

MD ADCO.2014.13_01_Final

Machinery ADCO WG on Market Surveillance

Good Practice Guide on Market Surveillance Interventions – Machinery Part 1: Guidance

Part 1: Guidance

STATUS OF THIS GUIDANCE

This document is a "Model for Market Surveillance Intervention" in relation to industrial and professional products within the scope of the Machinery Directive, which includes machinery, partially completed machinery, interchangeable equipment, lifting accessories, chains, ropes and webbing, removable transmission devices, as well as assemblies of machinery. It has been agreed by the Machinery ADCO to provide guidance to market surveillance authorities.

- **It is not intended that market surveillance authorities adopt this approach for products intended for consumer use and in scope of the General Product Safety Directive¹.**
- **This Guide not legally binding on any member state or national administration.**
- **The Guide is not directly applicable to interventions with machinery at the border, where Customs may lead.**
- **The Guide does not cover sanctions, since they are subject to national legislation and are not harmonised**

This guide reflects the Machinery ADCO's understanding of the legal position with respect to European market surveillance legislation as at May 2014.

As a "live" document it will be subject to revision, particularly when EC Regulation 765/2008 is replaced.

BACKGROUND NOTE

At the October 2011 Machinery ADCO Group meeting in Lisbon, a working group (WG) was set up in order to develop a good practice guide for market surveillance intervention mainly in relation to industrial or professional products. The group consisted of market surveillance authorities (MSAs) and Ministry officials from Denmark (DK), France (FR), United Kingdom (UK), The Netherlands (NL), Germany (DE) and Norway (NO).²

The publication of EC Regulation 765/2008 and Decision 768/2008 and the need for machinery specific consistent practical guidance for all ADCO members prompted this work which has been presented to the main ADCO meeting several times. Account has also been taken of similar work undertaken in other ADCO Groups, particularly the Pressure ADCO, with whom the Machinery ADCO WG have shared drafts.

It is proposed that this May 2014 document will be presented as a key source to the forthcoming Horizontal ADCO Chairs Working Group on Market Surveillance Guidance.

¹ The general safety obligation of Article 3.1 of GPSD (2001/95/EC) does not apply because Annex 1 of the Machinery Directive 2006/42/EC covers all risks. Only measures which are "more specific" in the GPSD can be used by MSA for consumer goods, otherwise the measures of EC Regulation 765/2008 are applicable.

(http://ec.europa.eu/consumers/safety/prod_legis/docs/20100324_guidance_gspd_reg_en.pdf)

² A "Good Practice Guide on Market Surveillance Intervention – Machinery" was agreed at the ADCO Group meeting in October 2012, (ADCO.MD.2012.Rev.1). This May 2014 version is an update of the 2012 Good Practice Guide.

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[See Part 2 for the Example Letters and Machinery Directive Safeguard Form](#)

Part 2: Annex 1: Guidance on the content of letters supporting key flowchart outcomes, and Example Letters for Market Surveillance Interventions

Part 2: Annex 2: Example letters for sending to Importers/distributors

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0 Introduction

Market surveillance should be seen in the context of solving issues at a European level, following the principle of cooperation by all market surveillance authorities, between member states (MS) and within MS. To promote this, MS should participate in Administration Cooperation (ADCO) groups and seek to use specific tools to exchange relevant information (e.g. via ICSMS, RAPEX, CIRCABC). In an environment of a globalised market it is very important to work effectively and efficiently together in the field of market surveillance, particularly on the basis of an adequate exchange of experiences and through cross border projects, where possible coordinated by the Machinery ADCO, and supported by the Commission.

For many years the Machinery Directive (MD ADCO) group has been meeting to discuss and coordinate market surveillance activity in the machinery sector. The single market obligations placed on MS by the Machinery Directive, and delivered by market surveillance authorities (MSAs), were reinforced in 2010 by EC Regulation 765/2008 and Decision No 768/2008/EC.

Accordingly, in 2011 the Machinery ADCO decided to capture the long established principles and ways of working in the form of a model document to be made available to all MS and their MSAs. The aim was to promote consistency and good practice within the legal system outlined by the Machinery Directive and EC Regulation 765/2008, acknowledging that constraints may arise from national policy and law.

A Working Group (WG) was established with representatives from six MSAs to take this work forward, consulting at intervals with the whole ADCO by presenting and discussing draft papers at the main ADCO meetings. This document is the conclusion of the work to date (May 2014).

1. Overriding principles

In undertaking this work the Machinery ADCO and WG wish to affirm a number of long standing principles that have been observed by many undertaking market surveillance in the machinery sector:

- that of the “Initiating Authority principle”, whereby the MSA who finds the problem with a product and is best placed to describe it, attempts to resolve it in the voluntary phase on a European market-wide basis,
- that MSAs in different MS cooperate³ with each other for the effective delivery of market surveillance, where appropriate coordinating action, whether on a case by case basis, or through the ADCO with specific projects,
- that, subject to national policies and observing the proportionality principle⁴, action taken is based not just on risk, but also on compliance, which may be described by one or more harmonised machinery standards, to ensure the single market is not undermined, and,
- whilst in the main seeking a voluntary approach to compliance, where required (e.g. Safeguard action⁵) or appropriate (e.g. through enforcement), not hesitating from taking mandatory action to resolve the issue.

³ Article 24 of EC Regulation 765/2008

⁴ Article 18 of EC Regulation 765/2008

⁵ Article 11 of 2006/42/EC

2. Purpose and content

This “model” Guide to Good Practice on Market Surveillance Intervention with Machinery is only intended as a guide for dealing with industrial/professional machinery, and cannot in any way over-ride national legislative provisions which must take precedence in the event of any conflict. The Guide does not cover sanctions, since they are subject to national legislation and are not harmonised.

Furthermore, the Guide is not applicable to interventions with machinery at the border, where Customs may lead⁶.

Due to various national circumstances, it may not be possible for all MS to follow the procedure completely at the present time. Members of the ADCO are advised to identify any barriers to following the model due to legal constraints in their country.

Legislation and practice doesn't stand still and it is acknowledged that this document will need to be revised in due course to remain a useful up-to-date resource for all undertaking market surveillance in the machinery sector.

3. A good practice procedure

Contained within this document are practical examples to help authorities improve or devise systems for market surveillance which the WG believes both align with the legal responsibilities and powers of MSAs and fulfil the above broad existing principles.

In addition to detailed flowcharts to aid processing and decision making (in the Annexes), suggested letter texts for communication with duty holders (see part 2), there are also checklists to support the analysis of compliance and communication of results (see end of Annex 1). The procedures outlined support the functioning of the internal market as described in the reference documents in Annex 4.

⁶ Market surveillance practice at border points varies between MS, also until goods have been cleared by Customs authorities they are not technically available for “placing on the market”, at which point they must be complaint.

4. Principles of market surveillance

4.1 Market surveillance authority – initiating authority approach

The market surveillance authority who has found the non-compliant product on their market ('MSA-1' / 'Initiating authority') should normally handle the case and try to solve the problem on a European level.

The principle is that:

- Successful market surveillance depends on cooperation between the various market surveillance authorities (MSA).
- The MSA who has found the non-compliant product in their market (MSA1) is required to take action to remedy the situation for their jurisdiction.
- The MSA1 should strive to solve the problems at the European level in dialogue with the manufacturer who always retains the legal responsibility to rectify the matter
- ICSMS, RAPEX and the ADCO group should be used for reference, information sharing and awareness raising.
- MSA1 should make early contact with MSA2 to alert them of the issue (e.g. by copying initial correspondence), and where necessary setting up contact points for the further exchange of information.
- MSA2 should assist MSA1 in the collection of information if it is required.
- If after pursuing the case MSA1 following the approach above is still not satisfied that the European supply aspect has been adequately addressed by the manufacturer/EU importer, it should formally raise the matter with MSA2 and other MSAs, using ICSMS, and where necessary through the ADCO.
- Safeguard action (see Annex 2) may need to be taken by MSA1 if the matter is not solved voluntarily.
- If the Commission upholds the "Safeguard" action MSA2 should then resolve the matter with its manufacturer/importer in respect of all supply other than in MSA1's territory, other MSAs acting as necessary and appropriately for any distributors (and importers) within their own territory.

4.2 The manufacturer or his authorised representative

It is solely the manufacturer⁷, or his authorised representative, who can be held responsible that a CE marked machine complies with the essential health and safety requirements of the Machinery Directive and has undergone the relevant conformity assessment procedure.

Therefore, a decision that a machine is not in compliance with the MD should normally not be taken before the manufacturer or his authorised representative has had the opportunity to present his technical file, and give their comments. If rapid intervention is required to avoid serious risk, the manufacturer should be heard as soon as possible afterwards⁸, and the decision re-evaluated.

⁷ The definition of "manufacturer" is defined in Article 2 (i) and includes the first importer of a non-CE marked machine into the EU.

⁸ Article 21 of EC Regulation 765/2008

4.3 Proportionality

Proportionality of action is enshrined in both the single European market obligations⁹ and in the policies of many MS and MSAs, and whilst compliance is not solely governed by risk (there may be formal non-compliance with markings and documents), risk assessment is a key tool in relation to market surveillance¹⁰. Distinction is made here between the manufacturer's (responsible person's) duty to assess risk as part of compliance with the Essential Health & Safety Requirements¹¹ (EHSRs), which must be comprehensive and very detailed, and that of a MSA assessing product conformity.

An important aspect of acting in a proportional manner is giving manufacturers the opportunity to put matters right (the voluntary phase), and even where formal mandatory action is required, only taking actions necessary to meet the objective.

4.4 Cooperation/coordination and role of ICSMS

The efficient exchange of information may facilitate cooperation which is required by Article 24 of EC Regulation 765/2008. Article 23 of the same regulation foresees the provision and maintenance of a general archiving and exchange of information system by the Commission, using electronic means, on issues relating to market surveillance activities, programmes and related information on non-compliance with Community harmonisation legislation.

The confidential secure internet based ICSMS database was adopted in 2013 by the Commission for this purpose and already enables the archiving of information, and through individual MSA access, the sharing of summary details on market surveillance interventions (e.g. by the simple exchange of the Product Information Number (PI No.), one MSA now can easily inform another MSA without needing to send a separate bundle of information e.g. at Step 4b, Annex 1. The other MSA can through ICSMS securely seek all of the information uploaded, making comment as necessary on any particular record (step 8, Annex 1), and fully identify the authority currently processing the matter.) This all helps facilitate cooperation and coordination of market surveillance activity.

In particular, within the system for market surveillance described by this model, cooperation may be assisted by ICSMS through "baton passing". Technically this is the transfer of ownership of a record on ICSMS to another MSA, and may come into play towards the end of the voluntary phase as described later, as well as during the mandatory phase, **if and exceptionally when, it becomes necessary** for MSA2 (or another) to take on the management of a particular market surveillance case.

However, the **ADCO asks that "baton passing" is only done by agreement** between the parties so that it is expected and successful (if not the attempt may fail and not foster good cooperation or any successful coordination).

The recommended procedure is that should a MSA wish to transfer the ownership of a record on ICSMS to another MSA ("pass the baton"), it should first make contact with that MSA:

- to confirm that they are the correct MSA in that MS for the activity, and
- that the "receiving" MSA is prepared to take the matter on.

To this end ICSMS provides for the search and identification of relevant MSAs in other MS, and the provision of their basic contact details (e:mail etc.).

⁹ Article 18 of EC Regulation 765/2008

¹⁰ Articles 19 & 20 of EC Regulation 765/2008

¹¹ See the General Principles in the introductory remarks of Annex I of 2006/42/EC

The Machinery ADCO requests that “Baton passing” should not be undertaken without such prior liaison, as this goes against the fundamental principles outlined in section 2: that of the ‘Initiator’ Principle, and of Cooperation/Coordination.

5 Voluntary phase

EC Regulation No 765/2008 and Decision No 768/2008 specify that the MSA should request the economic operator to solve the problem voluntarily. Since it is only the manufacturer that is responsible for full compliance with the Machinery Directive, the manufacturer should be requested to solve the problem within a reasonable time limit. The MSA should be in dialog with the manufacturer in this phase, called the ‘voluntary phase’. The manufacturer should be requested to solve the problem on a European level, and not only in the MS where the violation was discovered.

Since it is only the manufacturer that is responsible for full compliance with the Machinery Directive, the manufacturer should be requested to solve the problem within a reasonable time limit. The MSA should be in dialog with the manufacturer in this phase, called the ‘voluntary phase’. The manufacturer should be requested to solve the problem on a European level, and not only in the MS where the violation was discovered.

In the voluntary phase the MSA makes a formal inquiry to the person who has affixed the CE marking (by definition this is the manufacturer) even if located in another MS or 3rd country. The MSA explains which shortcomings they have found, identifying the specific issues, preferably by reference to particular essential health and safety requirements (EHSRs), and may include reference to the state of the art as described by relevant harmonised standards. They ask the manufacturer to present the relevant part of the technical file, and they ask for the manufacturer’s comments. For instance the machine may have been changed by another after being placed on the market, in which case the manufacturer cannot be held responsible for those later changes.

The MSA should also indicate which measures they expect the manufacturer to take (corrections, sales stop, withdrawal, recall). The MSA may ask in writing the manufacturer to modify the machine in order to bring it into compliance with the Machinery Directive, but the MSA should never request a specific method for doing so. If possible, the manufacturer should be given the opportunity to decide whether he wants to modify the machine, or stop the sale and withdraw and recall it if there is a health and safety risk.

It is noted that the Machinery Directive does not give powers of recall. This is a requirement of EC Regulation No 765/2008 that has to be implemented in national legislation (for consumer products the General Product Safety Directive gives some more specific powers of recall that can be used).

When the facts are available, or the reply dead line has expired, the MSA makes a ‘Conclusion on the inquiry’, stating the shortcomings, requesting the manufacturer solves the problem voluntarily within a given time limit.

A copy of the inquiry letter, or legal Notice (which will depend on national legislation) and the conclusion on the inquiry are sent to the MSA in the MS of the manufacturer (MSA-2) for information. Depending on the case, MSA-2 may contact the manufacturer (preferably by writing, copying in MSA-1) to make sure that he takes the necessary measures.

MSA-2 should not intervene in a way where the manufacturer could think that he doesn't need to answer the MSA-1, unless it has been agreed that MSA-2 takes over the case (which may include taking the matter on in ICSMS by accepting the 'baton').

A copy of the conclusion on the inquiry is also sent to the importer, distributor and Notified Body (if applicable), in order to make them aware of the MSA's opinion.

When the MSA is making an evaluation of compliance against the MD, initial information about the case must be uploaded to ICSMS, and afterwards the information must be updated as the case progresses. This is important as it can prevent another member state wasting resource duplicating work. A RAPEX¹² notification must be made where a serious risk has been identified and confirmed.

Example letters supporting this phase are provided in Annex 1 of part 2 of this guide.

6 Mandatory phase^{13 14}

If the manufacturer doesn't solve the problem within the time limit, MSA-1 must make a decision and order the manufacturer to rectify the non-conformity, citing the breach of law in MSA-1's country, also asking in the accompanying letter that the breach of the Machinery Directive is addressed in all EU/EFTA member states.

It should be noted that MSA-1 can only take legal actions against a manufacturer in another MS, for an offence committed in its own country. If the manufacturer continues to supply to other member states, the MSA situated in that Member State must take action to stop this continued breach after the Commission has given their opinion of the case.

The decision taken by MSA-1 must consider Article 11(1) of the Machinery Directive, the 'Safeguard clause'. If restrictive action has been taken and the machine has been manufactured or sold in another MS, the Safeguard action must be notified to the Commission and other MS in accordance with Article 11. See Annex 2 for further guidance.

7 Notified Bodies

If a Notified Body has been involved in the conformity assessment process for Annex IV equipment, it should be heard before making a conclusion on the inquiry, or a decision.

Certificates from Notified Bodies do not give a presumption of conformity. If the MSA finds that a certificate has been wrongly issued, they can proceed with the case against the manufacturer as described. However, it may be used as mitigation in any legal proceedings taken against the manufacturer and is likely to carry considerable weight.

¹² Community Rapid Information System (RAPEX).

¹³ When dealing with the mandatory phase, we take legal actions and we are dealing with compulsory restrictive measures. The mandatory phase starts when a MSA decide to use compulsory measures. We must be aware that eventually the European Court can judge our actions against a product justified/not justified. See Annex 1, point 6.

¹⁴ See Annex 1 Flow chart for market surveillance intervention (Machinery Directive) point 6. "Legal action taken by MSA-1 is only applicable for machinery made available on MSA-1's market."

A copy of the conclusion letter and/or a decision against the manufacturer should be sent to the Notified Body, with a request to withdraw the certificate, and a copy should be sent to the notifying authority for the Notified Body.

If certificates for non-annex IV products have been issued to the manufacturer the Notified Body should be informed that this is not a certificate under Article 12 and it must be made clear that the Notified Body is acting only as a consultant and not as a Notified Body¹⁵. It should be underlined that Notified Bodies may only use their name and number in relation to conformity assessment activities carried out under the specific conformity assessment module that foresees for a Notified Body to act.

Under Article 5(d) of the Machinery Directive the relevant conformity assessment procedure must be undertaken before the machinery is placed on the market/put into service. Accordingly Type-examination cannot be undertaken retrospectively after the product has been placed on the market/put into service. Any EC type-examination certificate issued will only be valid for products post-dating its publication.

8 Importers and distributors

The Machinery Directive (2006/42/EC) does not contain obligations for importers and distributors, except obligations concerning declarations and instructions (the person importing machinery and partly completed machinery into a language area must translate into the official language of that area). However, in some cases the importer may take on or be responsible for the product as if the manufacturer, and so be subject to the same obligations as the manufacturer. Annex 3 contains further specific guidance on interventions with importers and distributors, including when an importer is “deemed to be the manufacturer”. Supporting example letters that may be used for market surveillance interventions with importers and distributors are provided in part 2 (see examples A-D).

Distributors also have the following obligations concerning sale of chains, ropes and webbings in cut of lengths (according to the Commission Guide to the Application of the Machinery Directive)¹⁶:

“However distributors of chains, ropes and webbing must ensure that the relevant EC Declaration of Conformity, the reference of the certificate setting out the characteristics of the chain, rope or webbing and the manufacturer's instructions are supplied with the cut length of chain, rope or webbing to manufacturers of lifting machinery or lifting accessories or to users”.

This obligation does not appear directly from the Machinery Directive, so it must be supported by national regulations.

When the Machinery Directive is brought into line with EC Decision 768/2008, there may be other duties imposed on importers and distributors.

¹⁵ http://ec.europa.eu/enterprise/policies/single-market-goods/files/accreditation/doc-2012/certif-2012-06-rev1-certif-not-required_en.pdf

¹⁶ § 44 of http://ec.europa.eu/enterprise/sectors/mechanical/files/machinery/guide-appl-2006-42-ec-2nd-201006_en.pdf

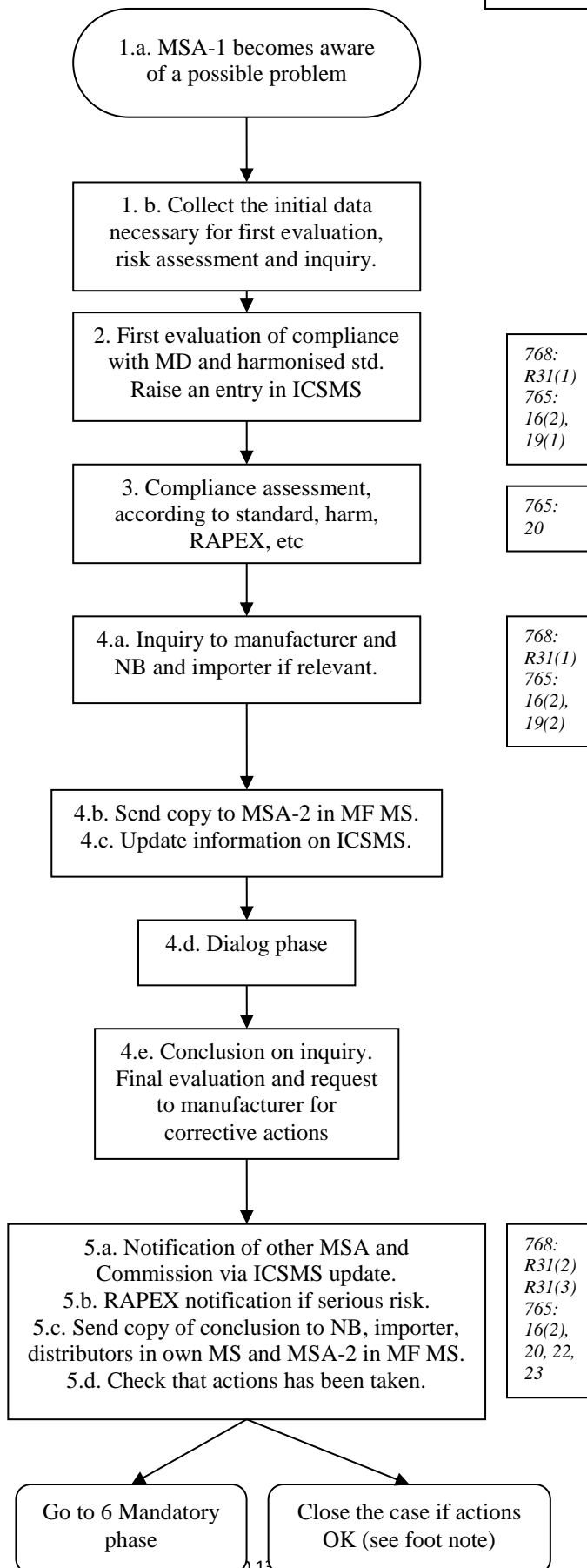
EC Regulation 765/2008 allows MSAs to take action against economic operators. 'Economic operator' is defined as the manufacturer, the authorised representative, importer and distributor. Intervention options under 765/2008 are not subdivided according to the type of economic operator. MSA's interventions should target the *relevant* economic operators in relation to the obligations they have in a given case. Interventions should be proportionate, i.e. a sales ban should not be issued against a distributor if it is possible for the manufacturer to correct the problem.

Actions against importers and distributors can be taken alongside the case against the manufacturer, or afterwards, depending on the case and the problem.

Besides the requirements of the Machinery Directive, it depends on national legislation what an importer and a distributor can be required to do.

Annex 1: Flow chart for market surveillance intervention (Machinery Directive)

The voluntary phase CE marked machinery



Remarks

KEY: MS: Member state
MSA: Market surveillance Authority
MF: Manufacturer or his authorised rep.

1.a. Based on reactive or proactive market surveillance.

1.b. May be collected by phone, internet, correspondence, visits etc.

2. If machine is compliant: Stop. Information should be uploaded to ICSMS.

3. Compliance assessment to be carried out according to standard, harm, RAPEX etc. If risk is low, case may be closed, depending on prioritisation. If risk is serious, normally step 4 and 5 should be followed, but it is possible to jump to step 6 if necessary.

4.a. The MF is heard about the nonconformities. He is asked to send relevant parts of technical file and his comments. He is asked to take necessary measures if he agrees. Measures to be indicated in the inquiry letter. Timeframe for reply is given. Importers and distributors can be heard depending on situation and national law

4.b. Copy to MSA-2 of inquiry letter is normally for information only. However MSA-2 in MF MS may contact MF to make sure that he cooperates with MSA-1. It may be necessary to request MSA-2 to assist with the case, or it may exceptionally be agreed that the case is passed on (by 'passing the baton' in ICSMS).

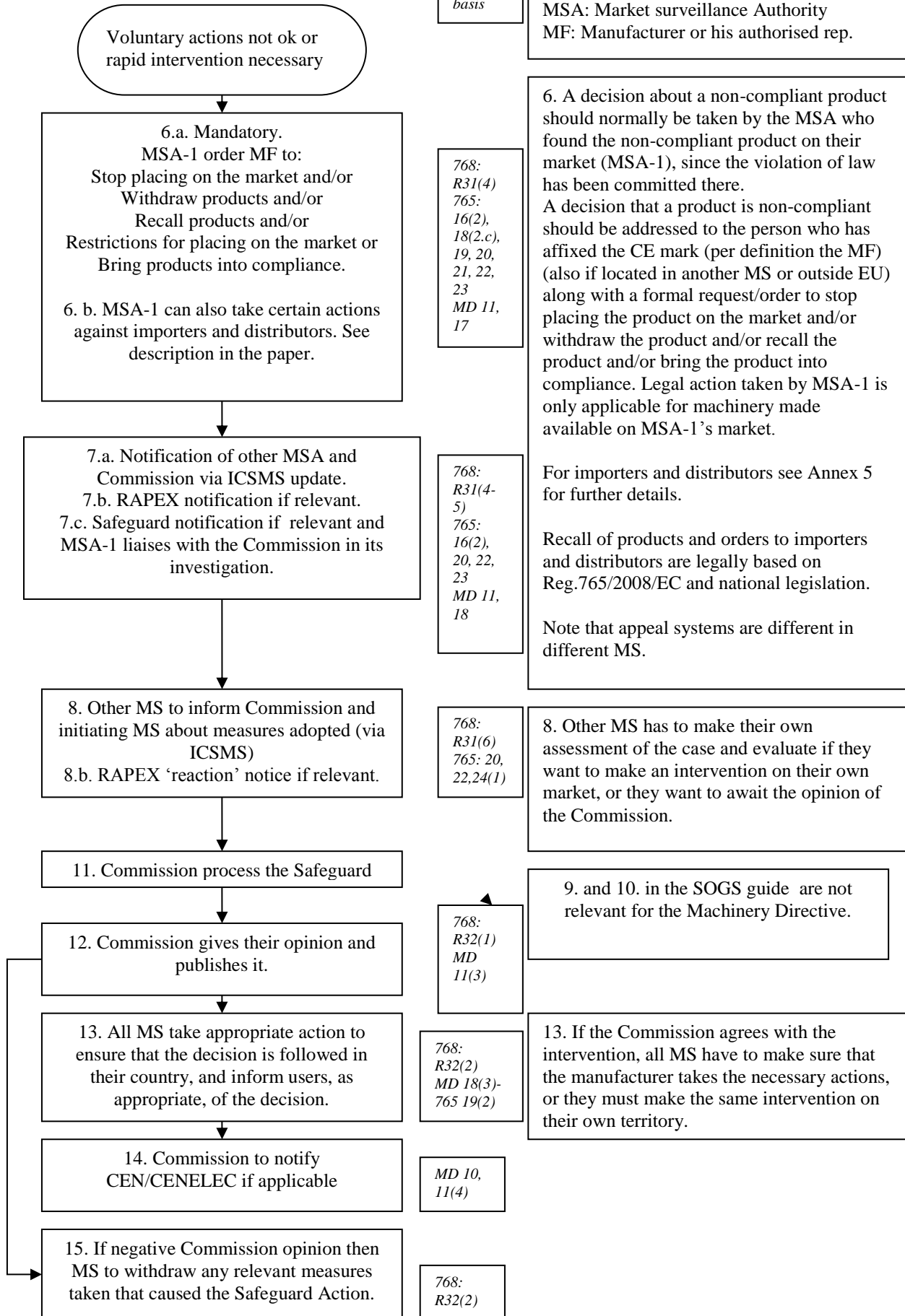
4.d. Dialog may be by correspondence, phone and/or visits.

4.e. If MSA-1 still evaluates that there is a non-compliance, this is concluded in a letter to MF, and he is requested to take the voluntary corrective actions specified in the letter. The MF should be requested to take action in all EU MS. Time limit is given for feedback and action.

5. Other MSA and Commission are informed via update on ICSMS, which allows them to monitor actions taken in their MS. It is only possible for initiating MSA to intervene against violations in their territory. However, initiating MSA should inform other MS if they become aware that actions are not voluntary taken in other MS.

Annex 1: Flow chart for market surveillance intervention (Machinery Directive)

Mandatory phase CE marked machinery



Annex 1: Flow chart for market surveillance intervention (Machinery Directive)

Notes to the flow chart:

Checklists could be drafted to address various points, e.g. listing typical data to be collected in relation to point 1 b).

In Part 2 of this Guide examples of letters (as used by the Danish Working Environment Authority) and additional guidance is given for the content of the following letters:

- Inquiry to manufacturer (flowchart point. 4.a) including
 - Annex I to the inquiry, listing the shortcomings in a table
- Inquiry to Notified Body (flowchart point. 4.a)
- Conclusion on inquiry (flowchart point. 4.e.)
- Information for foreign market surveillance authority (flowchart point. 4.b.)
- Decision against the manufacturer (flowchart point. 6).

Guidance concerning closure of a case depending on national legislation:

- Normally a written letter from the manufacturer, declaring which corrective actions he has taken, is considered to be adequate to close the case. Depending on circumstances it may be necessary to verify by inspection that the corrective actions have been carried out.
- If the manufacturer informs the MSA that he will change the machine before future deliveries, the case can be closed (in this respect). The MSA should not make any approval of the new design. If the modified machine should turn up to be non-compliant, this is considered a new case.
- It should be investigated if there are similar products from other manufacturers on the market, where market intervention are also necessary.

NB: In some MS, a non-compliant case cannot be closed without a sanction.

Application of the Safeguard Procedure

This Annex gives further guidance to points 6-15 of the flowchart for Market Surveillance interventions at Annex 1 on *the application of the Safeguard clause*.

The *Safeguard clause* is stipulated in article 11 of the Machinery Directive 2006/42/EC ('MD'). The safeguard clause is triggered when a Member State ('MS') takes *legally binding measures* restricting the free movement or putting into service (first use) of CE marked machinery on the EU market. It also regulates the formal *notification* by a MS to the EU Commission and other MS about measures taken, and it regulates the procedures for decision by the Commission on justification of the enforcement action¹⁷.

The second part of this Annex contains guidance from the Machinery ADCO group. The third section quotes from the relevant part of the Commission guide on the application of the Machinery Directive (2nd Edition).

Annex 2.1 is a flow chart giving an overview of the Safeguard procedure.

Annex 3 in Part 2 of this Guide contains an example of the notification form to be used for the Safeguard procedure which was approved by the MD ADCO group and the Commission at the October 2010 meeting.

This Annex does NOT give guidance on *when to make interventions* that are covered by the Safeguard clause. Also it does NOT contain guidance concerning the organisation of the market surveillance authority (MSA), and who should be given the power to approve intervention actions covered by the Safeguard clause, ie whether market surveillance inspectors should have the power themselves, or if an intervention should be approved by a MSA manager, or higher level.

¹⁷ The proposed Market Surveillance Regulation currently under negotiation may amend remove the provisions of the Safeguard procedure described by this annex and Article 11 of 2006/42/EC.

Guidance from the Machinery ADCO group

The revised Blue Guide published by the Commission in 2014, point 7.4.2.1 says:

“The application of the safeguard clause requires that the competent national authority decides to restrict or forbid the placing on the market and, possibly, the putting into service of the product, or has it withdrawn from the market. The contents of the decision should relate to all products belonging to the same batch or series. It must also have binding legal effect: it is followed by sanctions, if not respected, and can be subject to an appeals procedure. Court decisions, which restrict the free movement of CE marked product within the scope of the relevant Union harmonisation legislation, do not invoke the safeguard clause. However, where administrative proceedings initiated by the surveillance authority must be, according to the national law, confirmed by a court, such court decisions are not excluded from the safeguard clause procedure.”

Based on the above, it is concluded, that requests from MSA for corrective actions by the manufacturer in the ‘voluntary phase’ are not subject to the Safeguard clause. However, where there is a potential risk, it may be appropriate for an informal exchange of information to be made (e.g. by reference to the ICSMS PI No. and/or at the ADCO meeting with the Commission and the MS).

It also follows from Article 11 that machinery which was not placed on the market and is already in service, the use of which may be regulated or even prohibited by National legislation implementing the Use of Work Equipment Directive (2009/104/EC), cannot be the subject of the Safeguard clause. However, under EC Regulation 765/2008 the manufacturer can be requested to recall machinery which has already been put into service by the end user. It should be noted that measures to withdraw or prohibit from sale, or restrict the free movement of, other products of the same type may be subject to the Safeguard clause.

Also an intervention against a company who has manufactured a machine for their own use doesn’t have to be notified to the Commission and other MS, since the intervention measure is only affecting one MS, provided the machinery is not intended for placing on the market.

The safeguard clause doesn’t regulate interventions against partly completed machinery.

Letters with intervention decisions (measures) covered by the Safeguard clause may contain a reference to the Machinery Directive, article 11, for instance with the following text:

Annex 2: Safeguard Procedure

“Please note that [authority name] will notify the EU Commission and other member states about this decision in accordance with the Safeguard procedure in the Machinery Directive 2006/42/EC, article 11 point 2 [and regulation 765/2008 of the European Parliament and of the Council, article 20 (*if relevant*)”.

When an intervention decision covered by the Safeguard clause has been made, the Commission and other MS must be notified about the intervention decision. As explained in the Commission Guide, notifications have to be sent to the Commission and the other MS via the permanent representation in Brussels. Unless otherwise organised in the member state, the notification could be prepared by the inspector who has made the intervention decision, but it is recommended that the actual notification (ie sending the notification formally) is carried out by a single coordinating person from each MS (e.g. the member of the MD ADCO group or relevant Ministry). In member states with several MSAs, each MSA could have their own person responsible for making the notifications. It is up to the MS to decide whether the notifications can be sent directly from the person responsible for making them, to the permanent representation in Brussels, or if it has to be sent through a certain ministry, e.g. the foreign department.

The flowchart in Annex 2.1 gives an overview of the different steps involved in a safeguard clause procedure.

Annex 2.2 contains the notification form which should be used. It is not mandatory to use this form but it is recommended by the ADCO group and the Commission for the sake of consistency regarding the relevant information required to inform the Commission and MS.

All cases leading to a Safeguard action are expected to be found in the ICSMS system and a copy of the completed Safeguard notification form should be uploaded to ICSMS as well as reference made to any related RAPEX notifications that may have been made under article 22 of Regulation 765/2008 (however RAPEX notifications have in principle nothing to do with notifications related to the use of the Safeguard clause, and are not further discussed).

Intervention decisions made by a MS are only applicable to machinery made available on that MS's market. Therefore all other MS should take action to ensure that appropriate measures are taken in their countries.

Commission guidance on the application of the safeguard clause

Article 11 Safeguard clause

1. Where a Member State ascertains that machinery covered by this Directive, bearing the CE marking, accompanied by the EC declaration of conformity and used in accordance with its intended purpose or under conditions which can reasonably be foreseen, is liable to compromise the health and safety of persons and, where appropriate, domestic animals or property, it shall take all appropriate measures to withdraw such machinery from the market, to prohibit the placing on the market and/or putting into service of such machinery or to restrict free movement thereof.

...

§122 The safeguard clause

The safeguard clause is foreseen in paragraph (10) of Article 95 of the EC Treaty (now Article 114 of the TFEU) on which the Machinery Directive is based – see §2: comments on the citations:

“The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the noneconomic reasons referred to in Article 30, provisional measures subject to a Community control procedure”.

Article 11 sets out the procedure to be followed when the market surveillance authorities of a Member State discover that the presumption of conformity conferred by the CE-marking and the EC Declaration of Conformity is not founded – see §109: comments on Article 7 (1). The Safeguard procedure set out in Article 11 applies to machinery in the broad sense, in other words, it can be applied to any of the products listed in Article 1 (1), (a) to (f). It is not applicable to partly completed machinery.

When machinery is found not to comply with the applicable health and safety requirements despite the presence of the CE-marking, the Member State should first contact the manufacturer, his authorised representative or the person responsible for placing the machinery on the market and require him to bring the product into conformity or withdraw it from the market within a timeframe determined by the market surveillance authority – see §78 to §84: comments on Article 2 (i) and (j), and §100: comments on Article 4.

If the product is brought into conformity or withdrawn from the market voluntarily, there is no need to take the restrictive measures referred to in Article 11 (1) and consequently there is no legal basis for recourse to the safeguard procedure. However,

Annex 2: Safeguard Procedure

if the machinery concerned presents a serious risk, Regulation (EC) N° 765/2008 requires the Member State concerned to inform the Commission and the other Member States of the action taken using the RAPEX system.

In all cases where corrective action is taken by the manufacturer, it is important for the Member State concerned to inform the market surveillance authorities of the other Member States so that they can ensure that the necessary corrective measures are taken throughout the EU – see §100: comments on Article 4. This information can be communicated in the framework of the Machinery ADCO Group – see §144: comments on Article 19. Article 23 of Regulation (EC) N° 765/2008 foresees the establishment of a General EU information support system for this purpose [ICSMS].

If the non-conformity subject to corrective action taken by the manufacturer results from a deficiency in the harmonised standard applied, the Member State must also take action with respect to the harmonised standard, if necessary by means of the formal objection procedure – see §119 to §121: comments on Article 10.

If voluntary measures to bring the product into conformity are not taken within the time frame determined by the market surveillance authorities and if the non-conformity is liable to endanger the health and safety of persons or, where appropriate, domestic animals or property, the safeguard procedure set out in Article 11 must be followed.

Article 11 (1) describes the measures to be taken by the national market surveillance authorities. The measures may include suspending or prohibiting the placing on the market of the machinery and/or the putting into service of the machinery, or making these operations subject to certain restrictions. The form and content of the measures is a matter for the Member State concerned, but the measures must be both sufficient to protect the health and safety of persons and proportionate to the risk involved.

According to Article 21 (3) of Regulation (EC) N° 765/2008, before such measures are taken, the interested parties must be given the opportunity to express their views unless this is not possible because of urgency. If measures are taken without the interested parties being heard, they must be given the opportunity to express their views as soon as possible.

According to Article 20 of the Regulation, in the case of machinery presenting a serious risk requiring rapid intervention, Member States may also order the recall of machinery already placed on the market, both in the supply chain and in service, in order to protect the health and safety of users.

Annex 2: Safeguard Procedure

The measure taken by the Member State according to Article 11 (1) must state the exact grounds on which it is based and be notified as soon as possible to the party concerned who shall at the same time be informed of the legal remedies available to him – see §145: comments on Article 20.

The decision taken by the Member State shall be published – see §143: comments on Article 18 (3).

Article 11 (continued)

...

2. The Member State shall immediately inform the Commission and the other Member States of any such measure, indicating the reasons for its decision and, in particular, whether the non-conformity is due to:

- a) Failure to satisfy the essential requirements referred to in Article 5(1) (a);*
- b) Incorrect application of the harmonised standards referred to in Article 7(2);*
- c) Shortcomings in the harmonised standards themselves referred to in Article 7(2).*

3. The Commission shall enter into consultation with the parties concerned without delay.

The Commission shall consider, after this consultation, whether or not the measures taken by the Member State are justified, and it shall communicate its decision to the Member State which took the initiative, the other Member States, and the manufacturer or his authorised representative.

...

§123 The Safeguard procedure

Article 11 (2) and (3) set out the procedure to be followed at EU level when a national measure is taken in accordance with Article 11 (1). The measure must be notified by the Member State concerned to the European Commission, indicating the reasons for the measure. The notification shall be transmitted to the Commission by the Permanent Representation of the Member State concerned. At the same time, the other Member States must be informed. The information can be communicated through the Machinery ADCO Group using the CIRCA system – see §146: comments on Article 21. The Machinery ADCO Group has developed a special form to help Member States to transmit the necessary information.

The notification should clearly indicate the essential health and safety requirements with which the machinery fails to comply and explain the nature of the risks to which these non-conformities give rise. If the market surveillance authorities have assessed the conformity of the machinery with reference to the specifications of a harmonised standard, the relevant clauses of the standard should also be indicated.

Annex 2: Safeguard Procedure

In order to enable the Commission to carry out its enquiry without delay, the national authorities should transmit all relevant documents with the notification. Relevant documents may include:

- Photos or drawings of the machinery concerned showing the CE-marking and the defects concerned
- A copy of the EC Declaration of Conformity;
- The EC type-examination certificate or the certificate of approval of the manufacturer's full quality assurance system (if applicable)
- The relevant elements of the manufacturer's technical file if they are available
- The relevant extracts from the manufacturer's instructions
- Reports of any tests or inspections on which the measure is based
- Details of any correspondence exchanged with the parties concerned, such as the manufacturer or his authorised representative, the importer or the distributor of the machinery, or the Notified Body involved.

The Commission services then examine the notification and the supporting documents and consult the parties concerned in order to consider whether or not the measure taken by the Member State is justified. The parties concerned include the authorities of the Member State that has notified the measure, the manufacturer of the machinery concerned or his authorised representative and, where applicable, the Notified Body involved in the conformity assessment of the machinery. An opportunity is given to the parties concerned to meet the Commission services to present their observations if they so wish.

If necessary, the Commission may seek independent expert advice in order to assess the file and, in some cases, to inspect the machinery concerned or carry out tests. The Commission then adopts a Decision which is communicated to the Member State which took the initial measure, to the other Member States, and to the manufacturer or his authorised representative. The Commission's Decision is published in the Official Journal of the European Union – see §143: comments on Article 18 (3).

If the Commission decides that the measure taken by the Member State is justified, the other Member States shall take the measures necessary to ensure the protection of the health and safety of persons with respect to the non-compliant machinery. If, on the other hand, the Commission decides that the measure taken by the Member State is not justified, the measure shall be withdrawn.

Article 11 (continued)

...

4. *Where the measures referred to in paragraph 1 are based on a shortcoming in the harmonised standards and if the Member State which instigated the measures maintains its position, the Commission or the Member State shall initiate the procedure referred to in Article 10.*

...

§124 Shortcomings in harmonised standards

Article 11 (4) is applicable when the non-conformity notified according to Article 11 (1) and (2) is due to a shortcoming in the harmonised standard applied by the manufacturer. In that case, in addition to the procedure set out in Article 11 (3), a formal objection must be lodged either by the Member State concerned or by the Commission, according to the procedure set out in Article 10 – see §119 to §121: comments on Article 10.

Article 11 (continued)

...

5. *Where machinery does not conform and bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall so inform the Commission. The Commission shall inform the other Member States.*

...

§125 Action against the person who has affixed the CE marking

The provisions set out in Article 11 (1) to (4) deal with the measures to be taken with respect to products that bear the CE marking and that are liable to compromise the health and safety of persons and, where appropriate, domestic animals or property.

In addition to those measures, Article 11 (5) requires the Member State to take appropriate action with respect to the person who has affixed the CE marking on a non-compliant product and thereby taken the responsibility for placing the product on the market or putting it into service – see §141: comments on Article 16. That person may be the manufacturer his authorised representative or another person taking the responsibility for placing the product on the market who is considered as a manufacturer – see §78 to §81: comments on Article 2 (i).

The appropriate action shall be determined by the Member States according to the provisions implementing the Machinery Directive into national law. In general, the market surveillance authorities should first require the manufacturer or his authorised representative to take the measures necessary to put an end to the non-conformity. If

Annex 2: Safeguard Procedure

the necessary measures are not taken within the timeframe determined by the market surveillance authorities, appropriate sanctions must be applied – see §150: comments on Article 23.

In such cases, the Member States must inform the Commission and the Commission shall inform the other Member States. For this purpose, the General information support system foreseen in Article 23 of Regulation (EC) No 765/2008 shall be used. For non-conformities relating to the CE marking or the EC Declaration of Conformity – see §142: comments on Article 17.

Article 11 (continued)

...

6. The Commission shall ensure that Member States are kept informed of the progress and outcome of the procedure.

§126 Information on the Safeguard procedure

According to Article 11 (6), the Commission shall keep the Member States informed of the progress and outcome of the Safeguard procedure. The relevant information is provided to the Member States in the framework of the Machinery ADCO Group – see §144: comments on Article 19.

The Commission's Decision is published in the Official Journal of the European Union – see §143: comments on Article 18 (3).

Article 17 Non-conformity of marking

1. Member States shall consider the following marking not to conform:

(a) The affixing of the CE marking pursuant to this Directive on products not covered by this Directive;

(b) The absence of the CE marking and/or the absence of the EC declaration of conformity for machinery;

(c) The affixing on machinery of a marking, other than the CE marking, which is prohibited under Article 16 (3).

2. Where a Member State ascertains that marking does not conform to the relevant provisions of this Directive, the manufacturer or his authorised representative shall be obliged to make the product conform and to put an end to the infringement under conditions fixed by that Member State.

3. Where non-conformity persists, the Member State shall take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedure laid down in Article 11.

§142 Non conformity of marking

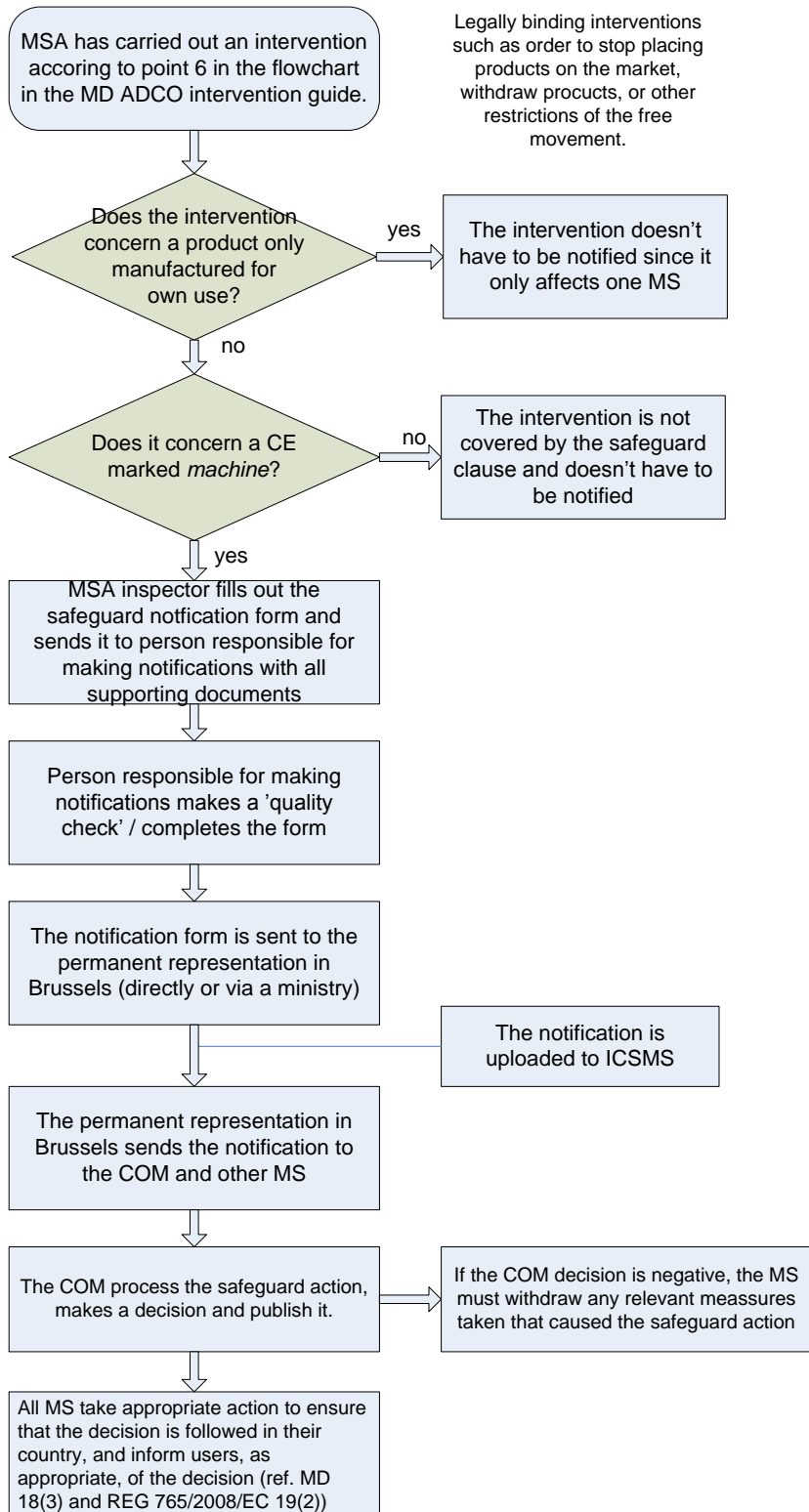
The Safeguard clause set out in Article 11 sets out the measures to be taken when machinery bearing the CE marking is discovered to be unsafe. Article 17 sets out the measures to deal with cases of formal non-conformity with the provisions of the Machinery Directive, where there is no indication that the machinery concerned is unsafe. These measures are in line with the obligation of the Member States to ensure the correct implementation of the regime governing the CE marking and to take appropriate action in the event of improper use of the marking set out in Article 30 (6) of Regulation (CE) 765/2008.

Article 17 (1) defines the three cases that are considered to constitute non-conformity of marking. Article 17 (2) states that Member States shall take the necessary measures to require economic operators to put an end to such infringements. The nature of the measures is left to the discretion of the Member States. Such measures do not have to be notified to the Commission or to the other Member States. The penalties for infringements against the provisions of the Machinery Directive must include penalties for non-conformity of marking – see §150: comments on Article 23.

Article 17 (3) sets out the procedure to be followed in case the measures taken to put an end to the infringements referred to in Article 17 (1) are not effective. In that case, the Safeguard procedure set out in Article 11 must be followed.

Annex 2: Safeguard Procedure

Annex 2.1, Machinery directive safeguard flowchart



Annex 3: Importers & Distributors

Interventions against importers and Distributors

This Annex details the process towards importers and distributors of machinery¹⁸ intended for professional (commercial and industrial) use. The Annex does not cover procedures for intervention in relation to border control.

Definitions and abbreviations used in this Annex

"Importer" shall mean any natural or legal person established within the Community who places a product from a third country on the Community market (definition taken from EC Regulation 765/2008).

"Distributor" shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market (definition taken from EC Regulation 765/2008).

"MF3" means a manufacturer in a third country who has CE marked the machine.

"Manufacturer" means any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by this Directive and is responsible for the conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use. In the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer. (Definition from MD, article 2 (i)).

"Authorised representative" means any natural or legal person established in the Community who has received a written mandate from the manufacturer to perform on his behalf all or part of the obligations and formalities connected with this Directive; (Definition from MD, article 2 (j)).

¹⁸ Machinery for consumers is also within scope of the General Product Safety Directive. The GPSD contains requirements for importers and distributors which deviate from this guidance paper.

Annex 3: Importers & Distributors

"Placing on the market" shall mean the first making available of a product on the Community market (definition taken from EC Regulation 765/2008, as used in the definition of importer. Has the same meaning as the definition in the MD: 'Placing on the market' means making available for the first time in the Community machinery or partly completed machinery with a view to distribution or use, whether for reward or free of charge).

"Making available on the market" shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge (definition taken from EC Regulation 765/2008).

Comments related to the manufacturer

A person from a third country is only considered to be a manufacturer in the sense of the MD if he has CE marked the machine with the intention of placing it on the Union market.

If the machine is physically manufactured in a third country, but not CE marked when entering the Union, it may not be placed on the market until it has been brought into full conformity, by either the 'real' manufacturer or another party. According to the Machinery Directive, article 2 (i) states that "in the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer". So actually, in this case the "importer" is considered to be the manufacturer and has the same responsibilities as a manufacturer. The Commission guide to application of the MD acknowledges this:

'§ 81 Other persons who may be considered as manufacturers

The provision set out in the second sentence of the definition of 'manufacturer' is intended to deal with the situation that arises for certain machinery imported into

Annex 3: Importers & Distributors

the EU. If a machinery manufacturer established outside the EU takes the decision to place his products on the market in the EU, he is able to fulfil his obligations under the Machinery Directive himself or mandate an authorised representative to perform all or part of these obligations on his behalf – see §84 and §85: comments on Article 2 (j). On the other hand, the decision to import machinery into the EU may be taken by an importer, distributor or user. In some cases, the machinery may be ordered from an intermediary such as an export company. In other cases, a person may purchase the machinery outside the EU and bring it into the EU himself, order machinery via the Internet, or purchase machinery in a free zone with a view to its distribution or use in the EU.

The person placing such machinery on the market in the EU may be able to ensure that the manufacturer fulfils his obligations according to the Directive. However, if that is not ensured, the person placing the machinery on the market in the EU must fulfil these obligations himself. The same goes for a person importing machinery into the EU for his own use. In these cases, the person placing the machinery or partly completed machinery on the EU market or putting machinery into service in the EU is considered as the manufacturer and must therefore fulfil all of the obligations of manufacturer set out in Article 5. (..)'.

Comments related to the authorised representative

There is no obligation for the manufacturer to appoint an authorised representative. If the manufacturer has appointed an authorised representative the case should be addressed towards the authorised representative with respect to the responsibilities that the manufacturer has delegated to him. However, in parallel, a case should also be addressed towards the importer, as described below, and shown in the flow chart in Annex 3.1.

If it is not known what responsibilities the manufacturer has assigned to the authorised representative the case may be addressed to both while seeking clarification from the manufacturer and authorised representative to establish what

Annex 3: Importers & Distributors

the written mandate states with respect to the obligations laid on the authorised representative.

Guidance on the duties of CE marked machine importers:

The following guidance is related to import of machinery which is intended to be placed on the European market by the manufacturer, ie **import of CE marked machinery**¹⁹.

There are no specific EU requirements on duties of importers of CE marked machinery for professional use. Based on the principles of EC Regulation 765/2008 and EC Decision 768/2008, the MD ADCO group finds that it will not be in conflict with the EU regulation to consider the following requirements as good practice. The text is based on the requirements of EC Decision 768/2008, but modified so it represents the MD ADCO groups opinion of what can be requested in relation to the import of machinery for professional use. The text below has no direct legal foundation, so it must be supported by national legislation in order to be followed.

- I. *Importers shall place only compliant products on the Community market.*

Where an importer considers or has reason to believe that a product is not in conformity with the Machinery Directive, he shall not place the product on the market until it has been brought into conformity, either by the 'real' manufacturer or by himself, taking the on the manufacturer's full responsibilities under his own name, according to the MD.

- II. *Importers shall ensure that the product is accompanied by Instructions in the language of the Member State of the machine destination.*

¹⁹ If not CE marked see the previous section for comments on the status of the importer (as another person who may be considered a 'manufacturer' for the purposes of the Directive).

Annex 3: Importers & Distributors

- III. *Importers shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Machinery Directive.*
- IV. *Importers shall, cooperate with the authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.*

Based on this, importers, like manufacturers, can be required to stop placing on the market, withdraw and/or recall non-compliant machine (where national legislation permits).

The "Initiating Authority principle" should also be used in relation to importers, ie the market surveillance authority in charge of the case (MSA-1) should also take initial responsibility for the case against importers situated in another MS, similar to cases against manufacturers in other MS.

Importers can also be required to translate the Declaration of Conformity and the Instructions (ref. MD, annex I, 1.7.4.1.b and annex II, 1.A).

Importers should not be required to change a machine. If the manufacturer or his authorised representative is not prepared to take responsibility for solving the problem, and the importer voluntarily decides to make a change on his own, that affects the requirements of the Directive: the importer will become the manufacturer of the machine, and must then take full responsibility to meet the requirements of the Directive.

If an end-user buys machinery directly from a manufacturer in a third country he shall not be considered as an importer if the 'imported' machine is CE marked by MF3. In this case the non-compliances should be addressed directly to the manufacturer (MF3).

Annex 3: Importers & Distributors

Guidance concerning multiple importers

The market surveillance authority in charge of the case should try to establish through investigation whether the non-compliant machinery is imported by several importers. If this is the case, actions should be taken against all importers. However, it is only possible for MSA-1 to take formal action against importers who have placed machinery on the authority's own market. MSA-1 should notify other relevant MS directly about other known importers in their countries.

Duties of machine distributors:

As for importers there are very few specific EU requirements on duties of distributors of machinery for professional use. Based on the principles of EC Regulation 765/2008, EC Decision 768/2008 and the 'Yonemoto vs. Finland' court case, the MD ADCO group finds that it will not be in conflict with the EU regulation to consider the following requirements, as good practice. The text is based on the requirements of EC Decision 768/2008, but modified so it represents the MD ADCO group's opinion of what can be requested in relation to import of machinery for professional use. The text below has no direct legal foundation, so it must be supported by National legislation in order to be used.

- I. *When making a product available on the market distributors shall act with due care in relation to the requirements applicable.*
- II. *Before making a product available on the market distributors shall verify that the product bears the CE marking, that it is accompanied by the Declaration of Conformity and by Instructions in the language requested in the Member State in which the product is to be made available on the market, and that the manufacturer has marked the product with his name and other markings as requested by the Machinery Directive.*

Where a distributor considers or has reason to believe that a product is not in conformity with the Machinery Directive, he shall not make the product available on the market until it has been brought into conformity.

Annex 3: Importers & Distributors

- III. *Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Machinery Directive.*
- IV. *Distributors shall cooperate with the authority, at its request, on any action taken to eliminate the risks posed by products which they have made available on the market.*

Distributors cannot be held responsible for a machine's compliance with the Machine Directive, unless they have made changes to the machine that mean the Directive must be applied again (a new conformity assessment process) when they then take on the manufacturer's responsibility.

Distributors can be required to stop making available on the market, withdraw and/or recall a non-compliant machine (where National legislation permits).

Distributors can be required to translate the Declaration of Conformity and the Instructions (ref. MD, annex I, 1.7.4.1.b and annex II, 1.A).

The above good practice guide shall not prevent member states making further demands on importers and distributors, which they may find in accordance with the principles of the internal market and where National legislation permits.

Annex 3: Importers & Distributors

Material supporting this Annex

Annex 3.1 in this part contains a flow chart of the intervention process relating to imported machinery.

Annex 2.2 in Part 2 of this Guide contains examples of standard letters used by the Danish Working Environment Authority. There are examples of the following letters:

A: Inquiry to importer of CE marked machinery.

B: Inquiry to “importer” of non-CE marked machinery (who is actually the manufacturer according to the MD).

C: Decision against importer of CE marked machinery.²⁰

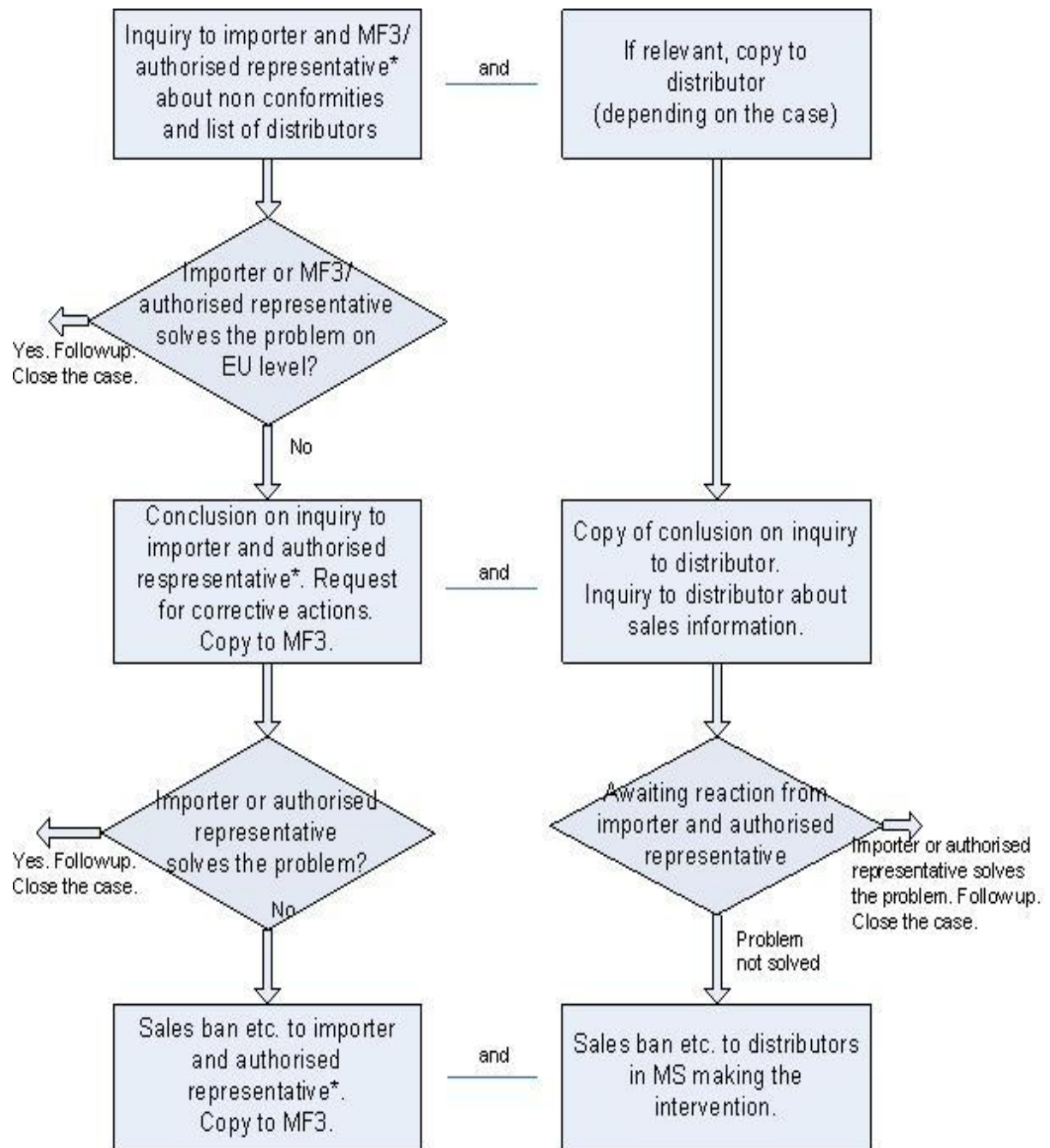
D: Prohibition to importer on placing CE marked machinery on the market.²

and an Annex 1 to the above letters A-D.

²⁰ Decision and prohibition letters concerning non-CE marked machinery are the same as manufacturer letters.

Annex 3: Importers & Distributors

Annex 3.1 Flowchart showing the main principles in intervention cases against imported machines.



* Actions against manufactures authorised representative depending on the scope of the mandate given.

Market surveillance Framework²¹

1. **New Legislative Framework (NLF)** for the marketing of products
 - a. **EC Regulation No. 765/200822** of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing EEC Regulation No. 339/93
 - b. **EC Decision No. 768/2008/EC** of the Parliament and Council relating to a common framework for the marketing of products

2. Sectorial EU legislation

The Machinery Directive (2006/42/EC)

http://ec.europa.eu/enterprise/sectors/mechanical/documents/legislation/machinery/index_en.htm

Commission Guide to the Machinery Directive 2006/42/EC

http://ec.europa.eu/enterprise/sectors/mechanical/files/machinery/guide-appl-2006-42-ec-2nd-201006_en.pdf

3. SOGS²³ (Senior Officials Group) Guidance

- a) SOGS-MSG, CERTIF 2010-05 REV1 - Overview of market surveillance procedures (Including safeguard clause mechanism) in the area of harmonised products.
- b) CERTIF 2010/04 - Risk assessment for market surveillance
- c) SOGS-MSG N023 REV1 EN-CERTIF 2011-02 REV1 - Draft ROADMAP – Enhancing the Market Surveillance enforcement for goods – A multi-annual plan

4. Court cases

Court ruling from 2005, Yonemoto vs. Finnish Government concerning obligations of machine distributors (referred to as ‘importers’ in the ruling, as Yonemoto had ‘imported’ the machine from France).

5. Other relevant framework documents

- a) Directive 2001/95/EC of 3 December 2001 on **general product safety** (GPSD) (managed by Directorate-General Health and Consumers (DG SANCO), contains provisions on how to ensure safe consumer products. For instance, GPSD provides the legal basis for [RAPEX](#)
- b) The Blue Guide on the implementation of EU product rules 2014
- c) Best practice techniques in market surveillance (PROSAFE guidance)

²¹ <http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/market-surveillance/>

²² OJEU L 218/30 of 13.8.2008

²³ The expert group on internal market products (IMP) replaces SOGS – including SOGS – market surveillance group (MSG) (with the exception of standardisation because Regulation (EU) No 1025/2012 article 22 establishes a specific standardisation committee).

Machinery ADCO WG on Market Surveillance

Good Practice Guide on Market Surveillance Interventions – Machinery Part 2: Example letters & forms

PART 2 – Example letter/forms

Introduction

This part 2 of the Good Practice Guide on Market Surveillance Intervention provides guidance on, and examples of, English language letters that are used by the Danish authorities, so they refer to the Danish National legislation alongside the Machinery Directive.

They are offered as examples that may be adapted by other member states for use if they choose.

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Guidance on key items that should be in the various letters

1: Key items that should be contained in the inquiry letter to the manufacturer (see Guide Part 1, Annex 1 flow diagram point. 4.a.)

Identification of the authority and their competence in according to the Machinery Directive.

Identification of the manufacturer and the machine concerned. (Details may be listed in an annex).

Description of legislation and breaches observed. (Details may be listed in an annex).

Information about the obligations of the manufacturer according to the MD.

Information about obligations of the user according to the Work Equipment Directive.

Requested measures to be taken voluntary, if the manufactures agrees that he is responsible for the non-conformities.

Requested response from the manufacturer containing:

- comments on the observations made by the authority
- comments on the alleged breach of legislation, explained in the above,
- information about the measures the manufacturer intends to initiate to meet his obligations under the Machinery Directive, including a time frame for implementing.
- relevant technical documentation etc. on conformity assessment, and other information relevant for the case [specify if possible]
- a list of the distributors to whom the manufacturer has supplied machinery of the same type.

A date for response should be specified.

Information about further steps and possible consequences.

A copy of the letter should be sent to

- the notified body, if such a body has assisted
- the foreign market surveillance authority, if the manufacturer is domiciled in another EU country
- importer and distributor depending on the case

2: Key items that should be contained in the letter to the manufacturer with conclusion on the inquiry (see Guide Part 1, Annex 1 flow diagram point. 4.e.)

Identification of the manufacturer and the machine concerned.

Reference to the inquiry letter with case details (could be attached as an annex).

Information about new details not covered by the inquiry letter, e.g. dialog, visits etc.

Reference to manufacturer's response to the inquiry.

Part 2 Annex 1: Example letters for sending to manufacturers etc

Final assessment and evaluation by the authority.

Requested measures to be taken voluntary by the manufacturer.
A date for response and implementing should be specified.

Information about further steps and possible consequences.

A copy of the letter should be sent to

- the notified body, if such a body has assisted
- the foreign market surveillance authority, if the manufacturer is domiciled in another EU country
- importer and distributors in the MSA own country.

3: Key items that should be contained in the letter with inquiry to Notified Body (see Guide Part 1, Annex 1 flow diagram point. 4.a.)

Identification of the authority and their competence according to the Machinery Directive.

Identification of the manufacturer and the machine concerned. (Details may be specified in an annex, e.g. by enclosing a copy of the inquiry letter to the manufacturer).

Description of legislation and breaches observed. (Details may be listed in an annex).

Information about observations concerning the role of the notified body.

Requested response from the notified body containing:

- copy of the EC Type examination certificate, the test report made by the NB and if necessary relevant technical documentation in possession of the NB.
- comments on the observations made by the authority
- comments on the alleged breach of legislation

A date for response should be specified.

4: Key items that should be contained in the information letter to the market surveillance authority in manufacturer's country (see Guide Part 1, Annex 1 flow diagram point. 4.b.)

Identification of the authority.

Identification of the manufacturer and the machine concerned. (Details to be specified in an annex by enclosing a copy of the inquiry letter to the manufacturer).

Description of legislation and breaches observed. (Details to be specified in an annex by enclosing a copy of the inquiry letter to the manufacturer).

Information about future steps planned to be taken.

5: Key content of enforcement decision against the manufacturer (see Guide Part 1, Annex 1 flow diagram point. 6.a.)

Identification of the manufacturer and the machine concerned. (Details may be listed in an annex).

References to relevant correspondence in the case, e.g. inquiry letters, manufactures and NB response and conclusion on inquiry.

New information since the conclusion letter e.g.:

- that there is no response within the specified date
- Response saying that the manufacturer disagrees with the conclusion or are unwilling to bring the machine into conformity.

Reference to be made to relevant correspondence.

Final assessment (including risk assessment) and evaluation of non-conformities by the authority and comments on manufactures disputing arguments.

Decision by the authority. What is the manufacturer ordered to do e.g.:

- Bring products into compliance
- Stop placing on the market
- Restrictions for placing on the market
- Withdraw products from supply chain
- Recall products from end users

Date for compliance and feedback.

Legal basis for the decision.

Complaint possibility, if a exists, notification, publication, prosecution, etc.

Information about further steps and possible consequences, e.g. RAPEX and safeguard action notification (Annex 4), publication, prosecution etc.

A copy of the decision should be sent to

- the notified body (if applicable)
- the foreign market surveillance authority, if the manufacturer is domiciled in another EU country
- importer and distributors in the MSA own country.

Besides the above mentioned copies of the decision, further information actions are needed, see the flowchart.

[Enterprise name and address (*usually the manufacturer, but can, in exceptional circumstances, be another responsible under the Machinery Directive*)]

Example 1, Inquiry letter to the manufacturer.

Inquiry regarding placing on the market of [unique identification of a product (not all details, as these will be in the annex. However it must be clear that the letter and the annex relate to the same product)], which is deemed not to be in conformity with the requirements of Directive 2006/42/EC, the Machinery Directive.

The Danish Working Environment Authority (Danish WEA) under the Ministry of Employment is the authority responsible for surveillance of machinery subject to Directive 2006/42/EC, the Machinery Directive. The Machinery Directive has been implemented in Danish legislation in the Executive Order on Design of Technical Equipment.

The Danish WEA has ascertained evidence that the machinery mentioned above is being placed on the market by you and being put into service by [name and address of user enterprise/user (*the place(s) where ordinary inspection and/or market surveillance has made the observations*)].

The Danish WEA is of the opinion that the machinery fails to meet the requirements in Danish legislation, in that it does not conform with the essential health and safety requirements stated in article 5 of Directive 2006/42/EC, the Machinery Directive, cf. annex I, which corresponds to annex I of the Executive Order on Design of Technical Equipment.

Information on the machinery, the details of the alleged regulatory breaches and the observations made are stated in annex I enclosed with this letter. Each observation refers to the regulations in the Directive to which the observation relates.

According to the Directive, you as manufacturer are responsible for ensuring that the machinery conforms with relevant essential health and safety requirements and with other formal requirements concerning placing on the market. You are being held responsible for ensuring that, in the future, you only place on the market machinery which complies with these requirements and that you assume responsibility for implementing measures with regard to machinery, which has already been placed on the market.

Note should be taken of Directive 2009/104/EC, the Work Equipment Directive, which has been implemented in the Danish Executive Order on Use of Technical Equipment, no. 1109 of 15 December 1992 with subsequent amendments. According to these regulations an employer may only make available for employees work equipment which meets the relevant design requirements in Community directives and national regulations. By placing on the market machinery, which does not conform with the safety and health requirements of the Machinery Directive, you therefore bear a joint responsibility in the event that the enterprises, which make the machinery available for employees, fail to comply with current legislation.

Voluntary measures

If you agree with the assessment by the Danish WEA, this means that: in future you may only place on the market machinery, which complies with these requirements.

Part 2 Annex 1: Example letters for sending to manufacturers etc

[(if the shortcomings are serious, the following can be added):

- with regard to machinery already placed on the market you either
 - o must offer to bring all machinery of the same type into conformity with the Directive, or
 - o must withdraw all machinery of the same type from the market.
- with regard to machinery which have already been supplied to the end users you either
 - o must offer to rectify the defects for the end user, or
 - o must recall all machinery of the same type]

The Danish WEA request that you, as soon as possible and no later than [date]

- notify the Danish WEA whether you have any comments on what the Danish WEA has observed, cf. annex I , sections A and C,
- notify the Danish WEA of your opinion on the alleged breach of legislation, explained in the above,
- notify the Danish WEA of the measures you intend to initiate to meet your obligations under the Machinery Directive, including when you propose to initiate these measures,
- submit relevant technical documentation etc. on your conformity assessment, and other information relevant for the case [specify if possible *(if nothing is required, delete the point)*]
- submit a list of the distributors to whom you have supplied machinery of the same type.

Your comments should be submitted to:

Arbejdstilsynet
P.O. Box 1228
DK-0900 Copenhagen C, Denmark

Please include reference to the case no.

When the above time limit for the inquiry has expired, the Danish WEA will assess the case on the basis of the available information.

If you notify the Danish WEA that you disagree with the assessment of the Danish WEA, or if you fail to voluntarily take the necessary measures within a reasonable time limit, the Danish WEA may impose a prohibition on placing on the market pursuant to article 11 of the Machinery Directive, and inform the Commission etc.

A copy of this letter and annex I have been sent to

- [name and address of distributors and importers, if relevant, known to the Danish WEA]
- [name and address of the notified body, if such a body has assisted]
- [name and address of any foreign market surveillance authority, if the manufacturer is domiciled in another EU country]

Yours faithfully

Annex (to example 1 - Danish enquiry letter)

A. Information on the case and the product

| | |
|---|---|
| Information on the case | |
| Case no. | |
| Case officer | |
| Name and address of the enterprise at which the observation was made. | |
| Date of observation | |
| Circumstances of observation, e.g. inspection visit, accident investigation, market surveillance inspection or other, as well as case no. | |
| Information about the product and manufacturer: | |
| Product name (trade name) | |
| Product description | |
| Model, type and serial number | |
| Year of manufacture | |
| Name and address of manufacturer | |
| Name and address of authorised representative, if relevant | |
| Name and address of any importer, if relevant | |
| Name and address of person authorised to compile the technical dossier, if relevant | |
| Country of origin of product | |
| As far as possible, information about in what countries the product is being placed on the market | |
| As far as possible, information about distributors - names and addresses | |
| Conformity documentation: | |
| CE marking | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Declaration of Conformity | <input type="checkbox"/> Yes <input type="checkbox"/> Reference to the following harmonised C standard: <input type="checkbox"/> No |
| Declaration of incorporation for partly completed machinery | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Annex IV machinery/equipment | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Notified body – number | <input type="checkbox"/> EC type examination <input type="checkbox"/> Assessment of the quality system <input type="checkbox"/> No |
| Other directives covered by CE marking | <input type="checkbox"/> Yes, - which?: <input type="checkbox"/> No |
| Other labels | |

Annex I (to example 1 - Danish enquiry letter)

Part 2 Annex 1: Example letters for sending to manufacturers etc

B. Legal basis

| Type of regulation: | |
|---|---|
| Danish law | Section 30(1) and section 45(1) of the Working Environment Act; cf. Consolidated Act no. 1072 of 7 September 2010 with later amendments. |
| Danish executive orders | Sections [xx] and [yy] of the Executive Order on the design of technical equipment no. [612/2008]. |
| EU directive(s) | Article [xx] of Directive [2006/42/EC of the European Parliament and of the Council of 29 December 2009 on CE marking and partly completed machinery]. |
| EU Regulations | Regulation No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to placing products on the market etc. |
| The Danish Working Environment Authority website etc. | Danish regulations etc. are on the Danish WEA website www.at.dk , under 'Regulations'. See also the EU website http://eur-lex.europa.eu/ with access to EU regulations in official EU languages |

Annex I (to example 1 - Danish enquiry letter)

C. List of lack of conformity

(The list is not a result of a complete evaluation of the machine. There may be other points of lack of conformity than listed below).

| | Essential health and safety requirements cf. Annex I. | Observation – description, assessment and reason |
|----|---|--|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |

Formal non-conformities

| | Article / annex / point: | Observation – description, assessment and reason |
|----|--------------------------|--|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |

Example 2, Letter to manufacturer with conclusion of the inquiry.

Conclusion of the inquiry regarding the placing on the market of [unique identification of a product (not all details, as these will be in the annex. However it must be clear that the letter and the annex relate to the same product)], which is deemed not to be in conformity with the requirements of Directive 2006/42/EC, the Machinery Directive:

In a letter dated [dd mm yyyy], enclosed as annex I, you and relevant operators [and any notified body] have been consulted in relation to the observations of the Danish WEA. [Insert the outcome of the inquiry here - state whether the manufacturer or others have replied, whether the manufacturer or others have provided any additional information, and whether the manufacturer agrees or disagrees with the assessment of the Danish WEA, etc.].

[If the Danish WEA has conducted additional examinations, gathered or received information etc., please indicate this here. Here, you may also provide in more detail the response to the inquiry and the Danish WEA's comments, as well as other information]

Conclusion of the inquiry

Information on the machinery, the regulatory foundation and the observations made are stated in annex I enclosed with this letter. Each observation refers to the regulations in the Directive to which the observation relates. [Annex I has been updated on the basis of the inquiry and supplementary information (*dependent on which specific piece of new information etc. has arisen*).]

After having looked into the matter, it is still the assessment of the Danish WEA that the machinery mentioned above is not in conformity with the relevant requirements as stated in annex I to this letter.

This means that you can either take the necessary measures voluntarily to counter the risk or you must expect that the Danish WEA may impose a prohibition on placing on the market pursuant to the safety clause in article 11 of the Machinery Directive, and inform the Commission etc.

Voluntary measures

If you accept the assessment of the Danish WEA and voluntarily choose to take the measures necessary to counter the risk, this means,

- that before any future placing on the market of the machinery you must take measures to ensure that it conforms with the requirements of the Machinery Directive.

[The following depends on whether the observations made are deemed to be of such importance or severity that we believe measures must be taken regarding machinery that has already been placed on the market:]

Part 2 Annex 1: Example letters for sending to manufacturers etc

- with regard to machinery already placed on the market, you must either
 - o offer to bring all machinery of this type into conformity with the Directive, or
 - o withdraw all machinery of this type from the market.
- with regard to machinery which has already been supplied to the end users you must either
 - o offer the end users to make good the deficiencies, or
 - o recall all machinery of this type.

If you wish to take measures voluntarily regarding machinery that has already been placed on the market, these measures must be implemented by no later than [dd mm yyyy].

(If the manufacturer has accepted the Danish WEA's assessment and if the manufacturer's proposals for any voluntary measures are satisfactory, all we have to do here is 'sign' our approval. Partial approval etc. may be relevant and will have to be given an individual wording):

The Danish WEA has noted that you accept the assessment of the Danish WEA and that you have stated that you will voluntarily [description of what the manufacturer will do].

Feedback

(If the manufacturer has not provided any response to the inquiry, or if he has not immediately accepted the Danish WEA's assessments, or if it is otherwise unclear whether he accepts the assessment or whether he will take measures, and if so which measures, please use this paragraph):

No later than [dd mm yyyy (e.g. four weeks from this date)], you must report back to the Danish WEA whether you accept the assessment of the Danish WEA and, if so, which voluntary measures you will take.

(Additional correspondence may be necessary to follow up, including the final feedback as worded below.)

(If the manufacturer in his response to the inquiry or otherwise has indicated that he agrees with the Danish WEA's assessment, and that he will take the required measures voluntarily, please use this paragraph):

The Danish WEA has noted that you accept the assessment of the Danish WEA and that you have stated that you will initiate voluntary measures. Therefore, you must report back to the Danish WEA regarding the result of the voluntary measures no later than [dd mm yyyy (e.g. two weeks after the deadline for taking measures has expired)].

Other

(If the observed deficiencies are sufficiently severe): The Danish WEA draw your attention to the fact that, according to article 22(2) of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, the Danish WEA must notify the European Commission of any voluntary measures taken and communicated by an economic operator (RAPEX).

Part 2 Annex 1: Example letters for sending to manufacturers etc

If you take the necessary measures, the Danish WEA will not take any further action with regard to the observed machinery deficiencies (*unless we have assessed that there are grounds for penalty in the form of direct prosecution*).

A copy of this letter and annex I have been sent to

- [name and address of distributors and importers known to the Danish WEA]
- [name and address of the notified body, if such a body has assisted]
- [name and address of any foreign market surveillance authority, if the manufacturer is domiciled in another EU country].

Yours faithfully

Example 3, Inquiry letter to the notified body.

Inquiry regarding the placing on the market of [unique identification of a product (*same as in inquiry letter to manufacturer*)] which is deemed not to be in conformity with the requirements of Directive 2006/42/EC, the Machinery Directive.

The Danish Working Environment Authority (Danish WEA) under the Ministry of Employment is the authority responsible for surveillance of machinery subject to Directive 2006/42/EC, the Machinery Directive. The Machinery Directive has been implemented in Danish legislation in the Executive Order on Design of Technical Equipment.

The Danish WEA has ascertained that the machinery mentioned above is being placed on the market by [name and address of manufacturer], made available on the market by [name and address of relevant distributor/importer] and put into service by [name and address of user enterprise/user].

Information on the case states that, as notified body, you have [information on how the notified body has been involved].

The Danish WEA has assessed that the machinery fails to meet the requirements in Danish legislation, as it does not conform with the essential health and safety requirements stated in article 5 of Directive 2006/42/EC, the Machinery Directive, cf. annex I, which corresponds to annex I of the Executive Order on Design of Technical Equipment.

Information on the machine, the regulatory foundation and the observations made are stated in Annex I of the enclosed letter to the manufacturer. Each observation refers to the regulations in the Directive to which the observation relates.

The Danish WEA request that, as soon as possible and no later than [dd mm yyyy] you

- notify the Danish WEA whether you have any comments on what the Danish WEA has found, cf. annex I , sections A and C,
- notify the Danish WEA of your position on the above.
- submit [any technical documentation etc. in order to make an assessment of compliance - or anything else the market surveillance deems relevant (*if nothing is required then delete this point*)].

Once the deadline has expired, the Danish WEA will assess the case on the basis of the information available and notify you of the outcome.

Yours faithfully

Annexes:

- copy of inquiry letter to the manufacturer with today's date
- copy of Annex I

**Example 4, Information letter to MSA-2 in manufacturers country.
Information about inquiry regarding the placing on the market of [unique identification of a product (*same as in hearing letter to manufacturer*)] which is deemed not to be in conformity with the requirements of Directive 2006/42/EC, the Machinery Directive.**

The Danish WEA has ascertained that the machinery mentioned above is being placed on the market by [name and address of manufacturer], made available on the market by [name and address of relevant distributor/importer] and put into service by [name and address of user enterprise/user].

The Danish WEA has ascertained evidence that the machinery fails to meet the requirements in Danish legislation, in that it does not conform with the essential health and safety requirements stated in article 5 of Directive 2006/42/EC, the Machinery Directive, cf. annex I, which corresponds to annex I of the Danish Executive Order on Design of Technical Equipment.

The Danish WEA has written about this to the manufacturer. Information on the machinery, the details of regulatory breaches and the observations made are stated in annex I to the letter to the manufacturer. Each observation refers to the regulations in the Directive to which the observation relates.

For your information, the Danish WEA encloses a copy of the letter to the manufacturer and annex I.

When the time limit for comments has expired, the Danish WEA will make a conclusion on the inquiry relating to the manufacturer and inform you about this conclusion.

Yours faithfully

Annexes:

- copy of inquiry letter to the manufacturer with today's date
- copy of annex I

**Example 5, Enforcement decision letter to the manufacturer.
Marketing prohibition**

Enforcement decision regarding the placing on the market of [unique identification of a product (*not all details, as these will be in the annex. However it must be clear that the letter and the annex relate to the same product*)], which is deemed not to be in conformity with the requirements of Directive 2006/42/EC, the Machinery Directive

In a letter dated [date of inquiry letter], you have been consulted in relation to the observations of the Danish Working Environment Authority. [plus reference to inquiry of notified body and others if relevant].

In a letter dated [date of conclusion letter], the Danish WEA has sent you the conclusion on the inquiry, based on the information available.

[Insert what has happened since the conclusion letter, e.g.:

- that the manufacturer hasn't replied,
- that the manufacturer still disagrees with the assessment of the Danish WEA,
- that the manufacturer accepts the assessment of the Danish WEA, but that he is not prepared to take voluntary actions,
- etc.

Reference to relevant correspondence must be given.

DWEA arguments and comments shall not be given here – this is just facts about the case].

Information on the machinery, the regulatory foundation and the observations made are stated in annex I enclosed with this letter. Each observation refers to the regulations in the Directive to which the observation relates. [Annex I has been updated on the basis of the inquiry and supplementary information (*dependent on which specific piece of new information etc. has arisen*).]

Assessment by the Danish WEA

After having looked into the matter, it is the assessment of the Danish WEA that the machinery mentioned above is not in conformity with the relevant requirements as stated in annex I to this letter.

[*(here the reasons for the intervention must be given)*.]

Decision about prohibition on placing on the market [and other interventions if relevant]

[The manufacturer's name] is hereby ordered to stop placing on the market of [unique identification of the machine].

Before any future deliveries of the machine you must take the necessary measures to ensure that the machine is brought into conformity with the requirements, as specified in annex I.

Part 2 Annex 1: Example letters for sending to manufacturers etc

[Specify other enforcement orders if relevant, e.g.:

For machinery already placed on the market, but not yet supplied to end users, you must either

- offer to bring all machinery of this type into conformity with the Directive, or
- withdraw all machinery of this type from the market.

For machinery which has already been supplied to the end users you must either

- offer the end users to make good the deficiencies, or
- recall all machinery of this type.

The measures related to machines already placed on the market must be implemented no later than [dd mm yyyy].

Legal basis

Danish Working Environment Act, act no. 1072 of 7 September 2010 with later amendments, section 77 (3).

Danish Executive Order no. 612 of 25 June 2008 on the design of technical equipment, [list relevant §§ and annex points].

Feedback

You must report back to the Danish WEA regarding the measures taken to comply with this decision no later than [dd mm yyyy].

Guidance

[Guidance can be given about how the machinery can be brought into compliance. Reference can e.g. be given to the COM guide on the MD, relevant harmonised std.'s, NANDO database, etc. No specific technical solution can be given].

Appeals

Any appeal against this decision may, within 4 weeks, be submitted to the Danish Working Environment Board (Arbejds miljøklagenævnet) cf. section 81 paragraph. 2 of the Working Environment Act, cf. Consolidated Act no. 1072 of 7 September 2010 with later amendments.

Appeals must be submitted to: (Please include reference to the case no.)
Arbejdstilsynet
P.O. Box 1228
DK-0900 Copenhagen C
Denmark

Please note that an appeal against this decision has no suspensive effect.

Other

Please note that Danish WEA will notify the EU-commission in accordance with the safeguard procedure cf. the Machinery Directive 2006/42/EC article 11 point 2, the. At the same time, the other Member States will be informed.

Part 2 Annex 1: Example letters for sending to manufacturers etc

If any action is taken by you with regard to machines sold in other EU member states, as a consequence of this decision, please notify the Danish WEA about this.

A copy of this letter and annex I have been sent to

- [name and address of distributors and importers known to the Danish WEA]
- [name and address of the notified body, if such a body has assisted]
- [Name and address of any foreign market surveillance authority, if the manufacturer is domiciled in another EU country].

Yours faithfully

Annex 2 Examples of letters to importers /distributors as used by the Danish Working Environment Authority.

There are examples of the following letters:

EXAMPLE A: Inquiry to importer of CE marked machinery.

EXAMPLE B: Inquiry to “importer” of non-CE marked machinery (who is actually the manufacturer according to the MD).

EXAMPLE C: Decision against importer of CE marked machinery.¹

EXAMPLE D: Prohibition on placing CE marked machinery on the market.

and a Danish Annex 1 to the above example letters.

¹ Decision and prohibition letters concerning non-CE marked machinery are the same as manufacturer letters.

Example A:

Inquiry regarding [unique identification of a CE marked product], which is deemed not to be in conformity with the requirements of Directive 2006/42/EC, the Machinery Directive.

The Danish Working Environment Authority (Danish WEA) under the Ministry of Employment is the authority responsible for surveillance of machinery subject to Directive 2006/42/EC, the Machinery Directive. The Machinery Directive has been implemented in Danish legislation in the Executive Order on Design etc. of Machinery.

The Danish WEA has ascertained evidence that the machinery mentioned above has been manufactured by [name and address of manufacturer], placed on the market by you, distributed in Denmark by [name and address of distributor] and been put into service by [name and address of user enterprise/user].

The Danish WEA is, based on the available information, of the opinion that the machinery fails to meet the requirements in Danish legislation and corresponding EU legislation, in that it does not comply with the essential health and safety requirements stated in article 5 of Directive 2006/42/EC, the Machinery Directive annex I. [Addition if also formal non-conformities and rewording if only formal non-conformities].

Information on the machinery, the details of suspected regulatory breaches and the observations made are stated in annex 1 enclosed with this letter. Each observation refers to the regulations in the Directive to which the observation relates.

According to Danish law, you must, as an importer only place machinery on the market, which conforms to Danish legislation. This is stated in section 4 and section 8 of the Danish Act No 155 of 20th February 2013 on the design etc. of certain products.

Part 2 Annex 2: Example letters for sending to Importers/distributors

As an importer, you are responsible, under the Danish Regulations for ensuring that, in future, you only place on the market machinery, which complies with these requirements, and that you assume responsibility for implementing measures with regard to machinery, which has already been placed on the market.

Since the machinery is CE-marked by the manufacturer, the Danish WEA has also sent an inquiry to the manufacturer. We recommend that you inform the manufacturer and ensure, that he sends all relevant information to the Danish WEA.

Note should be taken of Directive 2009/104/EC, the Use of Work Equipment Directive, which has been implemented in the Danish Executive Order on Use of Technical Equipment, no. 1109 of 15th December 1992 with subsequent amendments. According to these regulations an employer may only make available for employees work equipment, which meets the relevant design requirements in Community directives and national regulations. By placing on the market machinery, which does not conform to the essential health and safety requirements of the Machinery Directive, you may bear a joint responsibility with the enterprise which makes the machinery available for employees.

Voluntary measures

If you agree with the assessment by the Danish WEA, this means:

- That you, before placing the machinery on the market in the future, for distribution or for use, must take corrective actions in order to bring the machinery in compliance with the requirements of the Machinery Directive
- That you, with regard to machinery already placed on the market, and now in the distribution chain, either:
 - a) *Must offer to bring all machinery of the same type into conformity with the Directive, or*
 - b) *Must withdraw all machinery of the same type from the market.*
- That you regard to machinery, which have already been supplied to the end users, you either

Part 2 Annex 2: Example letters for sending to Importers/distributors

a) *Must offer to rectify the defects for the end user, or*

b) *Must recall all machinery of the same type*

The Danish WEA request that you, as soon as possible and no later than [date]:

- Notify the Danish WEA whether you have any comments on what the Danish WEA has observed, cf. annex 1 , sections A and C,
- Notify the Danish WEA of your opinion on the alleged breach of legislation, explained in the annex 1,
- Notify the Danish WEA of the measures you intend to initiate to meet your obligations under the Danish act No 155 of 20th February 2013 on the design etc. of certain products, including when you propose to initiate these measures,
- Submit [relevant technical documentation etc. on your conformity assessment, and other information relevant for the case , or ensure that the manufacturer submits the information]
- Submit a list of the distributors to whom you have supplied machinery of the same type.

Your comments should be submitted to:

Arbejdstilsynet

P.O. Box 1228

DK-0900 Copenhagen C, Denmark

Please include reference to the case no.

When the above time limit for the inquiry has expired, the Danish WEA will assess the case on the basis of the available information.

If you notify the Danish WEA that you disagree with the assessment of the Danish WEA, or if you agree with assessment and fail to voluntarily take the necessary measures within the time limit set above, the Danish WEA may impose a prohibition on placing on the market pursuant to Article 11 of the Machinery Directive, and inform the EU Commission and other EU Member States.

Part 2 Annex 2: Example letters for sending to Importers/distributors

Besides the regulation, reference is made to the EU Commission guide to application of the Machinery Directive 2006/42/EC, and relevant harmonised standards. Information is available at Danish WEA homepage www.at.dk. [If relevant also refer to NANDO database].

A copy of this letter and annex 1 have been sent to:

- [if relevant, name and address of Danish distributors, known to the Danish WEA]
- [name and address of any foreign market surveillance authority, if the importer is domiciled in another EU member state – *for a list of authorities see CIRCABC Machinery ADCO folder 04 Member State Contact Points – or find the relevant one in ICSMS*]

Yours faithfully

Example B:

Inquiry regarding [unique identification of a non-CE marked product], which is deemed not to be in conformity with the requirements of Directive 2006/42/EC, the Machinery Directive.

The Danish Working Environment Authority (Danish WEA) under the Ministry of Employment is the authority responsible for surveillance of machinery subject to Directive 2006/42/EC, the Machinery Directive.

The Danish WEA has ascertained evidence that the machinery mentioned above has been manufactured by [name and address of manufacturer], placed on the market in the EU by you, distributed in Denmark by [name and address of distributor] and been put into service by [name and address of user enterprise/user].

The Danish WEA is, based on the available information, of the opinion that the machinery fails to meet the requirements in Danish legislation and corresponding EU legislation, in that it does not comply with the essential health and safety requirements stated in article 5 of Directive 2006/42/EC, the Machinery Directive annex I. [Addition if also formal non-conformities and rewording if only formal non-conformities].

Information on the machinery, the details of the suspected regulatory breaches and the observations made are stated in annex 1 enclosed with this letter. Each observation refers to the regulations in the Directive to which the observation relates.

According to Danish law you may only place machinery on the market if it complies with Danish legislation. This is stated in the section 4 of the Danish act no 155 of 20th February 2013 on the design etc. of certain products.

According to article 2(i) in the Machinery Directive you are considered as manufacturer of the machinery in question, since the original manufacturer didn't CE-mark the machinery for the purpose of placing it on the market in the EU.

Part 2 Annex 2: Example letters for sending to Importers/distributors

You are therefore held responsible for ensuring, that the machinery complies with the essential health and safety requirements and other formal requirements of the Machinery Directive. It's your responsibility that you in the future only place on the market machinery, which complies with these requirements, and you are responsible for taking measures with regard to machinery already placed on the market.

Note should be taken of Directive 2009/104/EC, the Use of Work Equipment Directive, which has been implemented in the Danish Executive Order on the Use of Technical Equipment, no 1109 of 15th December 1992 with subsequent amendments. According to the regulations an employer may only make available for employees, work equipment, which meets the relevant design requirements in Community directives and national regulations. By placing on the market machinery, which does not conform to the essential health and safety requirements of the Machinery Directive, you may bear a joint responsibility with the enterprise which makes the machinery available for employees.

Voluntary measures

If you agree with the assessment by the Danish WEA, this means:

- That you, before placing the machinery on the market in the future, for distribution or for use, must take corrective actions in order to bring the machinery in compliance with the requirements of the Machinery Directive.
- That you, with regard to machinery already placed on the market, and now in the distribution chain, either:
 - a) *Must offer to bring all machinery of the same type into conformity with the Machinery Directive, or*
 - b) *Must withdraw all machinery of the same type from the market.*
- That you, with regard to machinery, which have already been supplied to the end users, you either
 - a) *Must offer to rectify the defects for the end user, or*
 - b) *Must recall all machinery of the same type*

Part 2 Annex 2: Example letters for sending to Importers/distributors

The Danish WEA request that you, as soon as possible and no later than [date]:

- a) Notify the Danish WEA whether you have any comments on what the Danish WEA has observed, cf annex 1, sections A and C,
- b) Notify the Danish WEA of your opinion on the alleged breach of legislation, explained in annex 1.
- c) Notify the Danish WEA of the measures you intend to initiate to meet your obligations under the Danish Act No 155 of 20th February 2013 on the design etc. of certain products, including when you propose to initiate these measures,
- d) Submit [relevant technical documentation etc. on your conformity assessment, and other information relevant for the case, - or anything else which MSA finds relevant],
- e) Submit a list of distributors to whom you have supplied machinery of the same type.
- f)

The above information should be submitted to:

Arbejdstilsynet

P.O. Box 1228

DK-0900 Copenhagen C, Denmark

Please include reference to the case no.

When the above time limit for the inquiry has expired, the Danish WEA will assess the case on the basis on available information.

If you notify the Danish WEA that you disagree with the assessment of the Danish WEA, or if you fail to take the necessary measures within a reasonable time limit, the Danish WEA may impose a prohibition on placing on the market pursuant to article 11 of the Machinery Directive, and inform the EU Commission and other EU member states.

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Besides the regulation, reference is made to the EU Commission guide to application of the Machinery Directive 2006/42/EC, and relevant harmonised standards. Information is available at Danish WEA homepage www.at.dk. [If relevant also refer to NANDO database].

A copy of this letter and annex 1 has been sent to:

- [if relevant, name and address of Danish distributors, known to the Danish WEA]
- [name and address of any foreign market surveillance authority, if the importer is domiciled in another EU member state – *for a list of authorities see CIRCABC Machinery ADCO folder 04 Member State Contact Points – or find the relevant one in ICSMS*]

Yours faithfully

Example C:

Decision regarding [unique identification of a CE marked product], which is deemed not to be in conformity with the requirements of Directive 2006/42/EC, the Machinery Directive

In a letter dated [dd mm yyyy], including annex 1, you have been heard in relation to the observations of the Danish WEA. [Insert outcome of the inquiry here – state whether the manufacturer, the importer or others have replied, whether the manufacturer, the importer or others have provided any additional information, and whether the manufacturer and the importer agrees or disagrees with the assessment of the Danish WEA etc.]

[If the Danish WEA has conducted additional examinations, gathered or received information etc., please indicate this here. Here, you may also provide in more details the response to the inquiry and the Danish WEA's comments, as well as other information].

Decision

After evaluation of this case, it is the decision of the Danish WEA that the machinery mentioned above is not in conformity with the Danish regulation and the Machinery Directive.

Information on the machinery, the regulatory foundation and the observations made are stated in annex 1 to this letter. Each observation refers to the requirements in the Directive to which the observations relates. [Annex 1 has been updated on the basis of the inquiry and supplementary information (*dependent on which specific piece of new information etc. has arisen*)]

The decision comes into force immediately.

This means that you must either take the necessary measures voluntarily to correct the non-conformities or failing that, you should expect the Danish WEA to impose a prohibition on placing on the market according to the safeguard clause provisions in

Part 2 Annex 2: Example letters for sending to Importers/distributors

article 11 of the Machinery Directive, and inform the EU Commission and the other EU Member States.

Time limit for feed back

No later than [dd mm yyyy (e.g. four weeks from this date)], you must report back to the Danish WEA whether you accept the assessment of the Danish WEA and, if so, which voluntary measures you will take.

Legal basis

- Section 17,1 of the Danish act No 155 of 20th February 2013 on the design etc. of certain products.
- Section 4 of the Danish executive order of 10th June 2013 on the design etc. of machinery.

Voluntary measures

If you accept the assessment of the Danish WEA and voluntarily choose to take the measures necessary to counter the non-conformities, this means:

- That you, before placing the machinery on the market in the future, for distribution or use, must take corrective actions in order to bring the machinery in compliance with the requirements of the Machinery Directive.
- That you, with regard to machinery already placed on the market, and now in the distribution chain, either:
 - a) must offer to bring all machinery of the same type into conformity with the directive, or*
 - b) must withdraw all machinery of the same type from the market*
- That with regard to machinery, which have already been supplied to the end users, you either
 - *Must offer to rectify the defects for the end user, or*
 - *Must recall all machinery of the same type]*

Part 2 Annex 2: Example letters for sending to Importers/distributors

If you are voluntarily taking one of the above corrective actions regarding machinery already made available on the market, these measures must be completed no later than [dd mm yyyy].

Your feedback should be submitted to:

Arbejdstilsynet

P.O. Box 1228

Dk-0900 Copenhagen C

Denmark

Please include reference to the case number.

Other

The Danish WEA draws your attention to the fact that, according to article 22(2) of the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, The Danish WEA must notify the European Commission of any voluntary measures taken and communicated by an economic operator (RAPEX).

If you take the agreed corrective measures, the Danish WEA will not take any further actions with regard to the observed non-conformities.

Besides the regulation reference is made to the EU Commission guide to application of the Machinery Directive 2006/42/EC, and relevant harmonised standards. Information available at Danish WEA homepage www.at.dk. [If relevant (e.g. type approval or quality assurance) also refer to the NANDO database].

A copy of this letter and annex 1 have been send to:

- [name and address of the manufacturer]
- [name and address of Danish distributors known to the Danish WEA]
- [name and address of the notified body, if such a body has assisted]
- [name and address of any foreign market surveillance authority, if the importer is domiciled in another EU Member State]

Yours faithfully

Example D: Marketing prohibition

Enforcement decision regarding the placing on the market of [unique identification of a CE marked product] [the non-conformity is mentioned if it can be described in few words], which is deemed not to be in conformity with the requirements of Directive 2006/42/EC, the Machinery Directive.

In a letter dated [date of inquiry letter to the importer] enclosed by annex 1, you have been heard in relation to the observations of the Danish Working Environment Authority. [Other economic operators have also been heard where relevant] [Plus reference to inquiry of notified body if relevant].

In a letter dated [date of decision to the importer], the Danish WEA has sent you its decision, based on the information available.

[Insert what has happened since the decision, e.g.:

- That the importer hasn't replied
- That the importer still disagrees with the assessment of the Danish WEA
- That the importer partly disagrees with the assessment of the Danish WEA
- That the importer accepts the assessment of the Danish WEA, but that he is not prepared to take voluntary actions,
- etc ...

- including reference to relevant correspondence.

(Danish WEA arguments and comments shall not be given here – this is just facts about the case).

Information on the machinery, the regulatory foundation and the observations made are stated in annex 1 enclosed with this decision. Each observation refers to the requirements in the Directive to the observation relates. [Annex 1 has been updated on the basis on the inquiry, decision and supplementary information (*dependent on which specific piece of new information etc. has arisen*)]

Assessment by the Danish WEA

[Here comments are given on the information which is new after the decision]

After evaluation of all the information available, it is still the assessment of the Danish WEA that the machinery mentioned above is not in conformity with the relevant requirements of the [National regulations] implementing Directive 2006/42/EC as stated in annex 1 to this letter.

[(Preface to this part of the assessment could be worded e.g.)

“The Danish WEA emphasises in particular”]

Decision about prohibition of placing on the market

[Name of the importer] is hereby ordered to stop placing on the market of [unique identification of the machinery]. The decision covers machinery with non-compliances as specified in annex 1 to this decision.

Specify other enforcement orders if relevant, e.g.:

For machinery already placed on the market [after date - *if relevant*], but not yet supplied to end users, you must either

- Offer to bring all machinery of this type into conformity with the Directive, or
- Withdraw all machinery of this type from the market.

For machinery which have already been supplied to the end users [after date - *if relevant*], you must either

- a) Offer the end users to rectify the deficiencies, or
- b) Recall all machinery of this type.

The decision covers machinery on the Danish market.

Time limits

The decision to stop placing machinery on the market comes into force immediately.

Part 2 Annex 2: Example letters for sending to Importers/distributors

[The improvement notice on [withdrawal and/or recall] from the market comes into force immediately/no later than [dd mm yyyy] and covers all already supplied machinery/machinery supplied after [dd mm yyyy].

Feedback

You must report back to the Danish WEA regarding the measures taken in order to comply with this decision no later than [dd mm yyyy].

Your feedback must be submitted to:

Arbejdstilsynet

P.O. Box 1228

DK-0900 Copenhagen C

Denmark.

Please include reference to the case no.

Legal basis

- a) Section 17,1 of the Danish act No 155 of 20th February 2013 on the design etc. of certain products.
- b) Section 4 of the Danish executive order of 10th June 2013 on the design etc. of machinery.
- Article 20 [if serious risk, else article 19] of Regulation 765/2008 of the European Parliament and of the Council of 9th July 2008 setting out the requirements for accreditation and market surveillance relating to placing products on the market etc.

Guidance

Besides the Regulation reference is made to the EU Commission guide to application of the Machinery Directive 2006/42/EC, and relevant harmonised standards. Information available at Danish WEA homepage www.at.dk. [If relevant (e.g. type approval or quality assurance) also refer to the NANDO database]

Other

Part 2 Annex 2: Example letters for sending to Importers/distributors

Please note that according to [Regulation 765/2008 of the European Parliament and of the Council of 9th July 2008, article 20 (if relevant)] and [the Machinery Directive article 11,2] Danish WEA has notified this decision to the EU Commission and other Member States.

If any action is taken by you with regard to machinery sold in other EU Member States, as a consequence of this decision, please notify the Danish WEA about this.

A copy of this letter including annex 1 have been send to

- [name and address of the manufacturer]
- [name and address of Danish distributors known to the Danish WEA]
- [name and address of the notified body, if such a body has assisted]
- [name and address of any foreign market surveillance authority, if the importer is domiciled in another EU Member State]

Yours faithfully

Head of market surveillance

Annex 1 to the Danish letter examples A-D.

A. Information on the case and the product

| | |
|---|---|
| Information on the case | |
| Case no. | |
| Case officer | |
| Name and address of the enterprise at which the observation was made. | |
| Date of observation | |
| Circumstances of observation, e.g. inspection visit, accident investigation, market surveillance inspection or other, as well as case no. | |
| Information about the product and manufacturer: | |
| Product name (trade name) | |
| Product description | |
| Model, type and serial number | |
| Year of manufacture | |
| Name and address of manufacturer | |
| Name and address of authorised representative, if relevant | |
| Name and address of any importer, if relevant | |
| Name and address of person authorised to compile the technical dossier, if relevant | |
| Country of origin of product | |
| As far as possible, information about in what countries the product is being placed on the market | |
| As far as possible, information about distributors - names and addresses | |
| Conformity documentation: | |
| CE marking | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Declaration of Conformity | <input type="checkbox"/> Yes <input type="checkbox"/> Reference to the following harmonised C standard: <input type="checkbox"/> No |

Part 2 Annex 2: Example letters for sending to Importers/distributors

| | |
|---|--|
| Declaration of incorporation for partly completed machinery | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Annex IV machinery/equipment | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Notified body – number | <input type="checkbox"/> EC type examination <input type="checkbox"/> Assessment of the quality system <input type="checkbox"/> No |
| Other directives covered by CE marking | <input type="checkbox"/> Yes, - which? <input type="checkbox"/> No |
| Other labels | |

Part 2 Annex 2: Example letters for sending to Importers/distributors

B. Legal basis

| Type of regulation: | |
|---|---|
| Danish law | Section 4 and section 6 of the Act No 155 of 20 February 2013 on the design etc. of certain products. |
| Danish executive orders | Sections 4 of the Executive Order of 10 June 2013 on the design etc. of machinery. References to annex 1 appears from point C below. |
| EU directive(s) | Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, with later amendments. References to articles and annexes appears from point C below. |
| EU Regulations | Regulation No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to placing products on the market etc. |
| The Danish Working Environment Authority website etc. | Danish regulations etc. are on the Danish WEA website www.at.dk , under 'Regulations'. See also the EU website http://eur-lex.europa.eu/ with access to EU regulations in official EU languages. |

Part 2 Annex 2: Example letters for sending to Importers/distributors

C. List of lack of conformity

(The list is not a result of a complete evaluation of the machine. There may be other points of lack of conformity than listed below).

Essential health and safety requirements

| | Directive 2006/42/EC, article 5, annex I, point: | Observation – description, assessment and reason |
|----|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |

Formal non-conformities

| | Directive 2006/42/EC, article, annex, point: | Observation – description, assessment and reason |
|----|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |

Part 2 Annex 3 Machinery Directive Safeguard Form

NOTIFICATION UNDER ARTICLE 11 ² of 2006/42/EC (Machinery Directive)

This information is for restricted use of public authorities. This form is only to be considered a guide. Consequently, where necessary, additional information should be provided.

1. Name of the notifying authority

| | |
|---|--|
| a. Member State | |
| b. Full name and address, telephone and fax numbers, e-mail of the department and of the competent official supplying the information | |
| c. Date | |

2. Identification of the machinery and the manufacturer

| | |
|---|--|
| a. Product name (commercial name) | |
| b. Product description | |
| c. Model, type and serial number | |
| d. Year of construction | |
| e. Product category (CEN / CENELEC classification) | |
| f. Custom product code (TARIC code. Link: http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp?Lang=en) | |
| g. Name and address of the manufacturer | |
| h. Name and address of the authorised representative | |
| i. Name and address of the importer | |
| j. Name and address of person authorised to compile the technical file | |
| k. Country of origin of product | |
| l. Countries in which the equipment is placed | |

² Partly completed machinery is not subject to article 11 (see §122 of the Commission Guide 2nd Edition).

Part 2 Annex 3 Machinery Directive Safeguard Form

| | |
|------------------------------|--|
| on the market ³ | |
| m. Distributors ² | |

3. Proof of conformity

| | |
|---|--|
| a. CE marking | <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i> |
| b. Declaration of conformity | <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>yes, declaration referring to harmonised C-standard</i> <input type="checkbox"/> <i>no</i> |
| c. Declaration of incorporation for partly completed machinery ⁴ | <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i> |
| d. Annex IV Equipment | <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i> |
| e. Notified body number | <p>.....</p> <input type="checkbox"/> <i>EC type examination:</i> <input type="checkbox"/> <i>Assessment of Full quality assurance:</i> <input type="checkbox"/> <i>no</i> |
| f. Other directive(s) covered by CE marking | <input type="checkbox"/> <i>yes which one(s)?:</i> <input type="checkbox"/> <i>no</i> |
| g. Other markings | |

4. Details of the measures taken

| | Manufacturer | Importer into the EEA | Distributor |
|---|--------------------------|--------------------------|--------------------------|
| A) Type of measure | | | |
| Removal from circulation | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Prohibition of the placing of the equipment on the market | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| General measures making the placing of the equipment on the market subject to specific conditions | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Prohibition to further put into service | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Other (please describe) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B) Voluntary action: | | | |
| Recall from the market of the equipment | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

³ Information should be given as far as possible, with information on validity.

⁴ This field is valid for the informal information only

Part 2 Annex 3 Machinery Directive Safeguard Form

| | | | |
|---|--|--|--------------------------|
| No further placing of the equipment on the market | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Modification of equipment, instructions for use | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Other (please describe) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C) References to measures: | | | |
| Date: | | | |
| Reference: | | | |
| Method of notification: | | | |
| D) Brief summary: | | | |
| E) Has the manufacturer, authorised representative or importer been informed? | <input type="checkbox"/> <i>yes</i> | Method of notification: Date: | |
| | <input type="checkbox"/> <i>no</i> | | |
| F) Is the measure firm, or can it be the subject of an appeal? | <input type="checkbox"/> <i>firm</i> | | |
| | <input type="checkbox"/> <i>the possibility for an appeal exists</i> | | |
| | <input type="checkbox"/> <i>subject of an appeal (Please describe)</i> | | |
| G) Has the notify body ascertained or certified that the example of the equipment, after the corrective action, satisfies the provisions of the Machinery Directive?⁵ | <input type="checkbox"/> <i>yes</i> ⁶ <input type="checkbox"/> <i>no</i> | Name of notified body: Reference number of EC type-examination: Reference number of receipt of technical file: Reference number of adequacy certificate | |

5. Reasons for the measures taken

| | | |
|----|---|--|
| a. | <input type="checkbox"/> Failure to satisfy the essential requirements referred to in Article 5(1.a) of the Machinery Directive | <i>EHSR(s) reference</i> |
| b. | <input type="checkbox"/> Incorrect application of the standards referred to in Article 7(2) of the Machinery Directive | <i>EHSR(s) reference:</i> <i>Standard(s) reference:</i> |

⁵ This field is valid for the informal information only

⁶ For machinery listed in Annex IV, if the manufacturer or importer applied the procedure referred to in Article 12 (3.b) or (4.a), modification carried out must be validated by a notified body according point 6 of Annex IX. ("The applicant shall inform the notified body which retains the technical file relating to the EC type-examination certificate of all modifications to the approved type. The notified body shall examine these modifications and shall then either confirm the validity of the existing EC type-examination certificate or issue a new one if the modifications are liable to compromise conformity with the essential health and safety requirements or the intended working conditions of the type.")

Part 2 Annex 3 Machinery Directive Safeguard Form

| | | |
|----|---|--|
| c. | <input type="checkbox"/> Non conformity of marking (Article 17). | |
| d. | <input type="checkbox"/> Equipment listed in Annex IV for which the procedure referred to in Article 12 (3) or (4) have not been applied. | |
| e. | <input type="checkbox"/> Partly completed machinery for which the procedure in Article 13 has not been applied. | <input type="checkbox"/> <i>Technical file available to market surveillance authority</i> <input type="checkbox"/> <i>acceptable</i> <input type="checkbox"/> <i>not acceptable (please explain)</i> <input type="checkbox"/> <i>Technical file not available.</i> <input type="checkbox"/> <i>Assembly instructions described in Annex VI accompanying the product</i> <input type="checkbox"/> <i>acceptable</i> <input type="checkbox"/> <i>not acceptable (please explain)</i> <input type="checkbox"/> <i>Assembly instructions not available.</i> |

6. Brief description of faults, nature of hazards and/or shortcomings in standards observed

7. Additional information to be annexed

| | | |
|--------------------------|--|----------------|
| <input type="checkbox"/> | Photos or drawings of the machinery concerned showing the CE- marking and the defects concerned | <i># pages</i> |
| <input type="checkbox"/> | A copy of the EC Declaration of Conformity | <i># pages</i> |
| <input type="checkbox"/> | The EC type-examination certificate or the certificate of approval of the manufacturer's full quality assurance system (if applicable) | <i># pages</i> |
| <input type="checkbox"/> | The relevant elements of the manufacturer's technical file if they are available | <i># pages</i> |
| <input type="checkbox"/> | The relevant extracts from the manufacturer's instructions | <i># pages</i> |
| <input type="checkbox"/> | Reports of any tests or inspections on which the measure is based | <i># pages</i> |
| <input type="checkbox"/> | Details of any correspondence exchanged with the parties concerned, such as the manufacturer or his authorised representative, the importer or the distributor of the machinery, or the Notified Body involved | <i># pages</i> |