



## **ORGALIME comments (13-12-2002) on**

### **Commission “LVD UPDATE.2” Working Document dated 29-10-2002**

Orgalime represents the mechanical, electrical, electronic and metal working industries of 21 European countries. Its 32 member federations represent over 100 000 companies of all sizes. With production valued at 1200 billion euros in 2001, and employing 7.5 million people, the engineering industry is the largest industrial sector.

We are pleased to forward our comments on Commission third working document on the LVD Update, further to the outcome meeting of the last LVD Update Working Group meeting on 18-19 September 2002.

**1. Orgalime agrees on the Commission proposals for the following points:**

**1. 8. 9. 10. 11. 12. 13. 21. 22. 23. 27. 28. 29. 30. 31. 61. 62. 63. 64. 67. 71. 72. 81. 82.  
83. 84. 85. 86. 87. 88. 89. 90. 91. 95. 96. 98. 99. 100. 101. 102. 103. 104. 106. 107.  
124. 124. 131. 135. 136. 141. 143. 144. 147. 150.**

**2. Orgalime has no comments to make at this stage on the following points:**

**41. 42. 43. 44. 114. 119. 120. 121. 125. 126. 127. 128. 129. 130. 138. 139. 140. 152.**

**3. Orgalime is pleased to provide the participants in the LVD Update Working group with comments on the following points:**

**2, 4, 6, 14, 15, 16, 17, 18, 19, 20, 24 (chart included), 25, 26, 36, 37, 38, 39, 40, 45,  
46, 47, 48, 49, 51, 53, 57, 58, 59, 65, 66, 68, 70, 73, 74, 75, 76, 77, 79, 92, 93, 94, 97,  
105, 108, 109, 110, 111, 115, 118 and 122.**

**4. Orgalime proposes two alternative wordings under the following points:**

**20a and 108b**

**5. Orgalime proposes detailed explanations in annex to this document for the following points:**

- 59**
- 70 to 77**

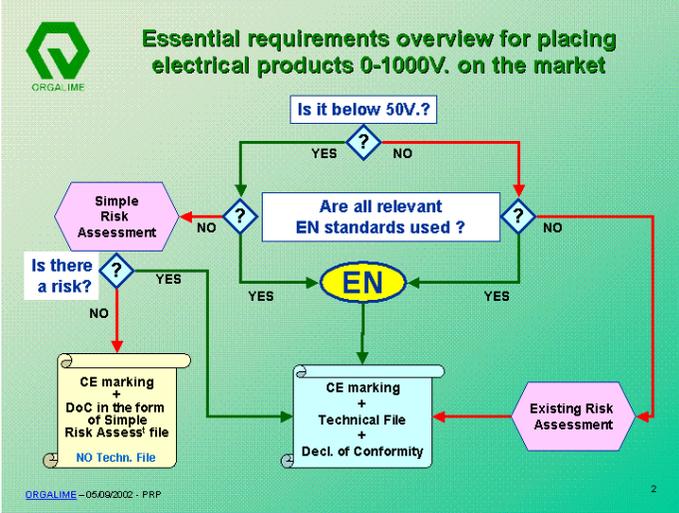
No.	Text of the consolidated LVD	Results of previous discussion and consultation	EC comments	ORGALIME comments
2.		<p>- Whereas electrical equipment must be designed and manufactured in such a way that electric, magnetic, and electromagnetic fields generated by the equipment do not exceed a safe level in compliance with the generally acknowledged state of the art taking due account of specific Community measures</p>		<p><b>ORGALIME does not agree</b> with Commission’s proposal for the following reasons:</p> <p><b>1. “And other non ionising radiations”</b>: It should be clearly mentioned which phenomena are at the source of the risks covered by the directive (See our detailed rationale under point n°108 and n°108b).</p> <p><b>2. “Reduced as far as reasonably possible”</b> alludes to the so-called “ALARA” policy, which is not appropriate for EMF risks. Here it would indistinctly apply on the one hand to the risk arising from non-ionising Infra-Red or Ultra-Violet radiations<sup>1</sup>, which is a known and serious risk that could be assessed, and on the other hand to electro-magnetic fields, which is an unknown and likely small risk, that could not be scientifically and practically assessed (no dose-response effect). In practical terms, the only thing that could be assessed is the level of exposure. If this level correspond to the frequency range recommended by ICNIRP, it “affords (...) a high level of protection” (CR 1999/519/EC), i.e. a safe level of exposure. It would be disproportionate to impose on manufacturers to reduce EMF as far as reasonably possible, even if they could demonstrate that they have reached the safe level, according to the existing Community measures.</p> <p><b>3.</b> One should not restrict the scope of the directive to the general public. ORGALIME suggest using the expression “<b>specific Community measures</b>”, being the non-binding recommendations, binding directives or harmonised standards, in order to refer to both the existing <a href="#">Council Recommendation</a></p>

<sup>1</sup> Cf. Safety standards of household and similar electrical appliances under the LVD: EN 60335-2-27:1992 - Particular requirements for ultra-violet and infra-red radiation skin treatment appliances for household and similar use and particular requirements and EN 60335-2-27:1997 for appliances for skin exposure to ultraviolet and infrared radiation.

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				<p><a href="#">1999/519/EC of 12 July 1999</a> on “the limitation of exposure of the <b>general public</b> to <b>electromagnetic fields</b> (0 Hz to 300 GHz)” and the draft directive on “minimum health and safety requirements regarding the exposure of <b>workers</b> to the risks arising from physical agents (<b>non ionising radiations</b>)” (Cf. <a href="#">COM(92)560 final</a>).</p> <p>Therefore, Orgalime proposes the following changes in Commission proposal:  <i>Whereas electrical equipment must be designed and manufactured in such a way that electric, magnetic, and electromagnetic fields <u>and other non ionising radiations</u> generated by the equipment <del>are reduced as far as reasonably possible, at least to a non-hazardous do not exceed a safe level in compliance with the generally acknowledged state of the art taking due account of <u>specific Community measures; Council Recommendation "on the limitation of exposure for the general public to electromagnetic fields (0 Hz to 300 GHz)" (1999/519/EC);</u></del></i></p>
3.		<b>Title of the directive</b>		<b>Title of the directive</b>
4.	<b>Directive</b> on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits	<b>Directive</b> xx/xx/EC of the European Parliament and of the Council relating to electrical equipment		<b>ORGALIME:</b> Whereas only the lower voltage limits are going to be deleted, it is clearer to mention “low voltage” in the title: <b>Directive</b> xx/xx/EC of the European Parliament and of the Council relating to <u>low voltage</u> electrical equipment
5.	<b>Article 1</b>	<b>Article 1: Scope and definitions</b>		<b>Article 1: Scope and definitions</b>
6.	For the purposes of this Directive "electrical equipment" means any equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and	1. 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		<b>ORGALIME:</b> Add “low voltage” like in point number 4: <i>This Directive regulates the health and safety requirements for <u>low voltage</u> 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.</i>

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	between 75 and 1 500 V for direct current, other than the equipment and phenomena listed in Annex II.	high level of health and safety.		
14.	Electric fence controllers	deleted	France: Objection because the intended use of these products is not inline with the aims of the directive.	ORGALIME's membership, except for its French constituency, supports the Commission's proposal
15.	Radio-electrical interference			ORGALIME: Agrees with the Commission's proposal to delete this item
16.	Specialized electrical equipment, for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the Member States participate.	(a) Specialised electrical equipment, for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the Member States participate.	It was agreed to provide further details of the impact of this exclusion, and all members were asked to provide examples of such equipment and agreements.	ORGALIME: Agrees with the Commission's proposal. The word "specialised" has to be maintained and not be replaced by a formulation such as "electrical equipment, specially designed, etc". In order to create a sharp borderline, which can be maintained by manufacturers and market surveillance inspectors as well, only equipment that can only be used on ships, aircraft and railways is excluded. Any time that equipment is used outside these areas, the LVD is applicable. The consequence for a broad area of equipment is that they are possibly covered by the LVD and the specific legislation (such as SOLAS and MARED for ships) and consequently have to apply to both administrative procedures. ORGALIME is of the opinion that clarity in this respect is more important than e.g. the obligation of double marking in some cases.
17.		(b) Electrical equipment specially designed for incorporation into motor vehicles	This exclusion was subject to discussion given the uncertainty of interface between the LVD and the Automotive directives, in particular for hand-held items.  Austria suggested that it might be better not to	ORGALIME: wording should be made in compliance with the wording on ships and aircrafts, i.e. exclude equipment that can only be used in motor vehicles and not elsewhere.

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			mention this exclusion so that if more specific requirements are available they would automatically apply whereas if not the LVD could be appropriate.	
18.		(c) Equipment covered by the Directive 98/37/EC on the approximation of the laws of the Member States relating to machinery		<b>ORGALIME:</b> This is only acceptable if the exclusion list in the draft machinery Directive is agreed and has come into force. The mutual exclusion has to be ensured.
19.		(d) High Voltage Step-down transformers with input voltage above 1000 Volt		<b>ORGALIME</b> has the following editorial comment: Add an “s” after “transformer”: <i>“High Voltage Step-down transformers with input voltage above 1000 Volt”</i>
20.		(e) Electrical equipment, which owing to their technical characteristics, to the energy applied or stored within and to their intended use, cannot pose any hazard covered by this directive;		<b>ORGALIME</b> does not agree with this para and suggests to delete it: <i>(e) Electrical equipment, which owing to their technical characteristics, to the energy applied or stored within and to their intended use, cannot pose any hazard covered by this directive;</i>
20a				<b>ORGALIME</b> proposes to add the exclusion of basic components in replacement of clause 25: <i>(j) <del>(k)</del> Basic components which are intended to be incorporated into electrical equipment, in such a way that their safety depends on how they are integrated into the other equipment</i>
23.		<b>Electrical equipment</b>		<b>Electrical equipment</b>
24.		Any appliance designed for use with a voltage rating not exceeding 1000 Volt for alternating current and 1500 Volt for direct current and intended for the purposes of generation, conversion, transmission,		<b>ORGALIME:</b> Agrees with the Commission’s proposal ORGALIME supports the withdrawal of the lower voltage limit, provided that the following procedure applies: see enclosed flowchart, as presented and agreed upon during the last LVD Update Working Group Meeting on 18-19 September 2002.

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		distribution or utilisation of electrical energy.		<p>If there is no harmonised standard available most industry sectors agree that equipment below 50 volts should be submitted to a simple risk assessment (that could be described in a CENELEC standard).</p> <ul style="list-style-type: none"> <li>- If the simple risk assessment procedure demonstrates an absence of risks, no additional administrative obligations such as declaration of conformity and technical file should be required for placing the equipment on the market. Only the simple risk assessment should be kept available for a period of 10 years.</li> <li>- If the simple risk assessment procedure demonstrates a risk, the manufacturer shall go through the usual procedure of CE marking, technical file, and declaration of conformity as pointed out in this flow-chart:</li> </ul> 
25.		Electrical components intended to be incorporated into electrical equipment and designed to fulfil a function in		<p><i>Electrical components intended to be incorporated into electrical equipment and designed to fulfil a function in such a way that their compliance with the Principal Elements of the</i></p>

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		such a way that their compliance with the Principal Elements of the essential health and safety requirements can be assessed independently, are deemed to be electrical equipment for the purpose of this Directive.		<p><i>essential health and safety requirements can be assessed independently, are deemed to be electrical equipment for the purpose of this Directive</i></p> <p><b>ORGALIME:</b> The proposed text is not clear and may cause many difficulties in practice. What are Principal Elements? It is much clearer to exactly define what is excluded, than to say what is included. In the latter case manufacturers and market inspectors have to conclude what is excluded. <b>ORGALIME proposes to delete this clause</b> and to replace it by an added exclusion of basic components (see proposed wording under Clause 20a).</p>
26.		Accessories intended to be used in conjunction with electrical equipment and designed to contribute to its safety functioning are deemed to be electrical equipment for the purpose of this Directive.		<p><b>ORGALIME:</b> Proposes a wording clearly addressing cable management systems:</p> <p><i>Cable management systems Accessories intended to be used in conjunction with electrical equipment and designed to contribute to its safety functioning are deemed to be electrical equipment for the purpose of this Directive.</i></p>
35.	<i>Article 5</i>	<i>Article 5</i>	To be discussed	<b>ORGALIME:</b> Agrees with the existing text of the Directive
36.	The Member States shall take all appropriate measures to ensure that, in particular, electrical equipment which complies with the safety provisions of harmonized standards shall be regarded by their competent administrative authorities as complying with the provisions of Article 2, for the purposes of placing on the market and free movement as referred to in Article 2 and 3 respectively.	1. Where equipment complies with the relevant harmonised standards whose references have been published in the Official Journal of the European Communities, Member States shall presume compliance with the essential requirements referred to in Annex I.		<p><b>ORGALIME:</b> Agrees with the Commission's proposal, conditional on the suggested Orgalime change:</p> <p><i>1. Where equipment complies with the relevant harmonised standards whose references have been published in the Official Journal of the European Communities, Member States shall presume compliance with the essential requirements referred to in Annex I.</i></p>

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37.	Standards shall be regarded as harmonized once they are drawn up by common agreement between the bodies notified by the Member States in accordance with the procedure laid down in Article 11, and published under national procedures. The standards shall be kept up to date in the light of technological progress and the developments in good engineering practice in safety matters.			<p><b>ORGALIME:</b> Although bodies meant in this point are notified, they are no Notified Bodies. Article 5 includes a phrase on the national standardization bodies. The proposal on article 11 in comment 51 shows that confusion might easily pop up. Therefore we propose to replace the phrase ‘bodies notified by the Member States’ by ‘national standardisation bodies, notified by the Member states’.</p> <p>Besides, we believe that the standard will give presumption of conformity at the date that the first national standards organisation has implemented the standard after the date of publication (DoP). Waiting for the publication in the OJEC, would further delay the availability of the standard for users. Therefore orgalime suggests the following change:</p> <p><i>Standards shall be regarded as harmonized once they are drawn up by common agreement between the <u>national standards organisations of bodies notified by the Member States in accordance with the procedure laid down in Article 11, and published under national procedures.</u> The standards shall be kept up to date in the light of technological progress and the developments in good engineering practice in safety matters.</i></p>
38.	For purposes of information the list of harmonized standards and their references shall be published in the Official Journal of the European Communities.			<p><b>ORGALIME does not agree</b> with the deletion of the phrase under point 38, for the reasons explained under 37. Therefore, the deletion of this phrase only does add delay.</p>
39.		2. Where a Member State or the Commission considers that a harmonised standard referred to in Article 5 does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State		<p><b>ORGALIME: Agrees</b> with Commission's proposal. The consequence of this requirement is that the LVD Working Party, which is a flexible and well working body, shall continue.</p> <p><b>It must be clearly understood that the European standards organisations should be consulted.</b></p>

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		<p>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 the 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 a harmonised standard, or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Communities.</p>		
40.	<i>Article 6</i>		To be discussed	<p><b>ORGALIME</b> believes that the existing text (covered by items 41 to 43) should remain as it is, except for the deletion of the reference to CEE, but not to IEC.</p> <p>Proposal for paragraph 1:</p> <p><i>1. Where harmonised standards as defined in Article 5 have not yet been drawn up and published, the Member States shall take all 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 the safety provisions of the International Electro-technical Commission (IEC) in respect of which the publication procedure laid down in paragraphs 2 and 3 has been applied.</i></p>
45.	<i>Article 7</i>		To be deleted	<p><b>ORGALIME</b> proposes to maintain the existing article 7 of the Directive: it should not be deleted.</p>

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46.	Where harmonized standards within the meaning of Article 5 or safety provisions published in accordance with Article 6 are not yet in existence, the Member States shall take all appropriate measures to ensure that, for the purpose 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 manufactured in accordance with the safety provisions of the standards in force in the Member State of manufacture, if it ensures a safety level equivalent to that required in their own territory.			<p><b>ORGALIME</b> believes that many European countries use Article 7 in their national legislation for the remainder of their national standards. Most of national standards are product standards for installation products and are used according to the national installation rules (CENELEC HD384). The presumption of conformity of these products is very useful. We can only delete Article 7 if the installation rules do not refer any longer to these product standards. This is only possible if there are adequate transitional measures, drawn up by CENELEC/TC 64. Failing this, severe safety problems will occur in some countries. ORGALIME is prepared to supply adequate examples during the coming LVD Update Working Group meeting, if necessary.</p>
47.	<i>Article 8</i>		To be discussed	<p><b>ORGALIME:</b> Keep the existing paragraph:</p> <p><i>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.</i></p>
48.	<i>Article 9</i>		To be discussed	<p><b>ORGALIME</b> is in favour to keep the existing Article 9</p>

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49.	<i>Article 10</i>		To be discussed	ORGALIME is in favour of the existing practice of the LVD Guide. If the existing directive text will be redrafted, the text of the LVD Guide should be taken into account.
50.	<i>Article 11</i>	<i>Article 11: Notified bodies</i>	To be discussed	<i>Article 11: Notified bodies</i>
51.	<p>Each Member State shall inform the other Member States and the Commission of the following:</p> <ul style="list-style-type: none"> <li>- the bodies referred to in Article 5;</li> <li>- the bodies which may make a report in accordance with the provisions of Article 8 or give an opinion in accordance with the provisions of Article 9;</li> <li>- the place of publication referred to in Article 5 (2);</li> </ul> <p>Any amendment to the above shall be notified by each Member State to the other Member States and to the Commission.</p>	<ol style="list-style-type: none"> <li>1. Member States shall notify the bodies referred to in Article 5 to the Commission and to the other Member States. Such notification shall state whether those bodies are competent for all electrical equipment covered by this Directive or whether their responsibility is limited to certain specific areas.</li> <li>2. Member States shall apply the criteria listed in Annex VI for the assessment of the bodies to be notified. Bodies, which comply with the assessment criteria fixed by the relevant harmonised standards, shall be presumed to comply with the aforementioned criteria as covered by the relevant standards. The Commission shall publish in the Official Journal of the European Communities the reference of those standards.</li> <li>3. The Commission shall publish in the Official Journal of the European Communities a list of notified bodies. The Commission shall ensure that</li> </ol>		<p><b>ORGALIME:</b></p> <p><b>§1:</b> The reference to Article 5 appears to be inappropriate. Bodies referred to in article 5 are the national standardisation bodies. The proposed text means that some national standards organisations have limitations, which apparently have to be compensated by another national body. In our view this is confused with notification of third parties meant in the existing articles 8 and 9.</p> <p>Therefore we suggest deleting the second indent of paragraph 1.</p> <p><i>Member States shall notify the bodies referred to in Article 5 to the Commission and to the other Member States.</i></p> <p><del><i>Such notification shall state whether those bodies are competent for all electrical equipment covered by this Directive or whether their responsibility is limited to certain specific areas.</i></del></p> <p><b>§2, §3 and §4:</b> Commission’s LVD Update working group should discuss it in the light of the result on the articles 8, 9 and 10.</p>

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		<p>this list is kept up to date.</p> <p>4. If a Member State finds that a notified body no longer meets the criteria listed in Annex VI, it shall inform the Commission and the other Member States thereof. The reference to this notified body shall be withdrawn from the list referred to in paragraph 3.</p>		
52.		<p><i>Annex VI</i> <i>Criteria for the assessment of the bodies to be notified</i></p>		<p><i>Annex VI</i> <i>Criteria for the assessment of the bodies to be notified</i></p>
53.		<p>1. The bodies notified by the Member States shall fulfil the following minimum conditions: (...) (d) independence of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with the product in question;</p>		<p>ORGALIME suggests to replace the word “product” by the word “equipment” in Commission’s proposal: <i>1. The bodies notified by the Member States shall fulfil the following minimum conditions:</i> (...) <i>(d) independence of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with the <u>equipment product</u> in question;</i></p>

No.	Results of previous discussion and consultation	Commission Comments	ORGALIME comments
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## Annex I

### Essential health and safety requirements

54.	Annex I		
55.	<b>ESSENTIAL HEALTH AND SAFETY REQUIREMENTS</b>		
56.	<b>Section I General requirements</b>		
57.	1. The manufacturer of electrical equipment is under the obligation to perform a risk assessment referring to the essential health and safety requirements; the electrical equipment must be designed and manufactured taking into account this assessment.		See <b>ORGALIME</b> comment under 58
58.	Applying harmonized standards covering all relevant essential health and safety requirements is considered to fulfil the obligation to perform a risk assessment.		<b>ORGALIME:</b> In principle ORGALIME can agree with the proposed wording of the Commission if this clause is maintained till the coming into force of the renewed Directive. However, point n°58 seems to be not a requirement but a clarification. If this phrase will be deleted the harmonised standards covering the risk assessment have no legal value and consequently another risk assessment has to be carried out. For that reason ORGALIME prefers the initial solution decided during the LVD Update WG meeting of September 2002: <i>.....either a risk assessment or to entirely follow the relevant harmonised standards.....</i>
59.	2. The obligations laid down by the essential health and safety requirements apply to electrical equipment in its intended purpose		<b>ORGALIME:</b> See the additional explanatory paper with specific ORGALIME comments on point number 59 to justify the following suggestion for change:

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	and in conditions which can be reasonably foreseen by the manufacturer throughout its anticipated lifetime.		2. The obligations laid down by the essential health and safety requirements apply to electrical equipment in its intended purpose and in conditions which can be reasonably foreseen by the manufacturer <del>throughout its anticipated lifetime.</del>
(...)			
60.	<b>I.1 Principals of safety integration</b>		<b>I.1 Principals of safety integration</b>
(...)			
64.	In selecting the most appropriate solution, the manufacturer must apply as far as reasonably possible the following principles in the order given below:		<b>ORGALIME:</b> OK
65.	– eliminate or reduce risks (inherently safe equipment design and construction);		<b>ORGALIME:</b> Editorial: According to prEN ISO 12100, Orgalime suggests: <i>- eliminate hazards or reduce risks by inherent design measures.</i>
66.	– take the necessary protective measures in relation to risks that cannot be eliminated;		<b>ORGALIME:</b> proposes the following: <i>- take the necessary protective measures in relation to risks that cannot be reduced by inherent design measures;</i>
(...)			
68.	Electrical Equipment shall be – designed and manufactured so that it can be safely and properly assembled, connected and maintained; – supplied with necessary special devices and accessories where it would otherwise not meet the ERs of the directive taking into account the intended use of the equipment.		<b>ORGALIME:</b> The second indent could be interpreted in ways that are not intended, such as requiring personal protective equipment to be provided with the product. Additionally, it would be dangerous to assume which particular special devices and accessories are needed, as this can vary significantly, depending on, for example, unexpected wire gauge, fittings, etc., at the installation site. Examples why this requirement is not feasible are to be found in many standards, e.g.: EN 61010-1: Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements – Clause 6.11.2.1 - power switch has to be integrated in the equipment or must be described;  EN 60974-1: Arc welding equipment — Part 1: Welding power sources –

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			<p>Clause 8.2 - mains supply is protected by external fuses or a protective switch, which is described by the manufacturer;</p> <p>EN 61558-1: Safety of power transformers, power supply units and similar — Part 1: General requirements and tests – Clause 8.5 - if fuses are not integrated in the equipment they must be described and specified.</p> <p>Therefore, Orgalime proposes:</p> <p><i>Electrical Equipment shall be</i></p> <ul style="list-style-type: none"> <li>– <i>designed and manufactured so that it can be safely and properly assembled, connected and maintained;</i></li> <li>– <del><i>supplied with necessary special devices and accessories where it would otherwise not meet the ERs of the directive taking into account the intended use of the equipment.</i></del></li> </ul>
69.	Section II Requirements regarding design and construction		Section II Requirements regarding design and construction
70.	II.1 Protection against electric shock and other electrical hazards		ORGALIME: See the ORGALIME proposal on this point number at the end of this paper
(...)			
73.	Electrical equipment must provide, where appropriate, adequate protection against electrical hazards arising from:	<i>“Electrical equipment must provide, where appropriate, adequate protection against electrical hazards resulting from excessive current passing through the human body and livestock arising from leakage current, transients from energy supply and electro-static charges and overload.”</i> Delete then items 58, 59 and 60.	ORGALIME: See the ORGALIME proposal on this point number at the end of this paper

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		This should be further discussed.	
74.	- leakage current;		<b>ORGALIME:</b> see comment under 70
75.	- energy supply;		<b>ORGALIME:</b> see comment under 70
76.	- electro-static charges;		<b>ORGALIME:</b> see comment under 70
77.	- arcs.		<b>ORGALIME:</b> see comment under 70
78.	<b>II.2 Protection against fire hazards</b>		<b>II.2 Protection against fire hazards</b>
79.	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.		<b>ORGALIME</b> suggests to replace "posed" by "initiated": the Directive should not take into account secondary consequential fires: <i>Electrical equipment must provide, where appropriate, adequate protection against fire hazards <del>posed</del> initiated by the electrical equipment itself or by substances produced, emitted or used by electrical equipment.</i>
80.	<b>II.3 Protection against mechanical hazards</b>		<b>II.3 Protection against mechanical hazards</b>
81.	Where applicable, electrical equipment must provide adequate protection against mechanical hazards, in particular, arising from:		<b>ORGALIME:</b> OK
82.	- instability;		
83.	- ejected objects;		
84.	- rough surfaces, sharp edges or corners;		
85.	- moving parts;		
86.	- vibration;		
87.	<b>II.4 Protection against other hazards</b>		<b>II.4 Protection against other hazards</b>
(...)			
92.	- burn due to excessive temperature of materials ejected or surfaces;		<b>ORGALIME:</b> Editorial comment: we suggest deleting “burn due to” for the following reason: the burn is the consequence of the phenomenon and not the phenomenon in itself. Further reverse the last part of the sentence to make it more understandable for the average reader, that <i>where applicable, electrical equipment must</i>

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			<p>provide adequate protection against the hazards arising from:</p> <p>- <del>burn due to extreme excessive</del> temperature of materials ejected or surfaces;</p>
93.	- biological and/ or chemical phenomena;		<p><b>ORGALIME:</b> All biological or chemical effects are not necessarily hazardous and are sometimes the intended result: e.g. cooling with an electric fan or heating thanks to an electric blanket. It should be made clear that the directive does not cover phenomena stemming outside the equipment itself. Therefore, Orgalime proposes the following changes:</p> <p>- <del>adverse biological and/ or chemical phenomena within the equipment itself;</del></p>
94.	- hygiene conditions for electrical equipment intended to come into contact with the human body or with products or substances to be ingested by or administered to human beings;		<p><b>ORGALIME does not agree</b> with Commission's proposal.</p> <p>The problem of the cleanability is solved by the standards already. Despite that the existing LVD does not include requirements for the cleanability of products the standards have solved it by including sufficient articles in the standards. This includes ridges and crevices, which could harbour organic material.</p> <p>This item should not include requirements to prevent allergies. For that purpose other directives are in force.</p> <p>The contact with food and beverages is already covered by other directives, such as 1989/109/EEC, or 1998/83/EC.</p> <p>Therefore Orgalime proposes to delete the paragraph under item n°94:</p> <p><del>–hygiene conditions for electrical equipment intended to come into contact with the human body or with products or substances to be ingested by or administered to human beings;</del></p>
(...)			
97.	- unattended operation;		<p><b>ORGALIME</b> proposes to delete this item “- <del>unattended operation;</del>” for the following reasons:</p> <p>If the equipment is intended to operate unattended, such as a fridge or a washing machine, the risks are fully covered by other requirements such as in point number 59.</p>
(...)			
105.	- interruptions or normally expected fluctuations in the power supply;		<p><b>ORGALIME</b> suggests to delete point n°105 because it is already covered by point n°98.</p>

No.	Results of previous discussion and consultation	Commission Comments	ORGALIME comments
			<p>point n°98:</p> <p><del>interruptions or normally expected fluctuations in the power supply;</del></p>
(...)			
108.	II.6 Protection against hazards arising from electric, magnetic, and electromagnetic fields		<p>ORGALIME: Proposes a change in the title of “Section II.6” for the reasons explained under point n°2 and below point n°108b:</p> <p><i>II.6 Protection against hazards arising from electric, magnetic, and electromagnetic fields <u>and other non ionising radiations</u></i></p>
108.b			<p>ORGALIME: proposes to add a point 108b, which reads:</p> <p><i>For the purpose of this directive:</i></p> <ul style="list-style-type: none"> <li>- <i>electric, magnetic, or electromagnetic fields designate non-ionising low, medium and high frequency waves or radiations from 0 Hz to 300 GHz;</i></li> <li>- <i>other non ionising radiations designate optical radiations or infra-red, visible or ultra-violet electro-magnetic waves from 300 GHz to 3.10<sup>15</sup> Hz.</i></li> </ul> <p>Indeed, it should be clearly mentioned which phenomena are at the source of the risks covered by the directive. Since the same phenomena are designated by different terms in specific European measures (being the recommendations, directives and harmonised standards), reference to those technical terms would clearly indicate that the current directive serve as a legal basis for the harmonisation of national measures:</p> <ul style="list-style-type: none"> <li>- for both for the general public and for workers;</li> <li>- for both EMF and optical radiations, which are both non ionising</li> </ul>
109.	Electrical 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 reduced as far as reasonably possible, at least to a non-hazardous level in compliance with the generally acknowledged state of the art.		<p>ORGALIME: Proposes changes because the ALARA policy is neither proportionate nor appropriate to the risk arising from electric, magnetic, and electromagnetic fields. See rationale under point n°2 and Orgalime on-line Information Note on EMF Risk Management: <a href="http://www.orgalime.org/pdf/EMF-RM02.pdf">http://www.orgalime.org/pdf/EMF-RM02.pdf</a>. Reference to <i>specific Community measures</i> (CR 1999/519/EC, Directive on physical agents for workers...) should be made in the text of the directive. The paragraph should read:</p>

No.	Results of previous discussion and consultation	Commission Comments	ORGALIME comments
			<p><i>Electrical 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 <u>limited to the extent necessary for its operation, reduced as far as reasonably possible, and operate at a safe at least to a non-hazardous level in compliance with the generally acknowledged state of the art, taking due account of specific Community measures.</u></i></p>
110.	<p>Electrical equipment intended to emit electric, magnetic, and electromagnetic fields which due to its intended purpose may present a hazard must be designed and manufactured in such a way the mode of operation can be easily controlled.</p>		<p><del>Electrical equipment intended to emit electric, magnetic, and electromagnetic fields which due to its intended purpose may present a hazard must be designed and manufactured in such a way the mode of operation can be easily controlled.</del></p> <p><b>ORGALIME:</b> suggest to delete point n°110, because it believes that it is up to the standardisation to define the mode of control for each “equipment which due to its intended purpose may present a hazard”, within the framework defined by specific Community measures, as referred to in point n°109 (in the light of point n°2 or as amended by Orgalime). Indeed:</p> <ul style="list-style-type: none"> <li>➤ If the equipment referred to in point n°110 is a medical equipment, it is separately regulated by the directive on medical devices;</li> <li>➤ If it is a work equipment / station, it is intended to be operated by a knowledgeable and trained worker and is deemed to be regulated by the physical agents directive: cf. draft proposal COM(92)560 final;</li> <li>➤ If the equipment referred to in point n°110 is to be used by the general public, such as a mobile phone or a microwave oven, it should comply with CR 1999/519/EC and the corresponding harmonised standards.</li> </ul> <p>C.f. Orgalime on-line Information Note on EMF Risk Management:  <a href="http://www.orgalime.org/pdf/EMF-RM02.pdf">http://www.orgalime.org/pdf/EMF-RM02.pdf</a></p>
111.	<p>Where electrical equipment presents a residual risk with regard to electric, magnetic, and electromagnetic fields and where the exposure requires particular</p>		<p><del>Where electrical equipment presents a residual risk with regard to electric, magnetic, and electromagnetic fields and where the exposure requires particular precautions, appropriate information shall be provided together</del></p>

No.	Results of previous discussion and consultation	Commission Comments	ORGALIME comments
	<p>where the exposure requires particular precautions, appropriate information shall be provided together with the electrical equipment.</p>		<p><del>with the electrical equipment.</del></p> <p><b>ORGALIME:</b> does not agree with this indent and believes it should be deleted. There is no point to add “particular precautions” to the precautionary approach embedded in either Council Recommendation 1999/519/EC or the draft directive for workers.</p> <p>Besides, there could not be any assessment of a “residual risk” arising from exposure to EMF, once the product has been designed in compliance with the exposure limits (based on ICNIRP guidelines) as set up in the existing protection schemes.</p> <p>It is to be noted that the mandate to European standards organisations within the framework of the LVD and of the RTTE already requires appropriate information to be delivered to consumers. Conversely, the Draft Directive Physical Agents requires the employer to take appropriate measures for protecting his employees, such as information and training. Therefore, it is not necessary to add such a redundant requirement for such non-assessable “residual risks”.</p>
112.	<b>II.7 Ergonomics</b>		<b>II.7 Ergonomics</b>
113.	Where appropriate, electrical equipment shall be designed and manufactured:		<i>Where appropriate, electrical equipment shall be designed and manufactured:</i>
(...)			
115.	<p>- in such a way that under the intended conditions of use the discomfort, fatigue and psychological stress faced by the operator is reduced to the minimum possible taking into account ergonomic principles and the generally acknowledged state of the art.</p>		<p><del>—in such a way that under the intended conditions of use the discomfort, fatigue and psychological stress faced by the operator is reduced to the minimum possible taking into account ergonomic principles and the generally acknowledged state of the art.</del></p> <p><b>ORGALIME:</b> does not agree with item n°115 copied from the Machinery Directive, because it believes that the wording does not fit to electrical equipment.</p> <p>We need some examples having an impact on the safety or on the health. If not, such a provision could be misinterpreted by Member states and give</p>

No.	Results of previous discussion and consultation	Commission Comments	ORGALIME comments
			them an opportunity to remove television sets, or personal computers, etc.. from the market for their prolonged use is tiring and can bring a psychological stress.
(...)			
116.	<b>Section III Information Requirements</b>		<b><i>Section III Information Requirements</i></b>
117.	<b>III .1 General</b>		<b><i>III .1 General</i></b>
118.	Electrical equipment shall be identified by means of type, batch, serial number, or any other information allowing for the identification of the product. This shall be marked legibly and indelibly on the equipment or, if this is not possible, on an accompanying notice.		<b>ORGALIME:</b> Point numbers 118 and 119 are included in order to improve the <u>traceability</u> of the product:  <i>Electrical equipment shall be identified by means of type, batch, serial number, or any other information allowing for the identification <u>and traceability</u> of the product. This shall be marked legibly and indelibly on the equipment or, if this is not possible, on an accompanying notice.</i>
(...)			
122.	The essential characteristics, the recognition and observance of which will ensure that electrical 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, on an accompanying notice.		<b>ORGALIME</b> believes that this point n°122 is superfluous because it is already covered by point n°120 and n°121 and should therefore be deleted. If it is not covered, it looks like pure bureaucracy. Nobody is going to read obvious labels. It should be made clear in installation and users manuals.

No.	Text of the <u>consolidated Low Voltage Directive</u>	Results of previous discussion and consultation; see working document LVD UPDATE.0	Comments
123.	<u>ANNEX III</u>		<u>ANNEX III</u>
...			
132.	- name and address of the manufacturer or his authorised representative established within the Community,	UK proposal: - name and address of the manufacturer or his authorised representative, established within the Community; <u>- where the manufacturer is established outside the Community, and where no authorised representative has been appointed within the Community, the name and address of the person within the Community holding the Technical Documentation or who can assemble the Technical Documentation;</u> General support given.	<b>ORGALIME:</b> OK supports the UK proposal to add the second indent to the existing text:  - <i>name and address of the manufacturer or his authorised representative, established within the Community;</i>  - <i>where the manufacturer is established outside the Community, and where no authorised representative has been appointed within the Community, the name and address of the person within the Community holding the <u>Technical Documentation or who can assemble the Technical Documentation;</u></i>
133.	- a description of the electrical equipment,	UK proposal: - a description of the electrical equipment, <u>including model number, etc.;</u> General support given	<b>ORGALIME:</b> Supports the UK proposal with the proposed change:  - <i>a description of the electrical equipment, <u>such as the including model number, etc.;</u></i>
134.	- reference to the harmonized standards,	UK proposal: - reference to the harmonised standards, <u>where these have been applied;</u> General support given.	<b>ORGALIME:</b> Supports the UK proposal:  - <i>reference to the harmonised standards, <u>where these have been applied;</u></i>
...			
137.	- the last two digits of the year in which the CE marking was affixed.	UK proposal: - <del>the last two digits of the year in which the CE marking was affixed.</del> General support given.	<b>ORGALIME:</b> Supports the UK proposal of deletion of this indent:  - <del><i>the last two digits of the year in which the CE marking was affixed.</i></del>
138.			
139.	<u>ANNEX IV</u>		<u>ANNEX IV</u>
140.	INTERNAL PRODUCTION		INTERNAL PRODUCTION CONTROL

No.	Text of the <u>consolidated Low Voltage Directive</u>	Results of previous discussion and consultation; see working document LVD UPDATE.0	Comments
	<b>CONTROL</b>		
142.	<p>1. 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>Where neither the manufacturer nor his authorized representative is established within the Community, this obligation is the responsibility of the person who places the electrical equipment on the Community market.</p>	<p>UK proposal: 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>Where neither the manufacturer nor his authorized representative is established within the Community, <del>this obligation is the responsibility of the each importer/person</del> who places the electrical equipment on the Community market <u>must hold a copy of the declaration of conformity, which will contain the name and address of the person within the Community holding the Technical Documentation or who can assemble the Technical Documentation as laid down in Annex III.</u> General support given.</p>	<p><b>ORGALIME:</b> We suggest to follow the example of the current Draft Machinery Directive, Annex VI; 2; 2nd sentence and thus delete the need to keep technical documentation on Community territory ground. Electronic access should be enough. We suggest the following change to the UK proposal:</p> <p><i>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.</i> <i>Where neither the manufacturer nor his authorized representative is established within the Community, <del>this obligation is the responsibility of the each importer/person who places the electrical equipment on the Community market must hold a copy of the declaration of conformity, which will contain the name and address of the person within the Community holding the Technical Documentation or who can assemble the Technical Documentation as laid down in Annex III.</del> <u>and he or his authorized representative established in the Community must keep it available within appropriate time at the disposal of the relevant national authorities.</u></i></p>
(...)			
145.	<ul style="list-style-type: none"> <li>- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,</li> </ul>		<ul style="list-style-type: none"> <li>- <del>conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,</del></li> </ul> <p><b>ORGALIME:</b> We have agreed in the last LVD Update meeting to delete this point. This is not necessary for safety and traceability. Even in the EMC Directive this clause was deleted. Safety mostly depends on insulation and protection measures and not how electrical equipment is working. The real safety features are required in the</p>

No.	Text of the <u>consolidated Low Voltage Directive</u>	Results of previous discussion and consultation; see working document LVD UPDATE.0	Comments
			essential requirements and consequently in standards, which can be used for testing. Drawings and schemes do not add much to that system.
146.	- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the electrical equipment,		<p><del>— descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the electrical equipment,</del></p> <p><b>ORGALIME:</b> We have agreed in the last LVD Update meeting to delete this point. If descriptions and explanations are not necessary for the user, this requirement means a lot of extra effort requested from the manufacturer, which will not result in more safety or traceability. Market surveillance services have to be proficient people, for whom it is not necessary to clarify how products work. This requirement will induce a lot of bureaucracy, which in case of complicated industrial products will rise to huge unnecessary costs.</p>
148.	- results of design calculations made, examinations carried out, etc.,		<p><del>results of design calculations made, examinations carried out, etc.,</del></p> <p><b>ORGALIME:</b> When the product complies with the harmonised standards, it is in conformity and that should be enough. 1</p>
149.	- test reports.		<b>ORGALIME:</b> If any are available, orgalime agrees to include test reports in the technical documentation.
151.	5. The manufacturer 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.	UK proposal: 5. The manufacturer <u>or his authorised representative</u> 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. General support given.	<b>ORGALIME:</b> Supports the UK proposal: 5. <i>The manufacturer <u>or his authorised representative</u> 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.</i>

## **Specific ORGALIME comments on point number 59**

### **Definition of the problem**

The document on LVD Update.1 shows in clause 59:

#### *Essential requirement 2:*

*The obligations laid down by the essential health and safety requirements apply to electrical equipment when used for its intended purpose or in conditions, which can be reasonably foreseen by the manufacturer throughout its anticipated lifetime.*

### **Considerations**

The existing LVD has no direct reference to the safety during the whole lifetime. Nevertheless, the spirit is that electrical equipment has to be safe during the whole lifetime. This is well understood by the standardization community, because there are many clauses in standards, which refer to the safety at the end of the lifetime.

The new LVD Update.2 shows this issue in clause 59, but the WG decided to consider the issue more in depth.

### **Product liability**

The Product Liability Directive requires responsibility from the manufacturer as regards proper design, construction and documentation of the product. But the user of the product is assumed to use the product in an appropriate way, taking the level of training and education of the “average user” of the product into account.

### **Manufacturer**

In all fairness the user may expect that a product has to be safe during its lifetime and that it will “die safely”. This expectation is partly dependent on what the manufacturer is saying. The WG agreed that the manufacturer’s opinion is more important than the opinion of e.g. the market surveillance. However, manufacturers are not happy to face a requirement to declare on beforehand what is the expected lifetime of his product. That will introduce unwanted liability and commercial side effects.

### **Maintenance**

A product has to be maintained according to the manufacturer’s instructions. These instructions have to point out what are the weak points in the product and which have to be inspected and/or maintained regularly in order to keep the product safe. The manufacturer has to keep in mind what is the foreseeable user. He has to take into account what is the average skill of this user. If a product will only be used by proficient people the manufacturer may assume that the way how products can become unsafe are at the level of proficiency of these people. However, if ordinary consumers can use the product the manufacturer should take into account no proficiency in this respect.

No.	Text of the <u>consolidated</u> Low Voltage Directive	Results of previous discussion and consultation; see working document LVD UPDATE.0	Comments
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### User

The answer on the question what is the lifetime is also dependent on what experience of users is. If in case of an accident with a coffee machine, a manufacturer declares that his machine will only survive 2 years, but in practice users know that this system will last 10 years, the manufacturer is not credible.

The user has also some responsibilities as is pointed out under Maintenance. When after a fall on the ground the consumer has identified a crack or a hole in the housing of his coffee machine it should be obvious that he decides that this is a dangerous situation which requires measures. These measures could be the decision that the lifetime is over, or that the product has to be brought to a proficient repair shop.

### Proposal:

The LVD should not mention which party has the preference to say what is the lifetime of a product. Clause 61 of the LVD Update.2 document includes enough requirements that the manufacturer has to produce a safe product, when used for its intended purpose, properly installed and used under foreseeable conditions. Further, from the Product Liability legislation the user has to act in a reasonable way.

If the inclusion of point number 96 is not enough or does not give enough clarity, we suggest to add an additional clause in the preamble, more or less equal to the article 2b of the GPSD:

*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;*

Also the future LVD Guide might contain a clarification in the light of the considerations above.

Therefore ORGALIME proposes

- to add a phrase on this issue in the preamble,
- to delete the words "throughout its anticipated lifetime" in point number 59 and
- to put this issue in the library of "items to remember while writing a new LVD Guide".

## **Specific ORGALIME comments on points number 70 – 77**

### **ORGALIME comments on points number 70 m- 77 on section II “Requirements regarding design and construction” Clause II.I “Protection against electric shock and other electrical hazards”.**

The discussion with experts from industry showed that this clause is not yet investigated enough in the Commission’s WG. Points number 73 – 77 give a list a some phenomena which may lead to electric shock. As such these phenomena itself are no electric shock.

Examples:

- Transients from energy supply or electric overload might degrade or break down the insulation. That might result in a possibility for an electric shock.
- Leakage current as such does not harm. Only, if a person can touch the part where a leakage current is flowing and the touchable voltage is high enough to be capable to cause an electric shock, there is a risk.
- The phenomenon arcs is even more questionable. Most arcs happen deeply within a housing, such as switches etc. For open arcs such as for welding purposes every human being knows that one should not touch the arc of welding equipment.

If we produce a list in the LVD of phenomena, which may cause electric shock, we are making a guide for standardization or kind of a study book. Both are not necessary in a directive, and moreover we might forget a phenomenon. It is the standardization process, which will cover in depth all phenomena that will cause electric shocks, as they have proved in the past years to do that adequately in the existing standards.

For the reasons listed above ORGALIME is of the opinion that the future LVD should not list the reasons why electric shocks can appear. The human body does not feel the reason why it is exposed to an electric shock. It simply feels only the result of the phenomena, which result is the electric shock.

The heading says “Protection against electric shock and other electrical hazards”. If we have considered that other hazards such as overheating and fire, mechanical etc hazards are covered elsewhere in the essential requirements, the only electrical hazard is shock.

Therefore ORGALIME is of the opinion that the heading should be: “Protection against electric shock” and that point number 71 and 72 are sufficient to cover the risk of electric shock. Consequently, point numbers 73 – 77 can be deleted.