

Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (Text with EEA relevance)

CHAPTER XII

SAFEGUARD CLAUSES

Article 46

Procedure for dealing with vehicles, systems, components or separate technical units presenting a serious risk at national level

1 Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that a vehicle, system, component or separate technical unit covered by this Regulation presents a serious risk to the health or safety of persons or to other aspects of the protection of public interests covered by this Regulation, the approval authority that granted the approval shall carry out an evaluation in relation to the vehicle, system, component or separate technical unit concerned covering all the requirements laid down in this Regulation. The relevant economic operators shall cooperate fully with the approval and/or market surveillance authorities.

Where, in the course of that evaluation, the approval authority that granted the approval finds that the vehicle, system, component or separate technical unit does not comply with the requirements laid down in this Regulation, it shall without delay require the relevant economic operator to take all appropriate corrective action to bring the vehicle, system, component or separate technical unit into compliance with those requirements, to withdraw the vehicle, system, component or separate technical unit from the market, or to recall it within a reasonable period, commensurate with the nature of the risk.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2 Where the approval authorities consider that non-conformity is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and the action required of the economic operator.

3 The economic operator shall ensure that all appropriate corrective action is taken in respect of all non-compliant vehicles, systems, components or separate technical units that it has placed on the market, registered or is responsible for its entry into service in the Union.

4 Where the economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the national authorities shall take all appropriate measures to prohibit or restrict the making available on the market, registration or entry into service of non-compliant vehicles, systems, components or separate technical units on their national market, to withdraw them from that market or to recall them.

5 The national authorities shall, without delay, inform the Commission and the other Member States of the measures provided for in paragraph 4.

The information provided shall include all available details, in particular the data necessary for the identification of the non-compliant vehicle, system, component or

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separate technical unit, its origin, the nature of the non-conformity alleged and the risk involved, the nature and duration of the national measures taken, and the arguments put forward by the relevant economic operator. In particular, the approval authorities shall indicate whether the non-conformity is due to either of the following:

- a failure of the vehicle, system, component or separate technical unit to meet requirements relating to the health or safety of persons, the protection of the environment or to other aspects of the protection of public interests covered by this Regulation;
- b shortcomings in the relevant acts listed in Annex II.

6 Member States shall within one month inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-conformity of the vehicle, system, component or separate technical unit concerned, and, in the event of disagreement with the notified national measure, of their objections.

7 Where, within one month of receipt of the information referred to in paragraph 6 of this Article, an objection has been raised by either another Member State or the Commission in respect of a measure taken by a Member State, that measure shall be evaluated by the Commission in accordance with Article 47.

8 Member States shall ensure that appropriate restrictive measures are taken in respect of the vehicle, system, component or separate technical unit concerned, such as withdrawal of the vehicle, system, component or separate technical unit from their market, without delay.

Article 47

Union safeguard procedure

1 Where, during the procedure set out in Article 46(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to the Union legislation, the Commission shall without delay evaluate the national measure after consulting Member States and the relevant economic operator or operators. On the basis of the results of that evaluation, the Commission shall decide, in accordance with the examination procedure referred to in Article 73(2), whether the national measure is considered justified or not.

The Commission shall communicate its decision to all Member States and to the relevant economic operator or operators.

2 If the national measure is considered justified by the Commission, all Member States shall take the measures necessary to ensure that the non-compliant vehicle, system, component or separate technical unit is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw or adapt the measure, in accordance with the decision referred to in paragraph 1.

3 Where the national measure is considered justified and is attributed to shortcomings in this Regulation or in delegated or implementing acts adopted pursuant to this Regulation, the Commission shall propose appropriate measures as follows:

- a where delegated or implementing acts adopted pursuant to this Regulation are concerned, the Commission shall propose the necessary amendments to the act concerned;
- b where UNECE regulations are concerned, the Commission shall propose the necessary draft amendments to the relevant UNECE regulations in accordance with the procedure applicable under the Revised 1958 Agreement.

Article 48

Compliant vehicles, systems, components or separate technical units that present a serious risk

1 Where, having performed an evaluation under Article 46(1), a Member State finds that vehicles, systems, components or separate technical units, although they comply with the applicable requirements or are properly marked, present a serious risk to safety or may seriously harm the environment or public health, it shall require the relevant economic operator to take all appropriate measures to ensure that the vehicle, system, component or separate technical unit concerned, when placed on the market, registered or after its entry into service, no longer presents that risk, to withdraw the vehicle, system, component or separate technical unit from the market or to recall it within a reasonable period, commensurate with the nature of the risk. The Member State may refuse to register such vehicles until the vehicle manufacturer has taken all appropriate measures.

2 For a vehicle, system, component or separate technical unit as referred to in paragraph 1, the economic operator shall ensure that corrective action is taken in respect of all such vehicles, systems, components or separate technical units placed on the market, registered or entered into service in the Union.

3 The Member State referred to in paragraph 1 shall within one month inform the Commission and the other Member States of all available details, in particular the data necessary for the identification of the vehicle, system, component or separate technical unit concerned, the origin and the supply chain of the vehicle, system, component or separate technical unit, the nature of the risk involved and the nature and duration of the national measures taken.

4 The Commission shall, without delay, consult the Member States and the relevant economic operator or operators and, in particular, the approval authority that granted the type-approval, and shall evaluate the national measure taken. On the basis of that evaluation, the Commission shall decide whether the national measure referred to in paragraph 1 is considered justified or not, and where necessary, propose appropriate measures.

5 The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 49

Vehicles, systems, components or separate technical units not in conformity with the approved type

1 Where new vehicles, systems, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark do not conform to the approved type, the approval authority which granted the EU type-approval shall take the necessary measures, including the withdrawal of type-approval, to ensure that vehicles, systems, components or separate technical units in production are brought into conformity with the approved type.

2 For the purposes of paragraph 1, deviations from the particulars in the EU type-approval certificate or the information package shall be deemed to constitute failure to conform to the approved type.

3 If an approval authority demonstrates that new vehicles, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark issued

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in another Member State do not conform to the approved type, it may ask the approval authority which granted the EU type-approval to verify that vehicles, systems, components or separate technical units in production continue to conform to the approved type. On receipt of such a request, the approval authority which granted the EU type-approval shall take the requisite action as soon as possible and at the latest within three months of the date of the request.

4 The approval authority shall request the approval authority which granted the EU type-approval for a system, component, separate technical unit or incomplete vehicle to take the necessary action to ensure that vehicles in production are brought back into conformity with the approved type in the following cases:

- a for an EU vehicle type-approval, where the non-conformity of a vehicle is attributable exclusively to the non-conformity of a system, component or separate technical unit;
- b for a multi-stage type-approval, where the non-conformity of a completed vehicle is attributable exclusively to the non-conformity of a system, component or separate technical unit that forms part of the incomplete vehicle or to the non-conformity of the incomplete vehicle itself.

5 On receipt of such a request, the approval authority concerned shall take the necessary action, if necessary in conjunction with the approval authority making the request, as soon as possible and at the latest within three months of the date of the request.

6 Where non-conformity is established, the approval authority of the Member State that granted the EU type-approval for the system, component or separate technical unit or for the incomplete vehicle shall take the measures set out in paragraph 1.

The approval authorities shall inform each other within one month of any withdrawal of EU type-approval and of the reasons therefor.

7 If the approval authority that granted the EU type-approval disputes the non-conformity notified to it, the Member States concerned shall endeavour to settle the dispute. The Commission shall be kept informed and, where necessary, shall hold appropriate consultations with a view to reaching a settlement.

Article 50

Placing on the market and entry into service of parts or equipment that may pose a serious risk to the correct functioning of essential systems

1 Parts or equipment that may pose a serious risk to the correct functioning of systems that are essential for the safety of the vehicle or for its environmental performance shall not be placed on the market, registered or enter into service and shall be prohibited, unless they have been authorised by an approval authority in accordance with Article 51(1) and (4).

2 In order to ensure the uniform application of paragraph 1, the Commission may adopt implementing acts to draw up a list of such parts or equipment on the basis of available information, and in particular information communicated by the Member States, regarding:

- a the seriousness of the risk to the safety or environmental performance of vehicles fitted with the parts or equipment in question;
- b the possible effect on consumers and after-market manufacturers of the imposition under this Article of a possible authorisation requirement for parts or equipment.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 73(2).

3 Paragraph 1 shall not apply to original parts or equipment and to parts or equipment that are type-approved in accordance with any of the acts listed in Annex II, except where the approval relates to aspects other than those covered in paragraph 1.

Paragraph 1 shall not apply to parts or equipment exclusively produced for racing vehicles not intended for use on public roads. If parts or equipment included in a list established by an implementing act referred to in paragraph 2 have a dual use for racing and on the road, these parts or equipment may not be made available to the general public for use in on-road vehicles unless they comply with the requirements of this Article. Where appropriate, the Commission shall adopt provisions for identifying the parts or equipment referred to in this paragraph.

4 The Commission shall be empowered to adopt delegated acts in accordance with Article 75 concerning the requirements which the parts and equipment referred to in paragraph 1 of this Article shall fulfil.

These requirements may be based on the acts listed in Annex II or may consist of a comparison of the parts or equipment with the environmental or safety performance of the original vehicle, or of any of its parts, as appropriate. In either case the requirements shall ensure that the parts or equipment do not impair the functioning of those systems that are essential for the safety of the vehicle or its environmental performance.

Article 51

Parts or equipment that may pose a serious risk to the correct functioning of essential systems — related requirements

1 For the purposes of Article 50(1), the manufacturer of parts or equipment shall submit to the approval authority an application accompanied by a test report drafted by a designated technical service which certifies that the parts or equipment for which authorisation is sought comply with the requirements referred to in Article 50(4). The manufacturer may submit only one application per type of part to only one approval authority.

If so requested by the competent authority of another Member State, the approval authority which has given the authorisation shall, within one month of receiving that request, send to the former a copy of the requested authorisation certificate together with the attachments by means of a common secure electronic exchange system. The copy may also take the form of a secure electronic file.

2 The application shall include details of the manufacturer of parts or equipment, the type, identification and part numbers of the parts or equipment, the vehicle manufacturer's name, type of vehicle and, if appropriate, year of construction or any other information permitting the identification of the vehicle to which the parts or equipment are to be fitted.

When the approval authority is satisfied, taking account of the test report and other evidence, that the parts or equipment in question comply with the requirements referred to in Article 50(4), it shall authorise the parts or equipment to be placed on the market and to be entered into service subject to the second subparagraph of paragraph 4 of this Article.

The approval authority shall issue a certificate to the manufacturer without delay.

3 The Commission may adopt implementing acts in order to lay down a template and numbering system for the certificate referred to in the third subparagraph of paragraph 2 of

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this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 73(2).

4 The manufacturer shall inform without delay the approval authority that gave the authorisation of any change affecting the conditions under which it was issued. That approval authority shall decide whether the authorisation has to be reviewed or reissued and whether further tests are necessary.

The manufacturer shall be responsible for ensuring that the parts or equipment are produced and continue to be produced under the conditions under which the authorisation was issued.

5 Before delivering any authorisation, the approval authority shall verify the existence of satisfactory arrangements and procedures for ensuring effective control of the conformity of production.

Where the approval authority finds that the conditions for issuing the authorisation are no longer fulfilled, it shall request the manufacturer to take the necessary measures to ensure that the parts or equipment are brought back into conformity. If necessary, it shall withdraw the authorisation.

6 Approval authorities from different Member States shall bring any disagreement in relation to the authorisation referred to in the second subparagraph of paragraph 2 to the attention of the Commission. The Commission shall take the appropriate measures in order to resolve the disagreement, including, where necessary, requiring the withdrawal of the authorisation, after having consulted the approval authorities.

7 Until the list referred to in Article 50(2) has been established, Member States may maintain national provisions dealing with parts or equipment which may affect the correct functioning of systems essential for the safety of the vehicle or its environmental performance.

Article 52

Recall of vehicles, systems, components or separate technical units

1 Where a manufacturer who has been granted an EU whole-vehicle type-approval is obliged, in accordance with Regulation (EC) No 765/2008, to recall vehicles placed on the market, registered or for which the manufacturer was responsible for the entry into service, because a system, component or separate technical unit fitted to the vehicle presents a serious risk to safety, public health or environmental protection, whether or not duly approved in accordance with this Regulation, or because a part not subject to any specific requirements under type-approval legislation presents a serious risk to safety, public health or environmental protection, that manufacturer shall immediately inform the approval authority that granted the vehicle approval.

2 Where a manufacturer of systems, components or separate technical units, who has been granted an EU type-approval is obliged, in accordance with Regulation (EC) No 765/2008, to recall systems, components or separate technical units which have been placed on the market or for which the manufacturer was responsible for the entry into service because they present a serious risk to safety, occupational safety, public health or environmental protection, whether or not duly approved in accordance with this Regulation, the manufacturer shall immediately inform the approval authority that granted the approval.

3 The manufacturer shall propose to the approval authority a set of appropriate remedies to neutralise the serious risk referred to in paragraphs 1 and 2. The approval authority shall

communicate the proposed remedies to the approval authorities of the other Member States without delay.

The approval authorities shall ensure that the remedies are effectively implemented in their respective Member States.

4 If the remedies are considered to be insufficient or not implemented quickly enough by the approval authority concerned, it shall inform the approval authority that granted the EU type-approval without delay.

The approval authority that granted the EU type-approval shall then inform the manufacturer. If the manufacturer does not propose and implement effective corrective measures, the approval authority which granted the EU type-approval shall take all protective measures required, including the withdrawal of the EU type-approval. In the case of withdrawal of the EU type-approval, the approval authority shall within one month of such withdrawal notify the manufacturer, the approval authorities of the other Member States and the Commission by registered letter or equivalent electronic means.

Article 53

Notification of decisions and remedies available

1 All decisions taken pursuant to this Regulation and all decisions refusing or withdrawing EU type-approval, refusing registration, prohibiting or restricting the placing on the market, registration or entry into service of a vehicle or requiring withdrawal of a vehicle from the market shall state in detail the reasons on which they are based.

2 Any such decision shall be notified to the party concerned, who shall, at the same time, be informed of the remedies available to it under the laws in force in the Member State concerned and of the time limits allowed for the exercise of such remedies.

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