

EVALUATION AND FITNESS CHECK (FC) ROADMAP			
TITLE OF THE EVALUATION/FC	Evaluation of the Machinery Directive 2006/42/EC		
LEAD DG – RESPONSIBLE UNIT	DG GROW/C3	DATE OF THIS ROADMAP	13/05/2016
TYPE OF EVALUATION	Evaluation, ex-post, mixed	PLANNED START DATE	Q1 / 2016
		PLANNED COMPLETION DATE	Q2 / 2017
		PLANNING CALENDAR	http://ec.europa.eu/smart-regulation/evaluation/index_en.htm
This indicative roadmap is provided for information purposes only and is subject to change.			

A. Purpose
(A.1) Purpose
<p>The purpose of this evaluation is to assess the performance of the Machinery Directive 2006/42/EC¹, by collecting evidence and information to analyse whether it is still fit for purpose in terms of effectiveness, efficiency, relevance, coherence and EU added value, and if needed, to point out where issues are and what improvements could be envisaged to improve the functioning of the Directive.</p> <p>As such, this evaluation may precede an Impact Assessment study in view of a potential revision of the Directive.</p>
(A.2) Justification
<p>After almost six years of implementation, it is necessary to assess in the context of regular evaluation of the acquis, if the Directive has achieved its objectives in an efficient, correct and relevant way and still has EU added value and on the basis of the conclusions on the performance of the Directive, whether a revision is necessary, e.g. simplification in line with the REFIT² programme and full alignment to the New Legislative Framework (NLF)³.</p> <p>This evaluation was linked to the REFIT programme in 2013⁴ as the purpose of the evaluation is to assess whether the Machinery Directive remains fit for purpose and that the benefits of the Directive are enjoyed at lowest cost and with a minimum of administrative burden, in full respect of the objectives of the EU Treaties.</p>

B. Content and subject of the evaluation
(B.1) Subject area
<p>The Machinery Directive 2006/42/EC provide harmonisation regulation at EU level for machinery, defined as an assembly of components, at least one of which moves, joined together for a specific application; the drive system of machinery is powered by energy other than human or animal effort. It is a "New Approach" Directive which establishes essential health and safety requirements for products placed on the EU market.</p>

¹ Machinery: http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery/index_en.htm

² Point 54 of Annex 3 to the Commission Work Programme 2015, COM(2014)910 of 16.12.2014: http://ec.europa.eu/atwork/pdf/cwp_2015_refit_actions_en.pdf

³ New Legislative Framework for marketing of products: http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

⁴ COM(2013)685

(B.2) Original objectives of the intervention
The objective of the Directive is to guarantee the free circulation of products in its scope and to ensure a high degree of safety for users and other exposed persons, as well as environment protection for the machinery used in pesticide applications.
(B.3) How the objectives were to be achieved
The Machinery Directive is based on Article 114 of the TFEU (ex-Article 95 TEC). The Directive is a total harmonisation Directive based on the principles of the "New Approach to Technical Harmonisation and Standards". It lays down the essential health and safety requirements that machinery must fulfil in order to be placed on the market as well as the applicable conformity assessment procedures to demonstrate that the machine fulfils the requirements. The majority of machinery in its scope can be self-certified by the manufacturer who must show compliance with the essential health and safety requirements of the Directive. Certain categories of machinery, with higher risks, defined in Annex IV to the Directive, can be certified making recourse to the involvement of a notified body or by the manufacturer himself when they are produced in compliance with the provisions of European harmonised standards that cover all the applicable essential health and safety requirements of those machinery. Harmonised standards are essential tools for applying the Machinery Directive when their references are published in the Official Journal of the European Union. However, their use is voluntary.

C. Scope of the evaluation/FC
(C.1) Topics covered
The scope of the evaluation study lies in the products range covered by the Machinery Directive, from small hand held electric tools to big industrial production lines, with a delimitation on the main categories and subcategories of products, intended to be placed on the EU market. The evaluation will be comprehensive and cover all aspects of the Directive (scope, essential health and safety requirements, and conformity assessment procedures). The evaluation will consider the territory of the EU and of the EFTA and will cover the period 2009-2014.
(C.2) Questions/issues to be examined
This evaluation will assess the relevance, effectiveness, efficiency, coherence and EU added value as well as significant economic, social and environmental impacts of the Machinery Directive after more than five years of implementation (see the detailed list of question below). In particular, it aims to identify the positive and the negative aspects related to the implementation of the Directive, including potential difficulties that may require regulatory or/and non-regulatory corrective measures. At the same time, the evaluation shall provide a better understanding of the structure of the machinery market in Europe and shall identify the main trends in the international trade. The evaluation includes among others, assessing its impacts on companies and users in the European Union, on the EU competitiveness, potential trade barriers that would limit the free movement of goods, impacts on innovation, and whether the provisions of the Machinery Directive appropriately guarantee that the products in its scope are designed and manufactured in such a way that they operate safely and present no danger to persons, domestic animals or property, in 'normal use'. Some of the aspects to be evaluated are the definitions of the products categories in Article 2 and in particular the definition of partly completed machinery, the interface with other internal market legislation, the clarity of the requirements for the modifications of the machinery already placed on the market, the relevance of the indicative list of safety components. The detailed list of evaluation questions is the following: <u>Description of the market</u> 1. What is the current situation and trends in the machinery market? <u>Relevance</u> 2. To what extent do the initial objectives of facilitating the functioning of the internal market and ensuring a high level of safety for machinery correspond to current needs of the market, manufacturers and users? 3. How are innovation and new technologies taken into account?

Effectiveness

4. To what extent has the Machinery Directive contributed to an effectively operating internal market for the products in its scope and to what extent has it achieved its aims with regard to the protection of health and safety of consumers and users, and where appropriate, domestic animals or properties for the products in its scope?
5. What are the positive factors and the negative factors (e.g. barriers) for an effective application and enforcement of the Directive, in particular through surveillance of machinery on the market?
6. Are there any aspects/means/actors that render certain aspects of the Directive more or less effective than others, and if there are, what lessons can be drawn from this?
7. How effective are MS authorities in identifying non-compliant products?
8. To what extent has the option of third party conformity assessment for Annex IV categories of machinery, been effective?
9. To what extent has the procedure for assessment of conformity with internal checks been effective in providing highest degree of health and safety for consumers and users?
10. How effective was the development and use of the European harmonised standards for the Machinery Directive?

Efficiency

11. What are the regulatory (including administrative) costs and benefits for the different stakeholders and/or other actors, and to what extents are these costs proportionate to the benefits achieved?
12. What are the reasons for discrepancies between Member States?
13. How affordable were the costs borne by the different stakeholders (manufacturers, users, conformity assessment bodies, standardisers and public authorities) given the benefits they receive? What does this represents in terms of administrative and reporting burdens on stakeholders and/or other actors?

Coherence

14. Are there overlaps or complementarities between the Machinery Directive and any other Community or international legislation (General Product Safety Directive, Type approval legislation for agricultural and forestry tractors, and for two or three wheel motor vehicles, Medical Device Directive, etc.). To what extent are they coherent?

EU added value

15. What is the additional value resulting from the Machinery Directive, compared to what could be achieved at national level? What is the added value of the Machinery Directive for stakeholders?

(C.3) Other tasks

Any other relevant information, contributions and proposals by the sectorial interested parties in view of possible further developments, revision and improvement of the Directive.

D. Evidence base

(D.1) Evidence from monitoring

The Directive does not foresee regular monitoring reports on the situation required by specific obligations, in addition to the mechanisms of information and cooperation between Member States, the Commission and the EU sectorial stakeholders and interested parties. See section D3.

(D.2) Previous evaluations and other reports

No studies have been carried out so far with respect to the implementation or monitoring of the Machinery Directive.

(D.3) Evidence from assessing the implementation and application of legislation (complaints, infringement procedures)

The mechanism of monitoring the implementation of the Directive is ensured through cooperation between Member States national authorities, including market surveillance authorities, the Commission services and stakeholders through regular meetings such as the Machinery Committee, the Working Group, the Administrative Cooperation Group of market surveillance authorities and Notified Bodies Group meetings.

The issues related to the implementation of the Directive have been widely discussed in past years in the Machinery Working Group with the representatives of the Member States, industry stakeholders, European Standardization Organizations, conformity assessment bodies, organizations representing

workers and consumers. Throughout this time, a series of guidance documents have been published, complementing the 2nd edition of the "Guide to application of the Machinery Directive 2006/42/EC"⁵, available on the Machinery webpages on EUROPA: http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery/index_en.htm and currently submitted to an update exercise.

A number of safeguard clauses have been addressed under Article 11 of the Directive, where certain non-conformity products have been withdrawn from the market. Objections against harmonised standards are further indicators to be analysed.

The experience with the Machinery Directive has appeared positive, being confirmed by the reasonably limited and stable volume of problems arising in the context of complaints and infringement, taking into consideration the wide range of industrial and consumer products within its scope. Nevertheless, it appears that the application of the Directive is not always easy for manufacturers, especially for SMEs, according to recent surveys on EU legislation.

(D.4) Consultation

The approach and methodology in the evaluation study will include both public and targeted consultations. On one hand, a public consultation open to general public will be carried out through on-line consultation tools (EUSurvey); on the other hand, more specific consultations will take place by means of interviews and surveys with the sectorial stakeholders concerned. They are mainly the competent authorities in Member States responsible for the implementation of the Directive, including market surveillance authorities; representatives from European industry associations and SMEs; representatives of European workers and consumer associations; representatives of the European Standardisation Organisations (CEN - European Committee for Standardisation and CENELEC - European Committee for Electrotechnical Standardization); the New Approach CEN-CENELEC consultants; and the European Coordination of Notified Bodies designated to carry out conformity assessment tasks under the Machinery Directive.

The different tools that will be used in the evaluation to reach stakeholders are:

- Targeted consultations and interviews with the representatives of the stakeholders mentioned above;
- 12-week internet based open public consultation, to be carried out in order to ensure transparency and accountability and to give any interested party the possibility to contribute. The questionnaire will be published on the 'Your Voice in Europe' website:

http://ec.europa.eu/yourvoice/consultations/index_en.htm

- Other tools might be proposed where deemed appropriate, in the course of the evaluation study, depending on the level of information needed. More details about the consultation strategy will be made available on the webpage dedicated to this evaluation on the DG GROW website on EUROPA, from http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery/index_en.htm.

This Roadmap will be available at the following EUROPA website: http://ec.europa.eu/smart-regulation/roadmaps/index_en.htm and will be open for feedback.

⁵ <http://ec.europa.eu/DocsRoom/documents/9483>