

03 February 2020

ORGALIM COMMENTS TO PROPOSALS TABLED FOR REVISION OF THE MACHINERY DIRECTIVE 2006/42/EC

PROPOSALS FOR REVISION OF THE MACHINERY DIRECTIVE 2006/42/EC		ORGALIM COMMENTS
<p>ARTICLE 1: SCOPE</p> <p>Should the MD applied to a machine a private person(consumer) manufacturers or imports from a third country to his/her private use should be clarified.</p>	FINL	<p>For Orgalim it is clear that the MD should apply in this case.</p> <p>We suggest that as this issue is horizontal it should be dealt with within the framework of the Blue Guide. The issue is already covered by the Guide to the application of the Machinery Directive 2006/42/EC edition 2.2 October 2019.</p> <p>See: MD guide § 17 Machinery for consumer use</p> <p>The Machinery Directive applies both to machinery for use by workers at work and to machinery for use by consumers or providing a service to consumers. In general, the design and construction of machinery must take account of the intended use.</p>
<p>Article 1 section 2 b</p> <p>Need for revision/justification of exclusion on specific equipment for use in fairgrounds and/or amusement parks Need for revision?</p>	UK	<p>NO COMMENT</p>

<p>There is continuously new type of equipment that are not designed to be used in a fairground or amusement park, but are highly comparable to such equipment which is the exclusion should be clarified, if kept in the new legislation</p>	<p>FINL</p>	
<p>Article 1 section 2c about nuclear installation</p> <p>Amendment (nuclear use)</p> <p>Machinery specially designed for use within or used in a nuclear installation and whose conformity with the Machinery Directive may affect (undermining) nuclear safety</p>	<p>FR</p>	<p>Orgalim supports the proposal</p>
<p>Article 1 section 2 f.</p> <p>Currently: exclusion for seagoing vessels and mobile offshore and machinery installed on board of such vessels and/or units.</p> <p>Specify that this point applies to machinery intended for safety of life at sea</p>	<p>FR</p>	<p>Orgalim is against this proposal.</p> <p>Reason: The proposal tabled adds uncertainty and is unclear. It adds a grey area that will create conflicts between the MD and the IMO requirements.</p> <p>Therefore, we believe this proposal is better fit for Directive 2014/90/EU on marine equipment.</p>
<p>Article 1 section 2 k.</p> <p>Remove the exclusion of low-voltage equipment from the scope of the Directive so that all machines, regardless of risk, are subject only to the MD.</p> <p>This would allow a clear separation between both product groups:</p>	<p>DE</p>	<p>Orgalim is against this proposal.</p> <p>Reason: The LVD's safety objectives already work well and there is no market relevance requiring such a shift.</p> <p>We suggest adding a clarification into the guide of interpretation for product groups which are relevant (e.g.: household appliances and ordinary office machinery)</p>

<p>-Everything which is by definition a machine falls under the Machinery Directive. -All other electrical products that do not meet the definition of a machine, e.g. cable, plug, installation material... etc. are covered by the Low Voltage Directive.</p> <p>Interface between the Machinery Directive and the Low Voltage Directive</p> <p>i) In the current MD there is a list of electrical appliances in the scope of the LVD that are excluded from the scope of the MD. This list does not consider new type of appliances that do not fit in the groups of the list as such but are comparable to them. The list should be updated or should be formulated as such that new type of products may be included in it continuously, when needed.</p> <p>ii) Products in the same package, i.e. B6a battery operated machine and a charger for the machine. It should be clarified that: -if the charger is embedded in the machinery, then the two products are to be treated as one product that is in the scope of one legislation (the MD) -if the charger is a separate product, then two different legislations apply (i.e. the MD applies to the machinery and the LVD applies to the charger).</p>	FINL	<p>Orgalim suggests adding new examples into the guide of interpretation on this issue. No modification of the MD is needed in this case.</p> <p>Orgalim supports a change but believes that “embedded” is not the correct wording. We suggest it would be better to use the word “integrated”.</p>
<p>ARTICLE 2 Definitions</p> <p>Machinery means:</p> <ul style="list-style-type: none"> - An assembly fitted with or intended to be fitted with a drive (...) 	FR	

<p>New to the legislation: for a specific application and for a use as defined by the manufacturer</p> <p>Proposal to clarify in the guide: Machinery must be useable for a specific application as applying to the complete machine and its intended use.</p>		<p>Orgalim supports the need for clarification of this definition, but we believe the clarification should be made in the Guide of interpretation. We suggest using the definition for “intended use” brought in ISO 12100.</p>
<p>Definition of PCM: clarification</p> <p>Add to the definition: any device installed after the machinery on which it is assembled has been put into service is not deemed partly completed machinery Or</p> <p>In an annex to the directive or in the future guide, define a restrictive list of equipment that may be deemed partly completed machinery</p> <p>Article 2 Definitions</p> <p>(g) partly completed machinery The idea of "partly completed machinery" should depend on what a manufacturer and customer agree upon. Basically, this determines who, in the end, is considered to be the manufacturer of the completed machinery or assembly. It is very closely related to the matter of substantial modification. It may be a good idea to remove the concept of "partly completed machinery" from the directive.</p> <p>It would be worth considering whether the term "partly completed machinery" should not be deleted. Most inquiries concern exactly the interface between complete</p>	<p>FR</p> <p>FR</p> <p>NL</p> <p>DE</p>	<p>Orgalim does not support this addition. Reason: this proposal does not bring any added value to the legal text and as industry representatives, we have not identified any practical problem with the current legal text. In case Member States would like to have further clarifications on examples of PCMs, these can be introduced in the Guide of interpretation.</p> <p>The list of equipment can in no way be either exhaustive or restrictive but only drafted to explain the principles.</p> <p>Orgalim (including NL industry representative) is of the opinion that the PCM definition and concept should not be removed from the directive. The confusion comes from the interpretation of what a PCM is. Orgalim suggests bringing clarification in the guide of interpretation and is happy to contribute to a better explanation.</p> <p>Orgalim does not support the deletion of the definition.</p>

and incomplete machine. It would therefore be worth considering whether to delete either the definition or , if no deletion is made, the requirements for incomplete machines to be equated to those of the complete machine.		Reason: The PCM manufacturer has the responsibility to select which of the ESHRs has to be fulfilled.
Article 2 Definitions Specific application: process that transforms a product as a result of operations performed by the machine. Lifting of persons and/or goods.	NB	Orgalim does not agree with the proposal. Reason: Should a clarification on the concept of specific application be needed, Orgalim recommends taking the explanation currently reported into the Guide (para 35) which industry considers to be sufficient and answers their market needs.
Article 2: Definitions State of the Art: does it require an economic definition?	UK	Orgalim supports the proposal to prepare a definition for the State of the Art. The following aspects are necessary for the definition: <ul style="list-style-type: none"> • the essential health and safety requirements set out in Annex I shall be satisfied by measures reflecting the State of the Art • Harmonised standards may reflect the State of the Art • the economic feasibility of the solutions, as expressed in Recital (14) of the Machinery Directive “State of the Art refers to the most recent stage in the development of a product, incorporating the newest ideas and features. Successfully tested measures shall be used for a more detailed determination. The decisive factor here is that technical testing is sufficient in some cases.”
ANNEX I 1.1.1. New:	FR	In Orgalim's opinion, a distinction between the collaboration and coexistence of robots and humans is not necessary as everything is

<p>Add a definition relating to the different work situations implementing a robot application, specifying that the preventive measures must be adapted to the different situations, avoiding any dangerous contact</p> <p>Situation of human-robot coexistence in a shared space without direct collaboration</p> <p>Work situation in a human-robot interaction (simultaneously or alternating work on a piece;</p>		<p>covered by the "intended use" see ISO 12100. The specific work situation would be addressed in the risk assessment of the manufacturer. In terms of safety, a distinction would lead to a reduction in the level of protection.</p>
<p>1.1.2. Principles of safety integration</p> <p>New:</p> <p>f) the machinery must be designed taking account of actual feedback from users on previous models or similar machinery</p>	FR	<p>Orgalim does not support this proposal.</p> <p>Reason: The proposal does not add any additional safety as the definition is vague and it does not indicate what kind of feed-back is expected from the users.</p>
<p>1.1.2. Principles of safety integration</p> <p>(a) Machinery must be designed and constructed according to human-centred principles so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.</p>	ETUI	<p>Orgalim does not support this proposal.</p> <p>Reason: The proposal is not clear on what "human centred principles" should be. Moreover, the principles of safety integration are sufficiently covered by Annex I, section 1.1.6, and by the special guide to ergonomics on MD.</p>
<p>The aim of measures taken must be to achieve productive, safe, usable machinery, and to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping</p>	ETUI	<p>Orgalim does not support this proposal.</p> <p>Reason: The Machinery Directive does not regulate productivity and serviceability as such. Furthermore, "productive" and "usable" are not measurable "terms" and they are neither known nor mentioned in relevant standards the relevant requirements are already set in EN 12100 and in relevant C standards for each machine type.</p>

		<p>However, if the effectiveness of the protective measures was meant, Orgalim suggests that the following additions could be made: “Protective measures must be designed according to the State of the Art, effective, they must not encourage manipulation and not unduly restrict the operator.”</p>
<p>1.1.2 Principle of safety integration</p> <p>+ Guide of interpretation to the MD (§173)</p> <p>Request: the manufacturer should inform the user by means of the instructions when maintenance should be carried out. Also in relation with 1.3.2. – risk of break-up during operation: the manufacturer should indicate the frequency of machine life-span inspection.</p>	PL	<p>Orgalim believes the proposed addition is not necessary. Reason: The manufacturer has to fulfil the obligations according to the provisions of Annex I, point 1.7.4.2(r) and 1.3.2(3). See also the clarification in §272 of the guide. According to the provisions of 2009/104/EC for the use of work equipment by workers at work, the employer is obliged to determine the deadlines for inspections of the work equipment. In doing so, the employer shall use the information contained in the manufacturer's instructions. On this basis, the employer shall also determine the criteria for the replacement of parts or the replacement intervals.</p>
<p>1.1.6 Ergonomics</p> <p>Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic, human factors, and usability knowledge and principles such as:</p> <p>New:</p> <ul style="list-style-type: none"> - Involving users during machinery design and development 	ETUI	<p>Orgalim believes the proposed addition is not necessary. Reason: The essential health and safety requirements are sufficient to allow the State of the Art in ergonomics to be further developed. A greater level of detail of these requirements would not be in line with the principles of the New Legislative Framework. Usability is not subject of the Machinery Directive. Human factors are already covered by the requirements on ergonomics, so there is no need to emphasise them again.</p> <p>Orgalim cannot support this proposal. Reason: In the case of machines manufactured in large series, direct involvement of users is not possible. However, manufacturers regularly incorporate knowledge gained from contact with customers and in their role as employers. Furthermore, CEN/ ISO Standardisation processes</p>

		already include voice of all stakeholders when drafting Harmonized standards.
<p>ESHRs relating to the design and construction of machinery Section 1.1.6; New:</p> <ol style="list-style-type: none"> 1. Machines equipped with machine learning technology must be able to respond to people adequately and appropriately 2. A machine equipped with machine learning technology must be indicate which actions they are about to perform and must provide details of the information on which these actions are based. 	NL	<p>This is not a proposal for an ergonomics requirement; therefore, the proposal cannot be supported. Reason: The human intervention and the priority of human intervention are already adequately covered by the requirements of Annex I. It is currently sufficient that the manufacturer is responsible for everything that the machine can do within the scope of "intended use. However, there are other industries in the software sector which are more advanced in this area and whose level of knowledge and existing regulations could be used.</p> <p>Orgalim cannot support this proposal. Reason: There are very fast decisions and fast sequences of decisions that do not allow for human registrable feedback. The amount of data generated usually does not allow direct tracking or even observation.</p>
<p>ESHRs relating to the design and construction of Machinery Section 1.2.1. safety and reliability of the control systems New:</p> <ol style="list-style-type: none"> 1. Machines equipped with machine learning are not permitted to make decisions or assessments in relation to injury to people or damage to the surroundings 2. Machine learning must not cause the machine to exhibit new actions that exceed its define task and working environment. 3. If they take incorrect decisions, machines equipped with machine learning technology must be 	NL	<ol style="list-style-type: none"> 1. Not necessary: Such a risk is already covered by the requirements of Annex I and the protective concept of the machine must take these risks into account. 2. Not necessary: This is already covered by the definition of the intended use by the manufacturer. 3. Orgalim suggests the following wording: It is in the interest of the manufacturer that the functioning of the safety system can be tracked to

<p>retrospectively correctable, to prevent any future recurrences of that particular error.</p> <ol style="list-style-type: none"> 4. The actions of a machine equipped with machine learning technology must be traceable in advance and retrospectively, based on transparency of the datasets used, as well as of the test environments and of the decision frameworks or assessment criteria for algorithm-based decision 5. The decision-making process of a machine equipped with machine learning technology must be logged and retained (in such a way that this information remain available for a minimum period of time which is yet to be determine and can be checked, for instance during audits or incident analysed. 		<p>detect the errors that led to incorrect decisions and to correct and prevent any future recurrences of that particular error.</p> <ol style="list-style-type: none"> 4. Safety-relevant information in terms of residual risks must be named and described by the manufacturer in the operating instructions. Certain parts of machine learning are the know-how of the manufacturer and part of the technical file according to Annex VII of the Machinery Directive. The protection of the manufacturer's trade secrets and know-how must continue to be ensured. 5. See no. 4
<p>Amendment of existing ESHRs</p> <ol style="list-style-type: none"> 1. The machine's control system can withstand the intended operating stresses or undesirable external influences if any errors or unforeseen conditions should occur in the control system, the machine should ideally revert to a safe state. 2. Faults in the machine's control system must not lead to hazardous situation 3. Errors in the control system logic must not lead to hazardous situations 4. Human errors during operation must not lead to hazardous situation 	<p>NL</p>	<p>Orgalim does not support the NL proposal. We propose to leave the text as it stands.</p>
<p>Section 1.2.1.</p>	<p>NL</p>	<p>Orgalim suggests keeping the current wording</p>

<p>Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:</p> <ul style="list-style-type: none"> — they can withstand the intended operating stresses and external influences, — a fault in the hardware or the software (the logic) of the control system does not lead to hazardous situations, — errors in the control system logic do not lead to hazardous situations, — reasonably 		
<p>New paragraph at the end of EHSRs: Safety and reliability of control systems</p> <p>The safety functions cannot change outside the limits of the manufacturer’s defined scope. This scope is validated and guaranteed by the machine manufacturer, regardless of any modifications to the settings or rules generated either by artificial intelligence or by operators in charge of the learning phases.</p>	FR	<p>Orgalim proposes the following wording:</p> <p>Safety-relevant parameters of a control system may only be set or changed within the limits specified by the manufacturer. The manufacturer defines these limits taking into account the protective measures for this.</p>
<p>1.2.4. Stopping</p> <p>Machines equipped with machine learning technology must be equipped with an emergency stop function, so that they can be deactivated/overridden at any time. Once the machine has been deactivated, the situation is safe</p>	FR	<p>Orgalim does not support this proposal as the provisions on emergency stop 1.2.4.3. already contain these requirements. Further, specifications can be found in EN 60204-1</p>
<p>Section 1.5.10 Radiation</p> <p>Update as per Directive No 2013/35/EU (risks of physical agents)</p> <p>New:</p>	NL	<p>Orgalim supports this proposal but suggests using the following text instead:</p> <p>The manufacturer provides information on the effect of electromagnetic fields on Health and Safety in the instruction manual in accordance with Machinery Directive Annex I, No. 1.7.4, to assist users in risk assessment</p>

<p>w. where the machinery is likely to emit functional electromagnetic fields or low-frequency electromagnetic fields which may cause an adviser or harmful effects on persons, in particular persons with active or non-active implantable medical devices, information on the level of electrical, magnetic or electromagnetic fields in a form to assist the user in conducting the risk assessment pursuant to Directive 2013/35/EC</p>		<p>in accordance with occupational safety regulations, if relevant to the provisions of Art 5.1 of the MD.</p>
<p>1.3.7. Risks related to moving parts</p> <p>Situation of human-robot coexistence in a shared space without direct collaboration, Work situation in human-robot interaction (simultaneous or alternating work on a piece)</p>	FR	<p>Orgalim does not support the FR proposal. Reason: This point has to be dealt with in the risk assessment. Standardisation also addresses this point in ISO TC 199 It has to be noted that the French Ministry of Labour issued in 2017 a guide about cobots where MD is fit for purpose : “Among the set of relevant Essential Health and Safety Requirements (ERHS) for the design and integration of a robotic system, ERHS 1.3.7 on risks related to moving parts and ERHS 1.1.6 on ergonomic principles have a central role in the control of contact risk and more generally for the management of the interaction or the close coactivity between the operator and the robot”</p>
<p>1.7.4.2. Content of the instructions</p> <p>(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed taking into account of the restrictions and actual and foreseeable working conditions, the description of the adjustment and maintenance operations that the user must</p>	FR	<p>Orgalim does not support the FR proposal. Reason: The amendment doesn't introduce new aspects, see also §272 of the guide. Already today, the manufacturer has to take the restrictions and the actual and foreseeable working condition into account by describing the adjustment and maintenance operations. Moreover, the amendment makes things unclear.</p>

<p>perform and the preventive measures that must be observed.</p> <p>New(w): The following information on emissions of hazardous substances from the machinery The characteristics of the capturing, filtration or discharge device when not provided with the machinery, and The flow rate for the emissions of hazardous materials and substances from the machinery, or The concentration of hazardous materials or substances around the machinery, or The effectiveness of the capturing of filtration device and the conditions to be observed to maintain its effectiveness over time. These values are either actually measures for the machinery in question or established based on measurements taken from machinery that is technically comparable, which is representative of the machinery to be produced.</p>		<p>This new requirement seems to be too broad and doesn't concern only the machinery itself. Requirements for the devices should be part of their respective legislation and not be part of the MD.</p>
<p>2.2. PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY 2.2.1. <i>General</i> CHEMICAL RISK</p> <p>New adding at the end of the paragraph:</p> <p>The portable machinery must have a device to capture emissions of hazardous substances at the source, if requires</p>	<p>FR</p>	<p>Orgalim does not support the change. Reason: The new text raises more questions than it provides clarity: which substances are considered hazardous enough, that they have to be captured? What does if requires mean? When is it not applicable?</p> <p>The risk is already covered by EHSR 1.5.13. The proposal tends to impose a technology, which is not the purpose of Machinery Directive. Technical solutions to a specific issue should be discussed in standardisation committees.</p>

<p style="text-align: center;">1. Instructions</p> <p>The instructions must give the following information concerning vibrations transmitted by portable handheld and hand-guided machinery: — the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s². Where this value does not exceed 2,5 m/s², this must be mentioned, — the uncertainty of measurement.</p> <p>New: add requirement for measuring and declaring peak value vibrations from percussive tools, or tools that have both rotating and percussive action</p> <p>Add repeated shock peak values to the MD</p> <ul style="list-style-type: none"> • Declaration of the vibration total value a_{hw} (three-axis). The same requirement as today. • Add a requirement for Declaration of the mean peak value from repeated shock vibrations during the measuring period. This is important especially for tools with percussive action. • Declaration of the uncertainty of both measurements. <p>Take out 2.5 m/s²</p> <p>We think that the dose-response relationship must be reconsidered taking into account also vibration emission from tools with percussive action. This means that 2.5 m/s² may not be a relevant limit value for vibration emissions.</p>	SE	<p>Orgalim believes this proposal needs further consideration.</p> <p>The Swedish proposal aiming to improve the information in the Machinery Directive on vibrations transmitted from handheld and hand-guided machinery regarding vibrations from percussive tools needs additional and detailed information on definitions, measurement methodology, relevant standards and how to present values before the next steps can be taken.</p> <p>Questions and issues that have to be addressed before the next steps can be taken are:</p> <ul style="list-style-type: none"> - Which standards shall be used to measure the peak values, are there already relevant standards or will they have to be created? - Clear definitions need to be developed for percussive and peak vibration values. - The necessary development of measuring instruments capable of handling a new measuring standard need to be ensured. <p>A change to the present text on Vibrations in the Machinery Directive must not lead to a deterioration or confusing legal requirements.</p> <p>Therefore, we don't see the need to take out the value of 2,5 m/s², but we require some clarifications on vibrations from percussive and/or tools with both rotating and percussive movements.</p>
--	----	---

<p>3.2.2. Seating</p> <p>Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the ground should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, their seats (the machinery) must be designed or equipped with a restraint system so as to keep the persons in their seats, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems should not be fitted if they increase the risk.</p> <p>NB: It must not be possible for the machinery to move if the restraint system is not active.</p>	FR	<p>Orgalim can agree to replace “their seat” by “the machinery”, or alternatively by “their seat (the machinery)”. Reason: The proposed change reflects the established state-of-the-art better.</p> <p>Orgalim does not support the proposed NB text: Reason: A restraint system disabling the movement of a machine when not active, would hamper the operation of the machine due to a high risk of detection errors. In cars such systems are not present either despite higher numbers of accidents. An alternative is to show an alarm message, if the operator did not wear the belt instead of forcing the machine to stop. The proposed text is design-restrictive and does not reflect the established State of the Art</p>
<p>3.5.3. Emissions of hazardous substances</p> <p>New adding at the end of the paragraph/</p>	FR	

<p>Mobile machinery designed for spraying or likely to be used for spraying chemicals must be equipped with filter cabins.</p>		<p>The proposal tends to impose a technology, which is not the purpose of Machinery Directive. Technical solutions to a specific issue should be discussed in standardisation committees.</p>
<p>3.5.4: Electrical risk (new)</p> <p>Mobile machinery is designed and manufactured so as to prevent the risk of contact with live overhead power lines or the risk of electrical arcing between any part of the machinery or an operator driving the machinery and an energized overhead power line under normal operating conditions and foreseeable misuse.</p> <ul style="list-style-type: none"> - When the risk of contact cannot be fully avoided, the machinery shall be designed and constructed so as to prevent any electrical hazards in the event of contact with an energized power line - Mobile machinery especially designed to perform work under power shall be designed and manufactured so as to prevent any electrical hazards in the event of contact with an energized power line under normal operating conditions and foreseeable misuse. 	FR	<p>This risk is already partly covered in Annex I, subclause 1.1.7 “Operating positions”, 2nd paragraph, and in §182 of the application guide of the Machinery Directive.</p> <p>The risk can be further covered by safety standards.</p>
<p>ANNEX II: Declarations</p> <p>B. Declaration of incorporation of partly completed machinery</p> <p>(...)</p>	FR	<p>Orgalim does not support the proposal.</p> <p>Reason: According to the actual concept that is in place within the MD, a PCM doesn't need to comply with any requirement. As a PCM is not used for itself in its unsafe condition, safety is not at stake. On a contractual basis, it is up to the supplier of the PCM and the machinery manufacturer to agree on certain aspects the PCM should comply with.</p>

<p>Adding:</p> <p>4. A sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the <i>Official Journal of the European Union</i>. Partly completed machinery cannot claim to meet the requirements of this Directive without satisfying any essential requirements</p>		<p>Furthermore, often the supplier of a PCM doesn't know what the PCM is intended to be used for. Thus, it seems not to be target-oriented that a PCM needs to comply with at least one essential requirement (as the wording is understood).</p>
<p>ANNEX IV Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied</p> <p>Option 1:</p> <p>A. add some machinery to Annex IV (example farming machinery like chippers, spreaders and balers</p> <p>B. add point 24: combination or assembly of machinery containing at least one item of machinery from points 1 to 23, if the composed assembly does not eliminate the risky component</p>	FR	<p>Orgalim decisively believes that Annex IV and the provisions of Art. 12 should remain unchanged.</p> <p>Orgalim does not support the proposals in Option 1 for the following reasons:</p> <p>A. To extend the list with specific machinery it should be clearly defined which characteristics result in placing the type of machinery on the list. Today the criteria are not very clearly defined to put the product on the list. And it is not clear who is to be involved in the decision-making process and how that selection process is to be run. There is also no clear time-line for when the list is updated. Currently an update is only possible with a revision of the MD. Meanwhile the evolution of products which are on the list and new evolved products could have improvements that mean that the criteria (if available) are no longer met for placing them on the list.</p> <p>➤ Before products are placed on the list, the process of evaluation must be made clear including the criteria for adding new products.</p>

<p>associated with this machinery (for example manual loading or unloading)</p> <p>C. another point 24!: machinery using AI which manages a safety function(s) when the AI is not integrated into a safety component.</p>		<p>➤ A mechanism should be in place to update the list more frequent.</p> <p>B. This is a very confusing proposal. An assembly containing a machinery on the list is qualified subject to the procedures of article 12. However, if a risk assessment shows that the risk has disappeared due to the measures taken in the machine assembly the final product should not necessary be subject to Article 12 . This proposal does not add new regulation practice.</p> <p>A solution might be to separate the risky component and to certify and make a risk assessment separately as a section in an assembly line without the parts of the assembly that do not influence the annex IV part.</p> <p>C. It is not clear what the proposal entails.</p>
<p>Option 2</p> <p>Establish cross-cutting machinery categories with certain risks and in this case, propose that a European group be set up</p> <p>Annex IV: procedures for assessing the conformity of machinery:</p> <p>For series-manufactured machinery: introduce a production monitoring procedure for the machinery in Annex IV to make sure there are no deviations in the production of a machine that has undergone a conformity assessment.</p>	FR	<p>Orgalim asks for further clarifications from FR.</p> <p>The scope and purpose of this European group are not clear in this proposal. Furthermore, such a European group should be established on a legislative ground. Changes should be subject to legislative powers. Will the machinery industry also participate in an advisory role? Is the role of this European group to establish criteria or to determine the products on the list.</p>
<p>ANNEX IV</p> <p>Should be changed in hazard categories instead of a limited list of machinery</p>	NL	<p>Orgalim does not support the change.</p> <p>Reason: This proposal has two sides of the medal. A limited list of machinery is a clearly defined "Yes or No" whereas hazard categories</p>

<p>Remove the option of self-assessment by the manufacturer, since the standards do not describe all hazards that are involved in the design of machinery.</p>	<p>NL</p>	<p>give room for interpretation which can unbalance the level playing field and add uncertainty for the manufacturer. Nevertheless, we feel it is more workable and transparent to have a list of products so long as the list is not static and gives room for changes due to new developments, like adding sensors or new developed safety functions which could lead to removing the product from the list.</p>
<p>ANNEX IV Approach similar to PPE Regulation 2016/425/EU: replace the current Annex IV with the classification of machineries into categories according to risk and/or function of the machine. The conformity assessment procedures are done for each category separately:</p> <p>Category I machines could be placed on the market under the current manufacturer's internal control procedure. -Category II would contain machines with higher risks and e.g. machines requiring type approval procedure and -Category III machines having highest risk and belonging to scope of type examination should have in addition also obligation of the manufacturing quality assurance. It might not be necessary to have 3 categories, 2 might be enough. In general, there is no need for use of third parties before placing on the market to such type of machinery to which type examination would not improve safety. A great deal of machinery types should be possible to be placed on the market without type examination.</p> <p>Annex IV Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied</p>	<p>FIN</p>	<p>Orgalim does not support the change. Reason: The categories suggested are not consistent with the current approach and categorisation of this directive as here summarised:</p> <ul style="list-style-type: none"> • Machinery Listed in Annex IV subjected to a conformity assessment with internal checks when it is manufactured in accordance with harmonised standards • Machinery Listed in Annex IV that are subject to one of the two conformity assessment procedures involving a Notified Body: EC type-examination or Full quality assurance. • All the other Machinery is anyway subjected to a conformity assessment with internal checks

<p>. Machinery for cutting and working wood or meat.(replaces points 1 to 8)</p> <ul style="list-style-type: none"> •2. Machinery with a risk of crushing/compression related to manual loading/unloading. (replaces p. 9 to 11 and 13) •3. Machinery for underground working of the following types: (identical to point 12) <ul style="list-style-type: none"> •3.1. locomotives and brake-vans; •3.2. hydraulic-powered roof supports. •4. Removable mechanical transmission devices including their guards. (identical to point 14) •5. Guards for removable mechanical transmission devices. (identical to point 15) •6. Machinery used to perform operations under a load or a vehicle. (replaces point 16) •7. Machinery for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres (identical to point 17) •8. Portable cartridge-operated fixing and other impact machinery. (identical to point 18) •9. Protective devices designed to detect the presence of persons. (identical to point 19) •10. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in section 2. (identical to point 20) 		
--	--	--

<ul style="list-style-type: none"> •11. Logic units to ensure safety functions. (identical to point 21) •12. Roll-over protective structures (ROPS). (identical to point 22) •13. Falling-object protective structures (FOPS). (identical to point 22) •14. Mobile machinery or machinery on carrying vehicles 		
<p>ANNEX IV: add lift appliances</p> <p>A significant difference between lifting appliances according to the Machinery Directive and lifts according to the Lifts Directive is, beside the speed, the design of the load carrier. While a fully closed load carrier is mandatory for lifts (according to the Lifts Directive), a load carrier for lifting appliances (according to the Machinery Directive) can be a platform without any wall, door or ceiling.</p>	Lifts NB	<p>In Annex IV we already have in the list the following devices: "17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres."</p> <p>Adding all the lifting appliances would be much too restrictive considering the current edition and would not increase the safety.</p> <p>We suggest adding the definition of lifting appliances in the new revision because currently it is not in the definition list and should be. This is mainly needed to clearly differentiate "lifting accessory" and "lifting appliances".</p>
<p>ANNEX IV</p> <p>A complete deletion of Annex IV is still conceivable</p>	DE	NO COMMENT
<p>ANNEX V</p> <p>Safety-related software must be considered as a safety device and therefore be included in Annex V</p>	NB	NO COMMENT
<p>Annex VII, part A, section 1, point (b) : procedures for assessing the conformity of machinery- too vague</p>	FR	NO COMMENT

Same for machinery in Annex IV		
<p>Annex VIII: Assessment of conformity with internal checks on the manufacture of machinery</p> <p>Define the notion of an internal check to specify the manufacturers' obligations regarding the manufacturing process/ Non-formalized and/or unsatisfactory procedure, traceability.</p>	FR	<p>Orgalim supports the proposal to better clarify the meaning of internal checks.</p> <p>Although we remind that it is already defined by the Machinery Directive and Guidelines that the Manufacturer is responsible for the machine as it is built "as-built" including the fabrication process and procedures needed.</p>
<p>CONSIDERATION ON REVISION OF THE MACHINERY DIRECTIVE AND AI</p> <ol style="list-style-type: none"> 1) The functioning environment for consumer robots is different to the closed environment in a factory as in a factory the environment is predetermined, whereas with consumers --for example a robot helping with luggage at a station --the robot acts in an open environment, not predetermined environment. 2) The issues of software updates are not totally covered. 3) The risk of hacking can make a machine unsafe. Is Art.1.2.1 (Annex I) on 'intended operating stresses and external influences, covering the risk of cyberattacks? 	ANEC	<p>See Orgalim Position Papers on the Machinery Directive, Cybersecurity and the recently published Orgalim manifesto on AI.</p> <ol style="list-style-type: none"> 1) In the conformity assessment procedure for all machines covered by the Machinery Directive, the manufacturer must determine the intended use, taking full account of the functions, operators, persons present and the environment of the machine. For this reason, the robots mentioned above do not operate in an open environment that cannot be foreseen. See the text above on intended use. 2) The obligations of manufacturers with regard to software updates should be clarified. The software update must fulfil the conditions laid down by the conformity assessment procedure. If this is not the case, it should be examined whether CE marking obligations must be fulfilled. 3) Orgalim is of the opinion that the requirements in Annex I, point 1.2 cover the effects of cyber-attacks. Orgalim suggests that this should be covered by updating the Harmonised Standards. See the text above on intended use.

<p>4) AI updates should always be considered a substantial modification, even if the intention is not to change the product. Machine learning can also have impact on safety, even if intention is not to change performance. In general, the concept of putting on market/into service need to be revised. Machine learning goes beyond these points and is going to change these boundaries.</p> <p>5) Powers of market surveillance authorities: to include access to coding/algorithms, to systems and new skills;</p> <p>Format and content of standards (eg. Machine-readable) Conformity assessment: access to algorithms, the conformity module has to be proportionate to the risk, including when created by the software. The conformity assessment has to take into account the period when things can happen not just once the equipment is placed on the market. The concept has to evolve.</p> <p>6) Digital user manuals: sometimes consumers do not have access to internet. This would make it difficult to just go to online documentation only. We are in favour of combination and offering both options. The most important instructions, on safe operation of machinery, should be in front of the user instructions, also on paper. From accessibility aspect, the size of characters must be big enough, minimum 3 mm for capital letters.</p> <p>7) New (sustainable) consumption patterns: renting gardening tools from shops or consumers networks, what about maintenance? And software updates?</p> <p>8) New essential safety requirements: accessibility requirements.</p>	<p>4) Orgalim does not support this addition.</p> <p>Orgalim believes that safety and liability legislation is currently fit for purpose and appropriate, when it comes to AI development. To this end, we invite stakeholders to have a look at the recently published Orgalim manifesto on AI.</p> <p>6) Orgalim supports the use of a Digital User Manual.</p> <p>7) Has to be clarified</p>
--	---

<p>9) Need for recital with a reference to UN Convention on the Rights of Persons with Disabilities and to take them into account in the standardisation process.</p>		<p>8) Has to be clarified</p> <p>9) Orgalim is of the opinion that all stakeholders should be involved in the standardisation process. This is the subject of the EU standardisation regulation and is therefore a horizontal issue that is better addressed in the EU standardisation regulation.</p>
<p>Guide of interpretation Chapter 86 “The machinery may need to be tested as part of the installation and commissioning process for a short and limited period under the full control of the manufacturer, which includes the control of the persons involved in the testing.</p> <p>New: the learning phase which is essential to the machinery using AI to be useable must be carried out, under the responsibility of the manufacturer, before the machine is placed on the market and the EU declaration of conformity is issued. The learning phase must be carried out without generating risk.</p>	FR	<p>Orgalim supports the addition of the French proposal. However, the last sentence gives rise to misinterpretation because of the prospect and responsibility of the manufacturer at this stage, the provisions on safety at work must be observed and protective measures taken accordingly.</p> <p>Orgalim suggests the following amendment to be added instead of the full text without changing the meaning of the current text.</p> <p>“The installation and commissioning process may include the learning phase which is essential for machinery using AI to be useable. Only in the cases where machine learning systems can affect machine safety should the learning phase be done under the responsibility of the manufacturer, before the machine is placed on the market and the EU declaration of conformity is issued.”</p>
End.		