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ORGALIME COMMENTS TO THE FINAL REPORT ON THE EVALUATION OF THE MACHINERY DIRECTIVE 2006/42/EC

Orgalime welcomes the Evaluation of the Machinery Directive 2006/42/EC (MD) in the framework of the Commission's Regulatory Fitness and Performance (REFIT) programme and is pleased to comment on the areas of improvement identified by the consultant, for the purpose of providing support in the evaluation process.

Orgalime represents the engineering industry, which is the largest industrial branch in the EU, with a turnover of around €2,000 billion in 2016. The industry accounts for a quarter of manufacturing output and a third of manufactured exports in the European Union.

In accordance with the consultant's report, Orgalime firmly believes the Machinery Directive is performing well and has reached its objectives of both providing a high level of safety for machinery users and facilitating the free movement of machinery in the internal market.

The adequate implementation of the Directive in the whole of the EU has helped the EU's manufacturing industries to remain competitive on the internal and global markets with positive consequences at both economic and social level.

The issues to be addressed which have been highlighted within the Evaluation report are as follows:

1. Adapting the Directive to fit/integrate with the New Legislative Framework

The current Machinery Directive 2006/42/EC, which has been applicable since 2009, is one of the first New Approach Directives which, although it has not been formally aligned under the New Legislative Framework (NLF), broadly reflects the spirit of the NLF.

In particular, with regard to the conformity assessment procedures, it is important to notice that, among the different modules, only module H (conformity based on full quality assurance) is still to be aligned to the NLF. However, manufacturers do not specifically need this alignment to apply the conformity procedures laid down in Article 5(1) and 12 of the Machinery Directive.

Therefore, if an alignment to the NLF were to be considered, it is worth highlighting that it will neither bring any added value in terms of health and safety requirements nor is it currently called for by economic operators. Nevertheless, although there is no urgency, in the name of Better Regulation principles, industry representatives consider that finalising the alignment of the Machinery Directive to the NLF will be necessary.

Orgalime, the European Engineering Industries Association, speaks for 41 trade federations representing the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs nearly 11 million people in the EU and in 2016 accounted for some €2,000 billion of output. The industry represents over a quarter of the output of manufactured products and over a third of the manufactured exports of the European Union.

2. Adapting the Directive to ensure suitability for new developments

With the increased use of ICT and robots in the machinery sector and taking into consideration that our industry is adapting to new developments like those resulting from digitisation, the question of whether the Machinery Directive is still fit for purpose naturally arises. The same question arises in the context of cybersecurity and the risk of hacking in relation to the safety of equipment.

The vast majority of industry representatives believes that the current Machinery Directive is still fit for purpose due to the format it has been laid down in.

The Directive defines the essential health and safety requirements that machinery needs to meet to be placed on the market, but manufacturers are free to use any specific technologies reflecting the State of the Art (whether described in standards or not) for the purposes of the MD. Therefore, manufacturers have the possibility to use any technological developments and innovation, under the abovementioned conditions.

As evidence that these new technologies are already being successfully used in our industries while meeting all the essential and safety health requirements of the Directive, you will find some concrete examples described in Annex I of this position paper.

3. Simplification of risk assessment procedures

Another issue for improvement described in the final report - without going into detail - is the need to simplify risk assessment procedures.

Orgalime industries firmly believe that, contrary to what is the case under other internal market product directives, the risk assessment procedures for equipment under the scope of the Machinery Directive cannot be made simpler and easier to use than they are today,

The requirements of the risk assessment procedures are laid down in the General Principles of Annex I of the Machinery Directive and are applicable to all machinery covered by the scope of the Directive. These requirements include simple and easy to follow methodologies for risk assessment procedures. Further and complementary information is also provided by harmonised standard EN ISO 12100:2010 that companies can use on a voluntary basis, if necessary. This standard specifies 'the basic terminology, the principles and the methodology for achieving safety in the design of machinery'.

Procedures are also described for identifying hazards, estimating and evaluating risks during all phases of the machine's life-cycle and for the elimination of hazards or their sufficient reduction.

These requirements are easy to apply, not only for multinationals, but also for small and medium sized enterprises with limited financial resources, which can adopt competitive solutions through the use of Module A (internal production control) and the voluntary use of harmonised standards.

Based on the experience of our members, what should be improved in the risk assessment area is not the process itself, but the reality of acquiring a third-party certification from a notified body. In fact, the lack of a uniform approach among notified bodies creates uncertainty concerning the procedures for getting the certification and the costs of the process, with obvious consequences for the expense to be borne by companies, which indirectly impacts the market.

4. Improvements to definitions/demarcations between particular types of machinery

The definitions laid down in the Machinery Directive are generally very clear and fit for purpose. They are also easily understood by the economic operators impacted by this piece of legislation, whether these are manufacturers or users.

The main definitions of a machine, an assembly, a safety component or an interchangeable equipment, for instance, are clearly defined in Article 2 of the Directive.

It is worth remembering that when issues occurred concerning clarifications for particular types of machinery, they were discussed internally between industry stakeholders to find a compromise for every party involved and, if no compromise was found, the issue was tabled at the Machinery Working Group where Member States and industry can have their say on whether, from a rigorous point of view, a particular type of machinery falls under the scope of the Machinery Directive or not.

The clarifications achieved as a result of these discussions appear in Edition 2.1. of the Guide to application of the Machinery Directive 2006/42/EC, which was recently published by the European Commission and to which all stakeholders, including Orgalime, contributed.

Nevertheless, even if the above-mentioned procedures have proved to be efficient over the years, it is important to underline that, in many cases, the problems industry experienced involved diverging interpretations of some of the requirements by market surveillance authorities which led to unclear situations and confusion among industry stakeholders. The above-mentioned procedures which can be used by all economic operators, have proved to be efficient over the years.

5. Improved convergence/harmonisation with other similar Directives/Regulations

The consultant's final report highlighted some overlaps and inconsistencies with other directives, mainly with the Low Voltage Directive (LVD) and the Electromagnetic Compatibility Directive.

On this matter, it is important to remember that Article 3 of the Machinery Directive is very clear and its provisions are understood without doubt by the vast majority of economic operators: "Where for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply to that machinery in respect of such hazards from the date of implementation of those other Directives."

This article should, in our opinion, be given as an example of good practice for other product directives.

Unfortunately, details concerning the above-mentioned inconsistencies are not further developed, except when it comes to market surveillance inspection of equipment covered by both the MD and the LVD for example.

Based on the output of the MD Evaluation study, it seems to be an incorrect interpretation of Article 3 of the Machinery Directive, rather than a shortcoming of the Directive itself.

We, therefore, believe that these overlaps, when they exist, can be easily overcome through non-legislative instruments (such as the Guide to application of the Machinery Directive 2006/42/EC), which do not create further burden or legal uncertainty for manufacturers.

6. Ensuring increased/improved inspection and therefore widespread compliance of the Directive

It is generally admitted by all economic operators who place machines on the EU market or those who import directly from third countries, that market surveillance authorities should be better coordinated so as to ensure inspections in the Member States are performed adequately and with homogenous criteria. Unfortunately, this has not been the case according to industry stakeholders, as it was abundantly reported in the final Evaluation report, that the number of inspections in Member States is too low and that national authorities' efforts to identify unsafe machines are often ineffective. Non-compliant machines evidently create risks to the health and safety of users as well as an environment of unfair competition.

We are aware that European Commission is making every effort to ensure a common EU approach on enforcement of product legislation in the internal market and we look forward to the expected proposal on this issue. Orgalime has issued a number of position papers on the issue of enforcement, the last one of which, dated 21 September 2017 is "[Simpler and more effective market surveillance of products is urgently needed](#)".

Conclusions

As repeatedly mentioned, keeping an industrial base in Europe will only be possible with a strong and competitive manufacturing industry, at the core of the European economy (see also [our core policy statement on the REFIT of the Machinery Directive 2006/42/EC](#)).

To reach the objectives of growth and jobs for the future of Europe, manufacturers need a stable and effective legislative framework. For much of our industry, the Machinery Directive 2006/42/EC is the core piece of product legislation enabling companies to place state of the art and safe machinery on the Single Market. In our view, the legislation is performing as it should.

We, therefore, urge decision makers to keep the Directive in its current form with minor modifications, if at all necessary, but not impacting its essential requirements and its basic philosophy.

See Annex attached

Responsible Advisor: Eleonora Piccinni



The European Engineering Industries Association

ORGALIME aisbl | BluePoint Brussels | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
 Tel: +32 2 206 68 83 | e-mail: secretariat@orgalime.org
 Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

Annex I: includes concrete examples of new technological developments covered under the Machinery Directive 2006/42/EC

- **Automated guided vehicles** electric motor vehicles pre-programmed to autonomously complete various tasks, such as path selection, collision avoidance, horizontal transportation, stacking or replenishing. They are generally controlled by computers or advanced laser technology. They are driverless trucks which can also be driven in a manual mode. AGV manufacturers need to make sure their equipment meets not only the essential requirements of traditional industrial machines, but also specific legislation covering the use of wireless technologies. The general industrial environment of AGVs is covered by the Machinery Directive but also by other legislation for those risks/hazards not included in the MD (RED for example). These vehicles, which are classified as mobile machinery under the scope of the Machinery Directive, are used in Orgalime industries to move material around warehouses.



- **Automated guided carts:** they are guided by magnetic tape on the floor for horizontal transport and/or to pick up and drop off loads. These carts have also safety scanner.
- **Robotic lawnmowers:** As the industry will be increasingly driven by the move towards sustainability, new technologies such as State of the Art batteries and remote controlled products will be used. The garden machinery sector is already ahead of many industries, with robotic mowers being one of the most promising personal robot applications. This kind of equipment are classified as machines under the scope of the Machinery Directive and their compliance with the ESHR make them safe to use.



- **Picking robots:** they are designated to automate the process of manually building mixed pallets.
- **Painting robots:** they are used to support painting activities in plants.
- **Digitalisation of the industry sector:** as is the case for other internal market legislation, manufacturers from our sector use the Declaration of Conformity in electronic format and/or supply electronic instruction for use. The European Garden Machinery association, which is an associate member of Orgalime, provides a quick start guide while keeping the full instructions electronically available (using, for instance, the manufacturers' website).

Cybersecurity: As the legislator is aware, cybersecurity is not only an issue related to machines but also to other types of products which could be integrated into a machine. To this end, we will be pleased to continue working in co-operation with decision makers to find the best instruments in order that equipment placed on the market are not only safe but also secure. With the recent tabling of the EC proposal of the Cybersecurity Act which will lay down requirements for European cybersecurity certification schemes, we believe it is too early to tackle this issue in relation with the Machinery Directive. As soon as the proposal is discussed both the European Parliament and the Council, we will be able to take a position in co-ordination with our members.



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ORGALIME aisbl | BluePoint Brussels | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 206 68 83 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438