furthermore, it is not necessary to list design, calculations etc. Only the information which is necessary for assessing compliance with the requirements of the Directive should be required.</p> <p>For this reason, ORGALIME proposes to delete the points concerning description and explanation and concerning design calculations.</p> <p>The list of elements requested for the Technical Documentation should be made as far as possible equivalent to the list mentioned in the Draft EMC Directive COM(2002) 759. Therefore ORGALIME proposes the following amendments:</p> <p style="padding-left: 40px;"><i>"3. Technical documentation must enable the conformity of the electrical equipment with the essential requirements of this Directive to be assessed. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the electrical equipment. It must include:</i></p>
190.	<ul style="list-style-type: none"> • a general description of the equipment, 		ORGALIME: OK
191.	<ul style="list-style-type: none"> • conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., 		ORGALIME: OK
192.	<ul style="list-style-type: none"> • descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the equipment, 		* descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the electrical equipment,

No.	Results of previous discussion and consultation	Comments received on LVD Update.3 remaining to be discussed	Comments from ORGALIME
193.	<ul style="list-style-type: none"> a list of the standards applied in full or in part, and descriptions of the solutions adopted to satisfy the safety aspects of this Directive where standards have not been applied, 		ORGALIME: OK
194.	<ul style="list-style-type: none"> results of design calculations made, examinations carried out, etc., 		ORGALIME: results of design calculations made, examinations carried out, etc.,
195.	<ul style="list-style-type: none"> test reports. 		ORGALIME: OK
196.	4. The manufacturer or his authorised representative must keep a copy of the declaration of conformity with the technical documentation.		ORGALIME: OK
197.	5. The manufacturer or his authorised representative must take all measures necessary in order that the manufacturing process shall ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.		ORGALIME: OK