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ANNEX I

Essential health and safety requirements relating to the the design and construction of machinery

GENERAL PRINCIPLES

2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY

[[F1]Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics and machinery for pesticide application must meet all the essential health and safety requirements set out in this chapter (see General Principles, point 4).**]**

Textual Amendments

F1 Substituted by Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application (Text with EEA relevance).

2.1. FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS

2.1.1. General

Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

The following requirements must be observed:

(a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible disposable parts must be used;

(b) all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must:

- be smooth and have neither ridges nor crevices which could harbour organic materials. The same applies to their joinings,
- be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum,
- be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces must have curves with a radius sufficient to allow thorough cleaning;

(c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery (if possible, in a ‘cleaning’ position);

(d) machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned;

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(e) machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that continuing compliance with this requirement can be checked.

2.1.2. Instructions

The instructions for foodstuffs machinery and machinery for use with cosmetics or pharmaceutical products must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.

2.2. PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY

2.2.1. General

Portable hand-held and/or hand-guided machinery must:

— depending on the type of machinery, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery under the intended operating conditions,

— except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles,

— present no risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible,

— permit, where necessary, visual observation of the danger zone and of the action of the tool with the material being processed.

The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.

2.2.1.1. Instructions

The instructions must give the following information concerning vibrations transmitted by portable hand-held and hand-guided machinery:

— the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s^2. Where this value does not exceed 2,5 m/s^2, this must be mentioned,

— the uncertainty of measurement.

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

If harmonised standards are not applied, the vibration data must be measured using the most appropriate measurement code for the machinery.

The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, must be specified.

2.2.2. Portable fixing and other impact machinery

2.2.2.1. General

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Portable fixing and other impact machinery must be designed and constructed in such a way that:

— energy is transmitted to the impacted element by the intermediary component that does not leave the device,

— an enabling device prevents impact unless the machinery is positioned correctly with adequate pressure on the base material,

— involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device must be required to trigger an impact,

— accidental triggering is prevented during handling or in case of shock,

— loading and unloading operations can be carried out easily and safely.

Where necessary, it must be possible to fit the device with splinter guard(s) and the appropriate guard(s) must be provided by the manufacturer of the machinery.

2.2.2.2. Instructions

The instructions must give the necessary information regarding:

— the accessories and interchangeable equipment that can be used with the machinery,

— the suitable fixing or other impacted elements to be used with the machinery,

— where appropriate, the suitable cartridges to be used.

2.3. MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS

Machinery for working wood and materials with similar physical characteristics must comply with the following requirements:

(a) the machinery must be designed, constructed or equipped in such a way that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter must be sufficiently stable during the work and must not impede the movement of the piece;

(b) where the machinery is likely to be used in conditions involving the risk of ejection of workpieces or parts of them, it must be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;

(c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;

(d) where the tool is incorporated into a non-fully automated machine, the latter must be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.

[F2 2.4. MACHINERY FOR PESTICIDE APPLICATION

2.4.1. Definition

‘Machinery for pesticide application’ means machinery specifically intended for the application of plant protection products within the meaning of Article 2(1) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market[1].

2.4.2. General

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The manufacturer of machinery for pesticide application or his authorised representative must ensure that an assessment is carried out of the risks of unintended exposure of the environment to pesticides, in accordance with the process of risk assessment and risk reduction referred to in the General Principles, point 1.

Machinery for pesticide application must be designed and constructed taking into account the results of the risk assessment referred to in the first paragraph so that the machinery can be operated, adjusted and maintained without unintended exposure of the environment to pesticides.

Leakage must be prevented at all times.

2.4.3. Controls and monitoring

It must be possible to easily and accurately control, monitor and immediately stop the pesticide application from the operating positions.

2.4.4. Filling and emptying

The machinery must be designed and constructed to facilitate precise filling with the necessary quantity of pesticide and to ensure easy and complete emptying, while preventing spillage of pesticide and avoiding the contamination of the water source during such operations.

2.4.5. Application of pesticides

2.4.5.1. Application rate

The machinery must be fitted with means of adjusting the application rate easily, accurately and reliably.

2.4.5.2. Distribution, deposition and drift of pesticide

The machinery must be designed and constructed to ensure that pesticide is deposited on target areas, to minimise losses to other areas and to prevent drift of pesticide to the environment. Where appropriate, an even distribution and homogeneous deposition must be ensured.

2.4.5.3. Tests

In order to verify that the relevant parts of the machinery comply with the requirements set out in sections 2.4.5.1 and 2.4.5.2 the manufacturer or his authorised representative must, for each type of machinery concerned, perform appropriate tests, or have such tests performed.

2.4.5.4. Losses during stoppage

The machinery must be designed and constructed to prevent losses while the pesticide application function is stopped.

2.4.6. Maintenance

2.4.6.1. Cleaning

The machinery must be designed and constructed to allow its easy and thorough cleaning without contamination of the environment.

2.4.6.2. Servicing

The machinery must be designed and constructed to facilitate the changing of worn parts without contamination of the environment.

2.4.7. Inspections

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It must be possible to easily connect the necessary measuring instruments to the machinery to check the correct functioning of the machinery.

2.4.8. Marking of nozzles, strainers and filters

Nozzles, strainers and filters must be marked so that their type and size can be clearly identified.

2.4.9. Indication of pesticide in use

Where appropriate, the machinery must be fitted with a specific mounting on which the operator can place the name of the pesticide in use.

2.4.10. Instructions

The instructions must provide the following information:

(a) precautions to be taken during mixing, loading, application, emptying, cleaning, servicing and transport operations in order to avoid contamination of the environment;

(b) detailed conditions of use for the different operating environments envisaged, including the corresponding preparation and adjustments required to ensure the deposition of pesticide on target areas while minimising losses to other areas, to prevent drift to the environment and, where appropriate, to ensure an even distribution and homogeneous deposition of pesticide;

(c) the range of types and sizes of nozzles, strainers and filters that can be used with the machinery;

(d) the frequency of checks and the criteria and method for the replacement of parts subject to wear that affect the correct functioning of the machinery, such as nozzles, strainers and filters;

(e) specification of calibration, daily maintenance, winter preparation and other checks necessary to ensure the correct functioning of the machinery;

(f) types of pesticides that may cause incorrect functioning of the machinery;

(g) an indication that the operator should keep updated the name of the pesticide in use on the specific mounting referred to in section 2.4.9;

(h) the connexion and use of any special equipment or accessories, and the necessary precautions to be taken;

(i) an indication that the machinery may be subject to national requirements for regular inspection by designated bodies, as provided for in Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides[(2)];

(j) the features of the machinery which must be inspected to ensure its correct functioning;

(k) instructions for connecting the necessary measuring instruments.**]**

Textual Amendments

F2 Inserted by Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application (Text with EEA relevance).

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(1) **[**[F2]OJ L 309, 24.11.2009, p. 1.**]**

(2) **[**[F2]OJ L 309, 24.11.2009, p. 71.**]**

Textual Amendments

F2 Inserted by Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application (Text with EEA relevance).