SPECTARIS e. V.
Berlin, Germany | 6th August 2021

FEEDBACK - Machinery Regulation

SPECTARIS Position Paper

On the proposal for a regulation of the European Parliament and of the Council on machinery products.

Regulatory Affairs

regulatoryaffairs@spectaris.de
www.spectaris.de

SPECTARIS • German Industry Association for Optics, Photonics, Analytical and Medical Technologies

Werderscher Markt 15
10117 Berlin
Tel. +49 30 414021-10

SPECTARIS
German Industry Association for Optics, Photonics, Analytical and Medical Technologies

SPECTARIS e. V.
Berlin, Germany | 6th August 2021

FEEDBACK - Machinery Regulation

1. Introduction:

On April 26th 2021, the European Commission published a proposal for a regulation on machinery products. This initiative aims to update the existing Machinery Directive 2006/42/EC in order to “align the Directive with EU harmonised legislation on product health and safety, and tackle the challenges that may arise from technical progress in digitization”. SPECTARIS welcomes this objective.

One aim of the inititative is to reduce the administrative burden and additional costs for operators by acknowledging digital forms for documentation. This is also a logical step towards meeting European sustainability goals outlined in the Green Deal and is strongly supported by SPECTARIS.

Nevertheless, SPECTARIS holds the opinion that adjustments to the current draft regulation are necessary. The reasons are outlined in the following points. Proposed changes and technical comments to the current draft are included in the Annex.

2. In detail:

- **Electrical equipment for measurement, control, and laboratory use**
  SPECTARIS recommends to explicitly list an exemption for "electrical equipment for measurement, control, and laboratory use, including but not limited to refrigeration systems, heat pumps and pressure vessels” under Article 2, (2) (o). Laboratory equipment is by definition machinery if it has integral electrical motors for e.g. pumps or refrigeration compressors, pressure vessels, measurement, control functions, or for analysis and other purposes and would thus fall in scope of the machinery regulation. This laboratory equipment, however, has comparable safety risks to equipment in scope of the standard for household appliances rather than risks listed for machinery according to Annex III. The essential health and safety requirements for electrical equipment for measurement, control, and laboratory use are furthermore fully covered by the EN 61010 standard series which has been harmonised under the Low Voltage Directive (LVD, 2014/35/EU). In addition, particular standards with further requirements for laboratory equipment for the heating of materials, for refrigerating equipment, for climatic and environmental testing and other temperature conditioning, for automatic and semi-automatic equipment for analysis and other purposes exist (compare EN 61010-2-010, EN 61010-2-011, EN 61010-2-012, EN 61010-2-81) that have all been harmonized unter the LVD. This laboratory equipment thus falls within the scope of the LVD and should therefore also be considered exempted from the scope of the machinery regulation - just like the products already listed under Article 2 (2) (m).

The same applies to laboratory equipment with pressure vessels. The risk assessment to determine the health and safety requirements, which apply to this equipment, are already covered by the Pressure Equipment Directive (PED, 2014/68/EU). If the equipment is exempted from the PED by Article 1 (2) (f) (iii), the EN 61010 series covers the safety and health requirements for such equipment.

SPECTARIS thus proposes to add "electrical equipment for measurement, control and laboratory use, including but not limited to refrigeration systems, heat pumps and pressure vessels" as an explicit exemption under Article 2 (2) (o) in order to clarify the scope and avoid misinterpretation and unintended overlaps of regulations. This is also in line with the listing of the other exemptions under Article 2 (2) where specific product regulations exist (e.g. (f) and (g)) as well as standards.

- **Medical devices / In vitro diagnostics**
  Medical devices (MD) and in vitro diagnostics (IVDs) are strictly regulated by their specific product regulations such as the medical device regulation (MDR) and in vitro diagnostic regulation (IVDR). These regulations include classification rules according to the risk profile of the product as well as strict conformity assessment rules and procedures that – for the majority of the products – are reviewed by third party conformity assessment bodies (Notified Bodies), including general safety and performance requirements, technical documentation and quality management systems. The current draft proposal for a machinery regulation is missing a clear demarcation from IVDs and medical devices, which by definition can also be machines, especially in the area of partly completed machinery. Partly completed machines like built-in parts such as robot arms, transport systems, centrifuges or pipetting systems are installed e.g. in analysis stations. These prepare and analyse e.g. blood samples fully automatically. Thus, the *entire system* falls under the IVDR and is strictly regulated by the IVDR. According to the current draft the partly completed machinery, however, would also fall under the machinery regulation that is included in the entire system. In order to avoid any contradictions and dublications SPECTARIS suggests to fully align the machinery regulation with the already existing MDR and IVDR and proposes to specify in the machinery regulation if there are risks deemed relevant for MD and IVD to which more specific requirements exist under the machinery regulation.

- **Transition period for standards**
  It is essential to ensure that the standards harmonized under the Machinery Directive 2006/42/EC and listed in the Official Journal continue to provide their presumption of conformity under the new machinery regulation.

Since it will take some time to draft a new standardization request that needs to follow a formalized procedure as well as new harmonized standards, a transition period should be included, either in article 17 or article 50. This provision should clearly state that the existing harmonized standards under the current directive may continuously be used for the presumption of conformity under the new machinery regulation until new harmonized standards are published in accordane with the new standardization request. It is crucial that no regulatory gap as well as legal uncertainties occur due to the transition from the directive to the regulation.

- **Align language requirements for IFU**
  SPECTARIS fully supports that the instructions for use (IFU) may be provided in a digital format. SPECTARIS also fully supports that the IFU shall be drafted in one or more official language(s) of the Union. However, there seems to be a misalignment between Article 10 (7) and provision 1.7.4.1 (b) of Annex III. Article 10 (7) states that "the machinery products are accompanied by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users, ***as determined by the Member State concerned***." Provision 1.7.4.1 (b) then requires that "where no 'Original instructions' exist ***in the official language or languages of the Member State where the machinery product is to be used,"*** that the manufacturer, or his or her authorised representative or the person bringing the machinery product "***into the language area in question"*** provide "***a translation into that/those language(s)***". The mandatory translation requirement does not take into account nor leave room for circumstances where a Member State may choose to allow IFU to be provided e.g to professional users, international research institutions or universities in a language that is not necessarily the official language of that Member State but commonly used and understood by those end-users. SPECTARIS therefore suggests to align Provision 1.7.4.1 (b) of Annex III in order to allow for practical solutions Member States may choose to provide for these circumstances.

Additional technical comments are listed in the following section.

3. Annex: Technical comments & proposed changes:

Page	Reference	Comment / Question	Proposed change
26	Article 2 (2) (o)	Clarify the exemption for electrical equipment for measurement, control, and laboratory use as this equipment is already regulated under the Directive 2014/35/EU. The risk assessment to determine the health and safety requirements for laboratory equipment with pressure vessels is already covered by the Pressure Equipment Directive (PED, 2014/68/EU). SPECTARIS thus proposes to add "electrical equipment for measurement, control and laboratory use, including but not limited to refrigeration systems, heat pumps and pressure vessels" as an exemption under Article 2 (2) (o)	Add an exemption under Article 2 (2) (o): "electrical equipment for measurement, control and laboratory use, including but not limited to refrigeration systems, heat pumps and pressure vessels"
26	Article 2 (2) (p)	Clarify the application of the machinery regulation in regards medical devices and in vitro diagnostics – in particular in regards to partly completed machinery and their assembly into medical devices and in vitro diagnostics.	Add a clarifying provision under Article 2 (2)

27	Article 3 (10)	The simplification of this definition is supported.	
31	Article 8	The application of the other EU regulations on CE marking, which cover the risks referred to more specifically, should be made clearer in the provision and, where appropriate, reflected in a second sentence of the provision. In any case, the explanation in the Machinery Guide should be included to allow the practical application of this provision.	
32-33	Article 10 (6)	The last sentence states “The contact details shall be in a language easily understood by end-users and market surveillance authorities.” This does not correspond to the model provisions of Decision 768/2008, see Annex I, R2(6) and can lead to misinterpretations and non-harmonized applications within the EU.	Align with the model provision of Decision 768/2008 and delete last sentence.
36	Article 14	This provision is highly welcomed.	
36	Article 15	This new provision is expressly welcomed.	
37	Article 17 or Article 50	It will take some time to draft a new standardization request that needs to follow a formalized procedure as well as new harmonized standards. It is therefore curcial to include a transitional provision in order to avoid legal uncertainties. This provision should clearly state that the existing harmonized standards under the current directive may continuously be used for the presumption of conformity under the new machinery	Add a transitional provision for existing standards harmonized under the current directive to continuously apply also in regards the machinery regulation.

		regulation until new harmonized standards are published in accordane with the new standardization request or technical specifications exist.	
53	Article 50 (2)	The duration of EC type-examination certificates of 60 months should not be shortened. Rather, an appropriate transition period that takes this into account is more appropriate.	
9	Annex III 1.1.9	The requirement cannot be implemented: a machine cannot collect evidence to the extent that someone interfered with its hardware, e.g. replaced a component. This requirement also goes beyond essential safety requirements related to the design and construction of a machinery product.	Comment on 1.1.9 second paragraph: Delete the last sentence: “The machinery product shall collect evidence of a legitimate or illegitimate intervention in the hardware component.” Comment on fifth paragraph: Delete the sentence: “The machinery product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery product or its configuration.”
22	Annex III 1.7.4	The provision that the instruction may be provided in digital format is very welcomed, especially in order to be able to take account of the challenges of digitalization, the updating of instructions and environmental issues. However, provision 1.7.4.1 (b) needs to be adjusted and aligned with article 10 (7). The mandatory translation requirement does not take into account nor leave room for circumstances where a Member State may	Suggestion to align provision 1.7.4.1 (b) with article 10 (7) as follows: “Where no ‘Original instructions’ exist in the official language or languages of the Member State where the machinery product is to be used, the language requirements are determined by the Member State concerned. Any translations of the “Original instructions”

		choose to allow IFU to be provided e.g to professional users, international research institutions or universities in a language that is not necessarily the official language of that Member State but commonly used and understood by those end-users.	shall bear the words “Translation of the original instructions”.”