

8 December 2020

Orgalim comments to proposals for the revision of the Machinery Directive 2006/42/EC tabled at the Commission Working Group meeting of 9-10 November 2020

Introduction

Orgalim recognises that the current economic, political and technological developments are raising questions around the Machinery Directive, leading the European Commission to look at options for a revision. We welcome the opportunity to provide comments and react to the proposals tabled by the Commission.

General Comment: Proposals to amend or extend the health and safety requirements of Annex I of the Machinery Directive should use wording which does not require the use of a particular technology or which favour the use of a particular technology. When amending the requirements of Annex I, it is essential to take account of enforceability by market surveillance authorities. Ambiguity should not be to the detriment of economic operators who have properly carried out and documented the conformity assessment procedure. The same applies by analogy to the standardisation process and the assessment of draft standards by HAS-Consultants.

Slide	WG-2020.91.1 - COM (VP slides) - MD WG 9&10 November 2020 final	Orgalim comments
07	Adaptation to the NLF	
	<ul style="list-style-type: none"> • Set the obligations and requirements for economic operators • Set the level of competence of the third-party conformity assessment bodies who assess products or quality management systems, and the control mechanisms for these bodies (notification and accreditation) • Determine which are the appropriate conformity assessment processes (modules which also include the manufacturer's declaration of conformity) to be applied • Impose the appropriate market surveillance mechanisms (internal and external) to ensure that the whole legislative instrument operates in an effective and seamless manner 	<ul style="list-style-type: none"> • The adoption of the NLF model provisions is welcomed. Deviations from these provisions should only be made if absolutely necessary. • The provisions for determining the competence of notified bodies under the NLF should be applied. • The conformity assessment modules of the NLF have proved their worth and should be adopted. However, only module A is required for machinery. For Annex IV machinery, module B is still needed. • As the provisions on market surveillance have been concentrated in the EU Regulation 2019/1020, no provisions on market surveillance are required in the new Machinery Regulation replacing the Machinery Directive 2006/42/EC.
09	New Technologies - Annex I General principles – risk assessment	
	<p><i>By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:</i></p> <p><i>— identify the hazards that can be generated by the machinery and the associated hazardous situations, including new hazards that can be generated during the whole machinery lifecycle as an evolution of its behaviour due to the machinery design.</i></p>	<p>Orgalim proposes to amend the addition to this requirement as follows:</p> <p><i>“including risks that can evolve during the machinery lifecycle as an intended evolution of its behaviour due to the machinery design”.</i></p>
10	New Technologies - Annex I: 1.1.6. Ergonomics	
	<p><i>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 principles such as:</i></p> <p>...</p>	<p>We propose to amend the addition to this requirement as follows:</p> <p><i>“- adapting the man/machinery interface to the foreseeable characteristics of the operators including with respect to machinery with intended evolving behaviour or logic,”</i></p>

	<p>— <i>adapting the man/machinery interface to the foreseeable characteristics of the operators including with respect to machinery with fully or partially evolving behaviour or logic,</i></p>	
11	New Technologies - Annex I: 1.1.9. Protection against corruption	
	<p>— <i>The machinery must be designed and constructed so that the connection to it of another device, by any feature of the connected device itself or by any remote device that communicates with the machinery does not lead to a hazardous situation.</i></p> <p>— <i>A hardware component that is critical for the machinery compliance with the relevant health and safety requirements shall be designed so that it can be secured. Security measures foreseen shall provide for evidence of an intervention.</i></p> <p>— <i>Software that is critical for the machinery compliance with the relevant health and safety requirements shall be identified as such and shall be secured.</i></p> <p>— <i>Software identification shall be easily provided by the machinery.</i></p> <p>— <i>Evidence of an intervention shall be available for a reasonable period of time.</i></p> <p>— <i>Machinery data, software that is critical for the machinery compliance with the relevant health and safety requirements shall be adequately protected against accidental or intentional corruption.</i></p>	<p>As the MD is formulated in a technology-neutral way, it also covers aspects of cyberattacks, i.e. the effects of a cyberattack on the safety of the machinery. Therefore, no adaptations of Annex I should be necessary. We suggest that cybersecurity should be taken into account accordingly and could be clarified in the recitals and in the guide. In addition, Orgalim believes that a product-related horizontal legal act on cybersecurity should be established in accordance with the principles of the NLF. See our position.</p> <p>The inclusion of requirements on cybersecurity in existing sector-specific legislation, e. g. in the Machinery Directive, is not considered appropriate, because only individual sectors are affected, this could lead to inconsistent (in the worst case contradictory) requirements and also to possible considerable additional costs for providing written evidence.</p> <p>To foster a constructive dialogue, we can propose the following amendments to the text proposed:</p> <p>1.1.9 Protection against corruption</p> <p>— <i>The machinery must be designed and constructed so that the connection to it of another device, by any feature of the connected device itself or by any remote device that communicates with the machinery does not lead to a hazardous situation.</i></p> <p>— <i>A hardware component that is critical for the machinery compliance with the relevant health and safety requirements shall be designed so that it is adequately protected against accidental or intentional corruption by cyberattack can be secured. Security measures foreseen shall provide evidence of an intervention.</i></p> <p>— <i>Software that is critical for the machinery compliance with the relevant health and safety requirements shall be identified as such and</i></p>

		<p><i>shall be adequately protected against accidental or intentional corruption secured.</i></p> <p><i>— The identification of the software which is installed on the machinery shall be easily provided at any time.</i></p> <p><i>— Evidence of an intervention or a modification of the software installed on the Machinery or its configuration shall be available for a reasonable period of time.</i></p>
12-17	<p>New Technologies - Annex I: 1.2. CONTROL SYSTEMS 1.2.1. Safety and reliability of control systems</p>	
12	<p><i>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:</i></p>	<p>Orgalim proposes to introduce a separate a new section entitled: "Control systems for software solutions or against cyberattacks"</p> <p>Justification: to ensure that the new requirements are restricted to these types of control systems</p>
13	<p><i>— they can withstand the intended operating stresses and intended and unintended external influences, including those coming from malicious third parties leading to a hazardous situation,</i></p>	<p>Proposal for amendment to 1st indent: <i>they can withstand the intended operating stresses and intended and reasonably foreseeable unintended external influences, including those coming from malicious third parties leading to a hazardous situation,</i></p>
14	<p><i>— machinery with fully or partially evolving behaviour or logic:</i></p> <p><i>a) must be intrinsic safe and must under all circumstances not be permitted to make decisions concerning life, injury and death of persons and damage to material and surroundings,</i></p> <p><i>b) must not cause the machine to perform actions that exceed its defined task and movement space,</i></p> <p><i>c) if taking incorrect decisions, the machinery placed on the market and new machinery to be placed on the market, must be correctable, to prevent any future recurrences of that particular error,</i></p>	<p>Comments to 2nd indent The Machinery Directive already covers the risk of the changing of safety functions in Annex I - Essential Health and Safety Requirements under General principles 1st indent. By definition, safety functions cannot change outside the limits of the machinery. If these additions are maintained it is necessary to define the terms "safety functions" and "learning phase" in this context.</p> <p>Possibly these items a) to e) would be suitable for a guideline rather than for the Regulation.</p> <p>Justification: The items are basically covered by the risk assessment and the resulting machine design resp. design of the control system.</p>

<p>15</p> <p>16</p> <p>17</p>	<p><i>d) the actions 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 decisions for conformity assessment and market surveillance purposes,</i></p> <p><i>e) the decision-making process must be logged and retained for conformity assessment and market surveillance purposes.</i> <i>— for autonomous mobile machinery, the control system must be designed to perform all of the above safety functions by itself.</i></p> <p><i>Particular attention must be given to the following points:</i> <i>— the safety-related parts of the control system must apply in a coherent way to the whole of an assembly of machinery and/or partly completed machinery. For cable-less control, a failure of the connection or a faulty connection must not lead to a hazardous situation.</i></p>	<p>a) Delete paragraph a) Justification: the current wording would make it impossible to apply AI in security functions.</p> <p>c) Suggestion for new wording: <i>if taking reasonably foreseeable incorrect decisions leading to dangerous situations, the machinery placed on the market and new machinery to be placed on the market, must be correctable, to prevent any future recurrences of that particular errors, or lead to a recall of the product</i></p> <p>d) Delete paragraph d) Justification: 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.</p> <p>e) Proposal to delete - first indent: "— for autonomous mobile machinery, the control system must be designed to perform all of the above safety functions by itself". Justification: 1. It should not be required that for mobile machinery all safety functions must run entirely on the machine itself. Instead, it should be required (and will be required elsewhere) that the machine behaves safely in the event of a fault in the external connection. 2. According to our understanding, this results in a general ban on distributed control systems for safety functions in autonomous mobile machines. A control system analogous to cable-less control (p.17: For cable-less control, a failure of the connection or a faulty connection must not lead to a hazardous situation.) seems to make more sense from our point of view.</p>
<p>18</p>	<p>New Technologies - Annex I: 1.2. CONTROL SYSTEMS</p>	

	1.2.6. Failure of the power supply and network connection	
	<i>The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply and network connection to the machinery must not lead to dangerous situations.</i>	We support this amendment
19	New Technologies - Annex I: 1.3. PROTECTION AGAINST MECHANICAL RISKS 1.3.7. Risks related to moving parts	
	<i>The prevention of risks of contact leading to hazard situations must be also adapted to: - <i>human-robot coexistence in a shared space without direct collaboration</i> - <i>human-robot interaction (simultaneous or alternating work on a piece)</i> Machinery with fully or partially evolving behaviour or logic must indicate which actions they are about to perform.</i>	No need for an addition. No amendment of Annex I is necessary in this respect. To be deleted.
20	New Technologies - Annex I: 3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY 3.1.1 Definitions	
	<i>(b) 'Driver' means an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control or may remotely supervise the autonomous mobile machinery regardless of the distance and/or the means of communication.</i> <i>(c) 'Autonomous mobile machinery' means mobile machinery provided with an autonomous mode ensuring the permanent control of its travel and its operations.</i> <i>(d) 'Autonomous mode' means operating mode without permanent interaction of an operator, in which mobile machinery ensures all the essential functions for the safety in the travel and working area.</i>	Proposal for (b) <i>by remote control or may remotely supervise the autonomous mobile machinery regardless of the distance and/or the means of control communication.</i>
		Justification: These requirements are covered in standards (see EN ISO 3691-4). Due to the complexity of the machines and its operation the MD should not define specific requirements. This is the task of harmonised standards.
		Proposal to delete (c) Justification: There is no apparent reason for this general requirement, and it does not seem to provide any gain in safety compared to the previously practised

		procedure of a local acknowledgement of the automatic operating mode on the respective machine.
21	New Technologies - Annex I: 3. OFFSET <u>RISKS</u> DUE TO THE MOBILITY OF MACHINERY 3.2.4 Supervisory control station	
	<i>Autonomous machinery has a supervision station specific to the autonomous mode located remotely from the machinery which only authorizes actions to stop, start or restart the machine. It is designed and built to authorize starting or restarting only when the driver has a direct or indirect view of the machine's movement and working area and the protective devices are operational. The information available at this station must enable the driver to receive useful information on the operation, movement and safe positioning of the machine in the travel and working area. This information enables the driver of the autonomous machine to be alerted to the occurrence of unforeseen or dangerous situations actual or impending, which requires intervention.</i>	Delete the new addition Justification: Autonomous machinery does not need any supervision. Existing EHSR (1.1.2 a) fully cover risks of autonomous machinery. Moreover, the new requirement proposal changes the safety procedure in the instruction handbook and is prescriptive for machines currently on the market, which were built according to the state of the art. For example, a robotic lawn mower built according to EN 50636-2-107. Proposal for new requirement: <i>If none of these possibilities is applicable, before the machinery starts, an acoustic and/or visual warning signal must be given. The exposed persons must have time to leave the danger zone or prevent the machinery starting up.</i>
22	New Technologies - Annex I: 3. OFFSET <u>RISKS</u> DUE TO THE MOBILITY OF MACHINERY 3.3.2 Starting/ moving	
	<i>The movement of an autonomous mobile machinery must take into account the risks related to the environment where intended to move and work.</i>	To be deleted. Already covered (Essential Requirement 1.1.2 a)
23	New Technologies - Annex I: 3. OFFSET <u>RISKS</u> DUE TO THE MOBILITY OF MACHINERY 3.3.3 Travelling function	
	<i>Autonomous mobile machinery must move and operate in an enclosed zone fitted with a peripheral protection system comprising guards and protective devices or must be equipped</i>	Orgalim suggests the alternative proposal: <i>In cases where the autonomous mobile machinery is protected by an enclosed zone with peripheral guard it must be designed to automatically stop its movements and operations where appropriate when a person or an animal crosses the peripheral protection system</i>

	<p><i>with protective devices intended to detect any human or animal presence in the surrounding of the machinery.</i></p> <p><i>Autonomous mobile machinery shall be equipped with a guiding or navigation system designed for locating and positioning the machinery according to the relevant operations while preventing the unexpected movements beyond the intended limits of his travel and working area.</i></p> <p><i>The protective devices and control system of autonomous mobile machinery must be designed to stop automatically its movements and operations to prevent the risks in the following situations:</i></p> <ul style="list-style-type: none"> • <i>where a person or an animal is detected in the travel and working area;</i> • <i>where a person or an animal is crossing the peripheral protection system and enters in the travel and working zone of the autonomous mobile machinery.</i> 	<p><i>and enters in the travel and working zone of the autonomous mobile machinery where they cause a risk to health and safety of persons or to safe machine operation.</i></p> <p><i>Where autonomous mobile machinery is equipped with protective devices capable of detecting any human or animal presence in the surrounding of a vehicle, that vehicle shall stop operation where appropriate when a human or animal comes within the immediate danger zone. Alternatively, a vehicle can continue to operate in a reduced risk mode if:</i></p> <ul style="list-style-type: none"> • <i>Impact hazard is within safe limits and;</i> • <i>Crushing forces are within safe limits.</i> <p>Justification: In our understanding, the Commission’s proposal results in the obligation to monitor the complete environment of a mobile machine by means of one or more personal protection devices. ISO 3691-4 also permits tactile protective devices with a triggering force $\leq 400\text{N}$ for this purpose. Derived from this (in agreement with BG Handel und Warenwirtschaft), no protective devices are necessary for contact forces $\leq 400\text{N}$. Therefore, the specification would conflict with the standard. See also ISO/TS 15066:2016</p>
24	<p>New Technologies - Annex I: 3. OFFSET <u>RISKS</u> DUE TO THE MOBILITY OF MACHINERY 3.3.5. Control circuit failure</p>	
	<p><i>A failure in the power supply to the power-assisted steering, where fitted, must not prevent machinery from being steered during the time required to stop it.</i></p> <p><i>For autonomous mobile machines, a failure in the steering system shall stop any movements of the machinery.</i></p>	<p>To delete the new addition</p> <p>This is too general a description, regardless of the risk that arises, there could also be risks that arise due to a forced stop. If the goal is protect humans and animals we must take into account that some machines intended to help elderly persons can’t stop in mid function.</p> <p>See also comment to slide 20</p>
25	<p>New Technologies - Annex I: 3. OFFSET <u>RISKS</u> DUE TO THE MOBILITY OF MACHINERY</p>	

	3.4.2. Moving transmission parts	
	<i>By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access. This exemption is not relevant for autonomous mobile machinery.</i>	Delete the new addition Justification: This is covered by Annex I 3.3.3 Travelling function (danger zone)
26	New Technologies - Annex I: 3. OFFSET <u>RISKS</u> DUE TO THE MOBILITY OF MACHINERY 3.4.8 Autonomous mobile machinery	
	<i>For autonomous mobile machinery associated with one or more trailers or towed equipment, their movements shall not generate any risks for persons and animals in the vicinity of the travel and working zone of the machinery. In addition, for this machinery, the approach manoeuvres to the charging stations or other fuel delivery system shall not create risks.</i>	Proposal for amendment: <i>For autonomous mobile machinery associated with one or more trailers or towed equipment where appropriate their movements shall not generate any risks for persons and animals in the immediate danger zone vicinity of the travel and working zone of the machinery.</i> Justification: see comment to slide 20
27	New Technologies - Annex I: 3. OFFSET <u>RISKS</u> DUE TO THE MOBILITY OF MACHINERY 3.5.1 Batteries 3.6.3. Instructions 3.6.3.3 Autonomous mobile machinery	
	<i>3.5.1 Batteries The automatic charging of batteries in particular for autonomous mobile machinery shall be perform without creating risks according to sections 15.1 and 1.3.8.2.</i> <i>3.6.3. Instructions 3.6.3.3 Autonomous mobile machinery</i> <i>The instructions for use shall specify the travel and working zones including the operating limits.</i>	Delete new Essential Requirement under 3.5.1 for batteries, Justification: it is not clear what kind of hazards/risks should be addressed in an automatic charging process (where no person would be involved). (in case it is maintained we suggest the correction of the numbering "15.1" to 1.5.1) Orgalim supports amendment 3.6.3.3

28	New Technologies - Annex V: INDICATIVE LIST OF THE SAFETY COMPONENTS	
	<p><i>(h) software with safety function</i> <i>(i) artificial intelligence with safety function</i></p>	<p>Propose to form new list of safety components Justification: the additions "h), i)" seem to be an extension of the Annex V list nr. 17 which refers to safety components for lifting equipment, this should not be the case.</p> <p>General comment to (h): Software can only be classified as a safety component if it has a safety function in the sense of Article 2(c), the conformity assessment procedure has been carried out and documented by the manufacturer with a specific hardware specification and the manufacturer states the specification of this hardware in the instructions so that it is known to the user as a prerequisite for putting into service. Only if the user operates the software on the hardware, which is specified in the instructions, it can be assumed to have a presumption of conformity.</p> <p>Orgalim proposes to delete "(i) artificial intelligence with safety functions" Justification: this is covered by h) we consider that AI is a software Besides, AI is not a function, but a technology and it is important to remind that the Machinery Directive is technology neutral.</p>
29	New technologies – Annex VII A. TECHNICAL FILE FOR MACHINERY	
	<p><i>The technical documentation shall include at least the following elements:</i> <i>(n) during the use of specific machinery categories with sensor-fed, remotely-driven, autonomous, AI with learning capability, if the operations are alimented by (sensorial) data, or if the software can evolve by itself, the trace log of all relevant elements – both the data and the versions of software - should be collected and kept synchronized for an eventual ex-post inspection.</i></p>	<p>Proposal to delete n) Justification: 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.</p>

30	<p>New technologies – Annex VII A. TECHNICAL FILE FOR PCM</p>	
	<p><i>The technical documentation shall include at least the following elements:</i> <i>(m) where appropriate, the source code or programmed logic that are safety-related, together with the relevant data, should be collected and kept synchronized to allow failure analysis or in case of inspection.</i></p>	<p>delete point (m) Justification: The source code remains in the technical documentation of the respective manufacturer of a product. It cannot be expected that the manufacturer of an incomplete machine will deliver its source code, and thus large parts of its know-how, to the machine manufacturer. After all, he does not have to and cannot supply the machine builder with the exact circuitry, board layout etc. of electronic components used in the incomplete machine. Where relevant, he only has to make this available to the market surveillance authorities.</p>
32	<p>Scope exclusions</p>	
	<p><i>Article 1 - Subject matter</i></p> <p><i>This Regulation lays down requirements for the design and manufacture of machinery, which is to be made available on the market, in order to ensure protection of the health and safety of users, domestic animals and property and establish rules on the free movement of machinery in the Union.</i></p> <p><i>The road circulation risks of machinery are not part of this Regulation.</i></p>	<p>We support this clarification</p> <p>Include: <i>are not part of this Regulation according to MD Art. 1.2. letter e)</i></p>
33	<p>Scope exclusions Low Voltage Directive products</p>	
	<p><i>(k) electrical and electronic products falling within the following areas, insofar as they are covered by Directive 2014/35/EU of 26 February 2014 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits or by Directive 2014/53/EU of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC:</i> — household appliances intended for domestic use, — audio and video equipment,</p>	<p>We support this amendment</p>

	<ul style="list-style-type: none"> — information technology equipment, — ordinary office machinery, — low-voltage switchgear and control gear, — electric motors; 	
35	Definitions Safety component	
	<p>'safety component' means a component:</p> <ul style="list-style-type: none"> — having any support, physical or digital, including a software — which serves to fulfil a safety function, — which is independently placed on the market, — the failure and/or malfunction of which endangers the safety of persons, and — which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function. 	<p>Proposal to delete</p> <p>— having any support, physical or digital, including a software</p> <p>Proposal to add new definition for safety software:</p> <p>software which fulfils these (above) criteria is also a safety component</p>
36	Definitions Partly completed machinery	
	<p>'Partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application which is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Regulation applies, other than an assembly that only lacks the upload or modification of a software. Any device installed after the machinery on which it is assembled has been put into service is not deemed partly completed machinery.</p>	<p>We do not support the deletion of the explanation: "which cannot in itself perform a specific application"</p> <p>Orgalim suggests this amendment:</p> <p>'Partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application because it is lacking some elements. Because of this incomplete status it cannot comply fully with all relevant essential health and safety requirements set out in Annex I. A drive system is partly completed machinery. Partly completed machinery is which is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Regulation applies.</p> <p>Orgalim proposes to move this addition to the recitals or the guidelines:</p> <p>other than an assembly that only lacks the upload or modification of a software. Any device installed after the machinery on which it is</p>

		assembled has been put into service is not deemed partly completed machinery.
37	Definitions Others	
	<ul style="list-style-type: none"> • <i>'instruction manual' means user manual in digital or paper format.</i> • <i>'safety manual' means safety instructions in printed format.</i> • <i>'data', 'software' (to be defined)</i> 	<p>Orgalim suggests this amendment: <i>"instruction manual' means user manual, including safety instructions, in digital and/or paper format."</i></p> <p>Delete "safety manual" Justification: If the product is a consumer product then the need for an instruction manual is required through the GPSD. Through these provisions the requirements are to provide the paper format on the request of the consumer. In addition, the user instructions always start with the safety information.</p> <p>'data', 'software' (to be defined) We propose to base these definitions on already established internationally recognised definitions, e.g. in the IEC Dictionary. Links: http://www.electropedia.org/iev/iev.nsf/display?openform&ievref=171-01-02 http://www.electropedia.org/iev/iev.nsf/display?openform&ievref=171-01-21</p>
39	Obligations of third parties involved in the machinery supply chain	
	1. <i>Third parties who do not qualify as manufacturers, importers or distributors of machinery shall ensure that the terms and conditions of sale and supply of software, components, data and other services in relation to the</i>	Third parties who do not qualify as Manufacturers, of components and suppliers or developers of software intended for machinery shall ensure that the terms and conditions of sale and supply of software, components, data and other services relating-in-relation to the safety

	<p><i>safety functions of the machinery do not prevent meeting any compliance obligation under this Regulation.</i></p> <p><i>2. Third parties involved in the supply chain under paragraph 1 shall cooperate with the manufacturers of machinery to ensure compliance with this Regulation within their capacities and responsibilities.</i></p>	<p><i>functions of the machinery do not prevent meeting any compliance with the obligations under this Regulation.</i></p> <p>Justification: This is already regulated in the Blue Guide and the new Market Surveillance Regulation. Further provisions in the new EU Machinery Regulation would lead to double regulation and inconsistencies.</p>
41	Presumption of conformity	
	<p><i>The Commission shall be empowered to adopt implementing acts establishing technical specifications that meet the essential health and safety requirements of this Regulation where the following conditions have been fulfilled:</i></p> <p><i>(a) no reference to harmonised standards is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012; or</i></p> <p><i>(b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard and there are undue delays in the standardisation procedure or the request has not been accepted by any European standardisation organisations; or</i></p> <p><i>...</i></p> <p><i>Machinery which is in conformity with the technical specifications or parts thereof shall be presumed to be in conformity with the essential health and safety requirements of this Regulation in so far as those technical or parts thereof cover those requirements.</i></p>	<p>Orgalim does not support this addition</p> <p>The proposed text on slide 41 is critical because, according to its wording, it may undermine the New Approach concept. In its current form we do not support it because it doesn't reflect sufficiently the following principles to which we would like to draw the attention:</p> <ol style="list-style-type: none"> 1. Traditional European standard-making process (i.e., Standardisation Request with reasonable time frame and requirements, standard worked out in an open, transparent, and democratic process without unjustified delay and then listed in the OJEU without unjustified delay) should be in all instances the preferred way for the concept of presumption of conformity. This should be reflected accordingly in the draft legal text. 2. Only if this process doesn't lead to a result, other means (as the proposed implementing acts) could be established to create a link between essential requirements and technical details how to meet them and create presumption of conformity. 3. For drawing up such implemented act we suggest using the opportunity of the machinery directive to establish certain guidelines (to be further drafted) that are to be followed.
43	EHSR 1.1.2. Principles of safety integration	

	<p><i>Machinery must be supplied with all the special equipment and accessories, test procedures and/or test equipment, essential to enable it to be adjusted, maintained and used safely.</i></p>	<p>The proposed addition to this requirement should be amended as follows: <i>Machinery must be supplied with all the special equipment and accessories, test procedures and/or test equipment, essential to enable it to be adjusted, tested, maintained and used safely.</i></p> <p>Justification:</p> <ol style="list-style-type: none"> 1) The maintenance phase is already thoroughly taken into consideration in the MD, through specific EHSRs in clause 1.6 and through the chapter "content of instructions", especially in sub-clauses 1.7.4.2.e), r) or s). Those EHSR already require providing information and instructions. 2) For professional products, test equipment is distributed through the dealer network in view of regular maintenance. 3) This requirement would also generate a large amount of testing equipment that would be sitting idly in storage for most of its life which is against environmental considerations.
44	<p>EHSR 1.2 Control systems 1.2.4.3. Emergency stop</p>	
	<p><i>Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.</i> <i>Machinery must be equipped with an emergency stop function, so that they can be deactivated/overridden at any time.</i></p>	<p>We support the deletion of the initially proposed addition. Justification: the provisions on emergency stop 1.2.4.3. already contain these requirements. Further, specifications can be found in EN 60204 -1</p>
45	<p>EHSR 1.5. Risks due to other causes 1.5.13. Emissions of hazardous materials and substances</p>	
	<p><i>Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided. These include hazardous chemicals, including nanomaterials, and biological materials and substances.</i></p>	<p>Orgalim proposes to delete this addition Justification: This should be clarified in guidelines and not in the MD. The requirements would make hand-held equipment too heavy.</p> <p>Proposal to delete</p>

	<p>Where a risk cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, captured, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.</p> <p>Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or capture, filtration (separation) and evacuation must be situated in such a way as to have the maximum effect.</p>	<p>Where a risk cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, captured.</p> <p>Justification: there is no difference between the meaning of contained and captured so no added value in the repetition.</p> <p>Proposal to delete capture, filtration (separation) and</p> <p>See justification above: no difference between contained and captured so no added value</p>
46	<p>EHSR 1.6. Maintenance 1.6.2. Access to operating positions and servicing points</p>	
	<p>Machinery must be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment, maintenance and cleaning of the machinery.</p> <p>The machinery accesses must be dimensioned and prepared for the use of rescue equipment in such a way that a timely rescue the immediate and gentle rescue of these persons is guaranteed at all times.</p>	<p>Orgalim proposes to delete the addition</p> <p>Justification:</p> <p>Such access is difficult to anticipate, as the use of rescue equipment will depend on what will be needed depending on the severity and location of the of the injured and the number of people required to operate the equipment.</p> <p>In addition, the rescue teams in different countries have different equipment of different dimensions making this requirement impossible to comply with.</p> <p>The addition would also lead to difficulties in applying the state of the art as represented by EN ISO 14122 and the evaluation of standards by HAS consultants can be expected.</p>
47	<p>EHSR 1.7 Information 1.7.4 Instructions</p>	
	<p>The instructions can be provided in a digital format and must be provided in paper format upon request.</p>	<p>Orgalim supports the flexible solution suggested in the text with the small clarification:</p>

	<p><i>Instructions that are essential for the putting into service in a safe way must be provided in any case in paper format together with the machinery.</i></p>	<p><i>The instructions can be provided in a digital format and upon request must be provided in paper format.</i></p> <p>We propose to delete the second line: <i>Instructions that are essential for the putting into service in a safe way must be provided in any case in paper format together with the machinery</i></p> <p>Justification: A paper might not always be the best solution for providing the safety related information. A product screen, plastic sheets or marking directly on the product can in some situations be a more appropriate solution for delivering safety relevant information. We suggest that the manufacturer can also provide the instructions as a download if the necessary information is supplied with the Machinery. Furthermore, we suggest that the conditions for the download and the time period available for the download be regulated. For this period, the regulations for the storage of the technical file according to Annex VII could be applied. Regulations could also be made for digital formats, so that the instructions are readable and can be concretised by standardisation.</p> <p>If the product is a consumer product then the need for an instruction manual is required through the GPSD. Through these provisions the requirements are to provide the paper format on the request of the consumer.</p> <p>Finally, Orgalim is against providing instructions as an obligatory requirement. This should be an addition if the complete instructions are supplied in a digital format. Providing this additional information should be down to the manufacturer's choice. (see slide 51)</p>
48-50	<p>EHSR 1.7 Information 1.7.4.2. Contents of the instructions</p>	
	<p><i>1. Each instruction manual must contain, where applicable, at least the following information:</i></p>	<p>Delete part of addition to (r):</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 account of the restrictions and actual and foreseeable working conditions.***

(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 emission of hazardous materials and substances from the machinery, or

the concentration of hazardous materials or substances around the machinery coming from the machinery or from materials/ substances used with the machinery, or

- the effectiveness of the capturing or filtration device and the conditions to be observed to maintain its effectiveness over time.

These values are either actually measured 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.

(y) the intended life limit of the machinery and/or of its components which have impact for the safety aspects;

*the preventive maintenance measures that should be observed **taking account of the restrictions and ~~actual and foreseeable working conditions:~~***

Justification:

The amendment does not 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 new requirement could be interpreted too broadly so as not to concern only the machinery itself. Requirements for the devices should be part of their respective legislation and not be part of the MD.

Delete new requirement w)

Justification: the proposed requirements are too detailed and are already covered by existing EHSR 1.5.13. and 1.7.4.2 l) (we suggest that the new text might be integrated in the MD Guide).

Furthermore, the proposal tends to impose a technology, which is not the purpose of Machinery Directive.

Specifically, on portable machinery, the risk of exposure is also a duty for employers who have to take appropriate measures on jobsites for the operators. This must be done by the provision of appropriate PPE, organisational measures (staff turnover) or the provision of additional equipment intended to reduce this exposure (e.g. water spraying/sprinkling equipment).

On mobile machinery, there is only an annex dealing with hazards due to mobility of machinery. The MD shall provide the Essential Health and Safety requirements while remaining technology neutral. Technical solutions to a specific issue should be discussed in standardisation committees.

Delete new requirement y)

Justification: In terms of functional safety, the life of a component might be considered to equate to the mean time to failure (MTTF) which can typically run into millions of hours and that information is unlikely to be of any use to the user.

51	<p>EHSR 1.7 Information 1.7.4.2. Contents of the instructions</p>	
	<p>2. Each safety manual must contain, where applicable, at least the following information:</p> <ul style="list-style-type: none"> • The business name and full address of the manufacturer and of his authorized representative if appointed; • The designation of the machinery as marked on the machinery itself; • A description of the intended use of the machinery; • A description of all the conditions which must be met with a view to start safely the utilization of machinery; • Warnings to prevent a foreseeable misuse of the machinery; • Where appropriate, a description of the necessary personal protective equipment; • The sequence of operations to be performed to start using the machinery; • Any necessary additional safety information required, depending on the risk assessment of the machinery; • Where appropriate, instructions for transport, assembly and installation. If software is required, the safety instructions shall explain how to install and make operational the software in a safe way; • Unique link to download access of the complete instruction manual, if the manual is not supplied in digital form together with the machine 	<p>Orgalim is against this as an obligatory requirement. This should be an addition if the complete instructions are supplied in a digital format. It should be down to the manufacturer's choice.</p> <p>General comment to last bullet: It is not clear what is meant by "unique link" we suggest to add an explanation in the footnote or in the guidelines.</p>
52	<p>EHSR 2.2. Portable hand-held and/or hand-guided machinery 2.2.1. General</p>	

	<p>Portable hand-held and/or hand-guided machinery must:</p> <p>...</p> <p>- have, where necessary, a device to capture emissions of hazardous substances at the source</p>	Orgalim does not support this addition
53	<p>EHSR</p> <p>2.2. Portable hand-held and/or hand-guided machinery</p> <p>2.2.1.1. Instructions</p>	
	<p>The instructions must give the following information concerning vibrations, expressed as acceleration [m/s²], and transmitted by portable handheld and hand-guided machinery:</p> <ul style="list-style-type: none"> — the vibration total value from continuous vibrations to which the hand-arm system is subjected, — the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected, — the uncertainty of both measurements. 	<p>Delete the proposed addition to Essential Requirement 2.2.1.1;</p> <p>Justification: the proposed new vibration quantity must be well defined and must be underpinned by corresponding standards for a representative measurement method which must be further ensure repeatability. This proposal does not cover the requirements of the current EHSR 2.2.1.1. This would mean, that for all machinery (even with low vibration level) an individual value have to be declared. We do not think that this would be proportionate, considering the fact that the value of 2,5 m/s² corresponds with the daily exposure action value standardised to an eight hour reference period as specified in Directive 2002/44/EC, Article 3. Below this value no particular measures have to be taken by the employer.</p>
54	<p>EHSR</p> <p>3. Offset risks due to the mobility of machinery</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, the machinery must be designed or equipped with a restraint system so as to keep the persons in their seats and/or in the protective structure, without restricting movements necessary for operations or movements relative to the structure caused by the</p>	<p>Delete new paragraph: "It must not (...) limitation of the machine"</p> <p>Justification: The requirement as added is not technology neutral and too general for all different types of mobile machinery. The specific requirements should be given in machine specific standards.</p>

	<p><i>suspension of the seats. Such restraint systems should not be fitted if they increase the risk.</i></p> <p><i>It must not be possible for the machinery to move if the restraint system is not active, except if it increases the risk. In that case, the driver has to be alerted by a visual or audible signal at the driving position combined with an automatic speed limitation of the machine.</i></p>	
55	<p>EHSR</p> <p>3.5. Protection against other risks</p> <p>3.5.3. Emissions of hazardous substances</p>	
	<p><i>The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the spraying of products. However, the operator must be protected against the risk of exposure to such hazardous emissions.</i></p> <p><i>Ride-on mobile machinery designed for spraying or likely to be used for spraying chemicals must be equipped with filtration cabs or equivalent safety measures.</i></p>	<p>Orgalim proposes this alternative to the addition: <i>"Cabs fitted to ride-on mobile machinery used for spraying shall be equipped with filtration."</i></p> <p>Justification: For cabs, the state of the art is to provide filtered cabs.</p>
56	<p>EHSR</p> <p>3.5 Protection against other risks</p> <p>3.5.4 Risk of contact with live overhead power lines</p>	
	<p><i>Mobile machinery is designed and manufactured so as to prevent the risk of contact or the risk of creating an electric arc 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.</i></p> <p><i>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.</i></p> <p><i>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</i></p>	<p>Orgalim proposes to delete the addition.</p> <p>Justification: The paragraphs are contradictory. In our view, the first section of the new 3.5.4 is sufficient for the formulation of an EHSR. The additional sections contain no significant additional information and the requirements are not proportionate to the existing hazards.</p>

	<i>power line under normal operating conditions and foreseeable misuse.</i>	
57	EHSR 4. Offset risks due to lifting operations 4.1.3. Fitness for purpose	
	<i>Where the machinery cannot be assembled in the manufacturer's premises or in the premises of his authorised representative, the appropriate measures must be taken at the place of use by the manufacturer or on his behalf. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.</i>	
58	EHSR 6.2 Control devices for machinery with lifting of persons	
	OPTION 1 <i>The control devices for these movements must be of the hold- to-run type manned at all times except where the carrier itself is completely enclosed.</i> OPTION 2 <i>The control devices for these movements must be of the hold- to-run type except where the carrier itself is completely enclosed. If there is no risk of the persons or the goods on the carrier colliding or falling and no other risks are added, the said devices may be replaced by control devices authorising automatic stops at preselected positions without the operator holding a hold-to-run control device.</i>	
59	Annex II- Declaration of conformity EU DECLARATION OF CONFORMITY OF THE MACHINERY	
	<i>The EU declaration of conformity must contain the following particulars: ... - The address where the machine is installed, only for lifting machinery installed in a building or a structure,</i>	The proposed requirement should be amended as follows: - The address where the machinery is installed, only for machinery for lifting persons from one level of the building to another level installed in a building or a structure,
61	Principles of human centric principles	

	<p>Recitals and/or 1.1.2. Principles of safety integration 1.1.6. Ergonomics</p>	
	<p>Recitals and/or 1.1.2. Principles of safety integration (b) Machinery shall remain subject to an appropriate level of human oversight and be designed and implemented in such a way that its functioning can be controlled and overseen by humans. Human oversight shall include the ability of humans to override or reverse the outputs of artificial intelligence and prevent its further use. 1.1.6. Ergonomics 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 principles such as: - Adapting machinery in a human-centric way that respects human dignity and personal autonomy of the humans who use it or may be affected by it.</p>	<p>Delete 1.1.2 (b)</p> <p>Justification: The objective of this new requirement is already achieved by the existing Annex I requirements, without the user having to continuously monitor and intervene. This new requirement is in contradiction with the ergonomic requirements of point 1.1.6, according to which monitoring activities requiring constant attention must be avoided.</p>
62	<p>Substantial modification Definition</p>	
	<p>Means a modification on the machinery, by physical or digital means, after being placed on the market and/ or put into service, not foreseen by the manufacturer, as a result of which the compliance of the machinery with this Regulation may be affected and when the machinery is made available on the market. Own use is excluded from this definition when the person that modifies the machinery is the only user and the function of the machinery is not modified. E.g. a private person increases the power of his/her lawnmower</p>	<p>Orgalim does not agree with the proposed wording. We do not believe that these proposals are helpful to provide clarity.</p>

63	Substantial modification Simplified conformity assessment	
	<ul style="list-style-type: none"> • Only for the modified aspects if the safety of the whole product is ensured. • Ad hoc technical file 	<p>Orgalim does not agree with the proposed wording. We do not believe that these proposals are helpful to provide clarity.</p>
64	Categories of machinery Annex IV List of machinery	
	<ul style="list-style-type: none"> • <i>The list does not represent the current state of the art in terms of high risks</i> • <i>A categorisation by risks is not the best option because the machinery use is based on the function e.g. cutting wood and not on the risk as other EU legislation e.g. PPE products</i> • Lack of information now to update the list: Delegated act • <i>Item to be added in the list:</i> <i>A machinery contains an AI system/ component to ensure a safety function while this component is integrated directly by the manufacturer without having recourse to a component of Annex V.</i> 	<p>delete 4th bullet</p> <p>Before applications of so-called AI are dealt with in detail, the term artificial intelligence requires a definition for the context of machinery. Today, there is no common understanding what AI really means and the variety of software referred to as AI is so wide that no verifiable requirements can be established without a clear definition. See also comment on slide 28 (i).</p>
65	Categories of machinery Annex IV Conformity assessment	
	<p>To keep or not the internal check option:</p> <ul style="list-style-type: none"> - If the list update would contain only high risk machines, a third party conformity assessment is more justified. - If the internal check option is kept when applying harmonised standards, the existence of harmonised standards is even more relevant. 	<p>Orgalim is against the extension of the list in Annex IV. Orgalim is in favour of fostering module A applied to machinery through the support of hENs.</p> <p>Justification: So far, there is no lack of standards reported regarding harmonised standards for Annex IV machinery and the widely used corresponding conformity assessment procedure as prescribed in Article 12 (3a) of 2006/42/EC. Therefore, deleting this procedure seems not to be justified nor proportionate. Furthermore, a deletion of this procedure would negatively influence the motivation of the stakeholders to develop and maintain harmonised standards for Annex IV machinery.</p>

ⁱ During the meeting the EC decided to make some modifications to their proposals. We take these into account in the proposals column but indicate the changes in red.