Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2014/0108(COD)	Procedure completed
Personal protective equipment Amended by 2017/0353(COD) Subject 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 4.15.15 Health and safety at work, occupational medicine 4.20 Public health 4.60.08 Safety of products and services, product liability		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	IMCO Internal Market and Consumer Protection		17/07/2014
		ECR FORD Vicky	
		Shadow rapporteur	
		epp ARIMONT Pascal	
		S&D WESTPHAL Kerstin	
		ROCHEFORT Robert	
		DURAND Pascal	
	Former committee responsible		
	IMCO Internal Market and Consumer Protection		
	Committee for opinion	Rapporteur for opinion	Appointed
	EMPL Employment and Social Affairs		30/09/2014
		EFD AGEA Laura	
	ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
	ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
	Former committee for opinion		
	EMPL Employment and Social Affairs		
	ENVI Environment, Public Health and Food Safety		
	ITRE Industry, Research and Energy		

Council of the European Union	Council configuration	Meeting	Date
	Economic and Financial Affairs ECOFIN	3445	12/02/2016
	Competitiveness (Internal Market, Industry, Research and Space)	3353	04/12/2014
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs	TAJANI Antonio	
European Economic and Social Committee			

Key events

27/03/2014	Legislative proposal published	COM(2014)0186	Summary
02/04/2014	Committee referral announced in Parliament, 1st reading		
20/10/2014	Committee referral announced in Parliament, 1st reading		
04/12/2014	Debate in Council	3353	
23/04/2015	Vote in committee, 1st reading		
23/04/2015	Committee decision to open interinstitutional negotiations with report adopted in committee		
30/04/2015	Committee report tabled for plenary, 1st reading	A8-0148/2015	Summary
10/11/2015	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE610.792 GEDA/A/(2015)010800	
19/01/2016	Debate in Parliament		
20/01/2016	Results of vote in Parliament		
20/01/2016	Decision by Parliament, 1st reading	T8-0012/2016	Summary
12/02/2016	Act adopted by Council after Parliament's 1st reading		
12/02/2016	End of procedure in Parliament		
09/03/2016	Final act signed		
31/03/2016	Final act published in Official Journal		

Technical information

Procedure reference	2014/0108(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amended by 2017/0353(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114
Other legal basis	Rules of Procedure EP 159

Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	IMCO/8/00401

Documentation gateway

Legislative proposal		COM(2014)0186	27/03/2014	EC	Summary
Document attached to the procedure		SWD(2014)0118	27/03/2014	EC	
Document attached to the procedure		SWD(2014)0119	27/03/2014	EC	
Economic and Social Committee: opinion, report		CES2799/2014	09/07/2014	ESC	
Committee draft report		PE546.721	28/01/2015	EP	
Amendments tabled in committee		PE549.462	03/03/2015	EP	
Committee opinion	EMPL	PE544.202	07/04/2015	EP	
Committee report tabled for plenary, 1st reading/single reading		A8-0148/2015	30/04/2015	EP	Summary
Coreper letter confirming interinstitutional agreement		GEDA/A/(2015)010800	12/10/2015	CSL	
Text adopted by Parliament, 1st reading/single reading		T8-0012/2016	20/01/2016	EP	Summary
Draft final act		00058/2015/LEX	09/03/2016	CSL	
Commission response to text adopted in plenary		SP(2016)191	16/03/2016	EC	
Text agreed during interinstitutional negotiations		PE610.792	22/09/2017	EP	
Follow-up document		COM(2023)0196	14/04/2023	EC	

Additional information

European Commission	EUR-Lex

Final act

Regulation 2016/425
OJ L 081 31.03.2016, p. 0051 Summary

Final legislative act with provisions for delegated acts

Personal protective equipment

PURPOSE: to lay down requirements for the design and manufacture of personal protective equipment (PPE) in order to ensure the health and safety protection of users and rules on its free movement in the Union.

PROPOSED ACT: Regulation of the European Parliament and the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Directive 89/686/EEC on personal protective equipment was adopted on 21 December 1989 and became fully applicable as from 1 July 1995. It sets out basic requirements that PPE must comply with in order to be made available on the EU market.

The PPE Directive applies to PPE that is defined as any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.

While the directive has successfully achieved its objectives in creating a single market and ensuring a high level of protection for users of PPE, certain problems have been encountered in its implementation. These concern products on the market that do not ensure an adequate level of protection, diverging approaches of the notified bodies, the effectiveness of the market surveillance as well as risks related to protective equipment which is currently not covered by the PPE Directive.

The proposal modifies and clarifies a number of the provisions of the existing Directive and aligns it with the provisions of Decision No 768/2008/EC establishing a common framework for the marketing of products (NLF Decision). The Commission has already proposed the alignment of nine Directives to the NLF Decision within an NLF implementation package adopted on 21 November 2011.

IMPACT ASSESSMENT: the preferred option consists of amending the PPE Directive as it: (i) lead to an improved level of protection of the health and safety of the users; (ii) ensures a more effective work of the market surveillance authorities and consequently reduces the non-compliant products; (iii) does not entail significant costs for economic operators and notified bodies.

CONTENT: this proposal intends to replace Directive 89/686/EEC on personal protective equipment by a Regulation. Its general objectives are to ensure a high level of protection of human health and safety whilst guaranteeing fair competition for economic operators on the Union market and simplifying the regulatory environment in this area.

The proposal also clarifies a number of provisions of the existing Directive and aligns it with those of the Decision No 768/2008/EC establishing a common framework for the marketing of products (decision on the new legislative framework).

Scope: the Commission proposes to enlarge the scope of the current PPE Directive by deleting the exclusions of PPE designed and manufactured for private use against heat, damp and water. The proposal keeps the other existing exclusions and clarifies that it does not apply to PPE for head, face or eye protection, subject to the relevant UNECE Regulation, of users of two- or three-wheeled motor vehicles.

Two PPE specific definitions have been added in order to clarify the applicable conformity assessment procedures: Individually adapted PPE and Made-to-measure PPE.

Making available on the market, free movement, obligations of economic operators, CE marking: the proposal:

- contains the typical provisions for product-related Union harmonisation legislation and sets out the obligations of the relevant economic operators (manufacturers, authorised representatives, importers and distributors), in accordance with the NLF Decision;
- obliges the manufacturer of PPE to draw up a technical documentation and to ensure that the PPE is accompanied by a copy of the EU declaration of conformity or a simplified EU declaration of conformity.

Notified bodies: the proposal sets out requirements for national authorities responsible for conformity assessment bodies (notified bodies). It leaves the ultimate responsibility for designating and monitoring notified bodies with the individual Member State.

Categories and Conformity assessment: the proposal simplifies the definition of the categories of PPE. The category only depends on the risk against which the PPE is intended to protect. Provisions are set out for made-to-measure PPE. PPE intended to protect the user against drowning, cuts by hand-held chain-saws, high-pressure cutting, bullet wounds or knife stabs, and harmful noise are subject to the most stringent conformity assessment procedure.

Minor amendments have been made which change marginally three essential health and safety requirements (EHSR) in order to remove requirements shown to be impracticable or that create confusion.

Application: the proposed Regulation will become applicable two years after its entry into force to allow manufacturers, notified bodies and Member States time to adapt to the new requirements. However, the designation of notified bodies pursuant to the new requirements and process needs to start shortly after the entry into force of this Regulation.

Transitional provisions are foreseen for products manufactured and the certificates issued by notified bodies under Directive 89/686/EEC so as to allow stocks to be absorbed and ensure a smooth transition to the new requirements.

DELEGATED ACTS: this proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union.

Personal protective equipment

The Committee on the Internal Market and Consumer Protection adopted the report by Vicky FORD (ECR, UK) on the proposal for a regulation of the European Parliament and of the Council on personal protective equipment.

The committee recommended that Parliament?s position adopted at first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

Purpose and scope: the Regulation lays down requirements for the design and manufacture of personal protective equipment (PPE) which is being made available on the market in order to ensure the protection of users and rules on its free movement in the Union.

Amendments aiming to include in the scope of the Regulation equipment to protect against oxygen deficiency (e.g. diving equipment), chemicals, biological agents and radiation/radioactive contamination, laser radiation and radioactive contamination, and explosive fragments are now inserted into Annex I, Category III.

Excluded from the scope of the legislation are PPE:

- designed to be used for self-defence, with the exception of PPE intended for sporting activities;
- intended for private use to protect against: (i) damp and water not of an extreme nature; (ii) heat, for which the economic operator does not explicitly describe and market the products as having a protective function;
- in the form of clothing intended for private use, with reflective or fluorescent garments which are exclusively included for reasons of design or decoration, and for which the economic operator does not describe and market the products as having a protective function;

- designed and placed on the market as artisanal products which are decorative in nature.

Definitions: Members wanted to see more specific technical provisions, regarding:

- connection systems as items essential to the PPE's function;
- adding a definition of 'demonstration' and 'field test' and permitting field testing to take place. Field tests should not be designed to test the protection performance of the PPE but to evaluate other non-protective aspects such as comfort, ergonomics and design.

Obligations of economic operators (manufacturers, importers, distributors):

Manufacturers should:

- keep the technical documentation and the EU declaration of conformity for at least five years after the PPE has been placed on the market (rather than 10 years as proposed by the Commission);
- ensure that instructions, as well as any labelling, are clear, understandable and intelligible;
- ensure that performance as recorded during relevant technical tests to check the levels of classes of protection provided by the PPE is available electronically or upon request.

Manufacturers should include with the EPP either the simplified EU declaration of conformity or include in the instructions or information leaflet the web site address where the EU declaration of conformity might be seen.

Importers should:

- indicate, on the PPE their contact details in the official language or languages of the Member State(s) in which the PPE is to be marketed;
- ensure that PPE is accompanied by the instructions and safety information in a language which can be easily understood by consumers;
- with regard to the risks presented by PPE, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.

Members stressed that importers and distributors should immediately inform the manufacturer and the competent national authorities if they have reason to believe that PPE that they have placed on the market is not in conformity with the Regulation.

Examination certificate: the PPE should be examined on the basis of the latest scientific evidence. The maximum period of validity of the EU type-examination certificate should be five years and a process for reviewing the certificate should be provided. Following a positive review, a renewed certificate may continue to be valid for further periods, each of which should be for a maximum of five years.

Presumption of conformity: unless otherwise provided for by Union harmonisation legislation, the withdrawal of a harmonised standard shall not invalidate existing certificates issued by notified bodies. Products produced in accordance with the existing certificate shall still benefit from continuing conformity with the essential requirements and may continue to be placed on the market until the end of the validity of the relevant certificates issued by notified bodies.

CE marking: the CE marking and, where applicable, the identification number of the notified body may be accompanied by a pictogram or other marking indicating the risk against which the PPE is intended to protect. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Notification of conformity assessment bodies: accreditation should be the general rule for notified bodies. Members also stipulated that:

- Member States must notify manufacturers if a notified body has ceased activity;
- any appeal procedure must be transparent and accessible.

Market surveillance: noting that the existing PPE legislation is in need of updating in line with the New Legislative Framework (NLF) on regulation of goods, Members introduced a new Chapter that will take into account: the requirements of the market surveillance regulation when the latter has been finalised; Union market surveillance and control of products entering the Union market; procedure applicable to PPE presenting a risk at national level, safeguard measures, etc.

Requirements for employers: Members clarified the requirements for employers who provide PPE to their employees. Accordingly, employers shall provide PPE that complies with the relevant Union provisions on design and manufacture with respect to safety and health.

Personal protective equipment

The European Parliament adopted by 577 votes to 48, with 86 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on personal protective equipment.

Parliament?s position, adopted at first reading following the ordinary legislative procedure, amended the Commission proposal as follows:

Purpose and scope: the Regulation lays down requirements for the design and manufacture of personal protective equipment (PPE) which is to be made available on the market, in order to ensure protection of the health and safety of users.

Amendments aiming to include in the scope of the Regulation equipment to protect against cleaning materials of weak action or prolonged contact with water. Other substances and mixtures which are hazardous to health include atmospheres with oxygen deficiency and harmful biological agents which are now inserted into Annex I, Category III which includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health.

Excluded from the scope of the legislation are PPE:

- designed to be used for self-defence, with the exception of PPE intended for sporting activities;
- designed for private use to protect against atmospheric conditions that are not of an extreme nature and damp and water during

dishwashing;
- for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States;
- for head, face or eye protection of users, that is covered by Regulation No 22 of the United Nations Economic Commission for Europe on uniform provisions concerning the approval of protective helmets and their visors for drivers and passengers of motor cycles and mopeds.

Definitions: PPE should also mean:

- equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety;
- connexion systems for equipment that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use.

Obligations of economic operators (manufacturers, importers, distributors):

Manufacturers and importers shall, when deemed appropriate with regard to the risks presented by PPE, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.

Manufacturers shall:

- ensure that the PPE is accompanied by the instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible;
- either provide the EU declaration of conformity with the PPE or include in the instructions and information the internet address at which the EU declaration of conformity can be accessed;
- further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE with this Regulation.

CE marking: the CE marking shall be affixed before the PPE is placed on the market. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Accreditation system: in the recitals, it is stipulated that the system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008.

Transparent accreditation ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies.

However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements

Appeal against decisions of notified bodies: notified bodies shall ensure that a transparent and accessible appeal procedure against their decisions is available.

Market surveillance: in line with the New Legislative Framework (NLF) on regulation of goods and in order to ensure legal certainty, Parliament proposed to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to PPE covered by this Regulation. Members also introduced provisions relating to the procedure at national level for dealing with PPE presenting a risk, Union safeguard procedure as well as PPE presenting a risk for the health and safety of persons.

Personal protective equipment

PURPOSE: to update internal market rules for personal protective equipment, in order to enhance consumer safety and ensure fair competition between companies.

LEGISLATIVE ACT: Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC.

CONTENT: the new Regulation updates the existing rules in directive 89/686/EEC. It lays down requirements for the design and manufacture of personal protective equipment (PPE), which is to be made available on the market, in order to ensure protection of the health and safety of users and establish rules on the free movement of PPE in the Union.

Scope: personal protective equipment offers protection against all kinds of hazards (e.g. heat, flames, chemicals, flying particles, mechanical shocks, etc.) in a range of different environments, whether it be the home, at work or on the sports field.

Examples include: head/ear/eye protection, breathing protection, body protection, and hand/leg/foot protection. Products intended for private use to protect against atmospheric conditions that are not of an extreme nature or to protect against damp and water, including dishwashing gloves, fall outside of the scope of the Regulation.

This Regulation covers PPE which is new to the Union market when it is placed on the market; that is to say, it is either new PPE made by a manufacturer established in the Union or PPE, whether new or second-hand, imported from a third country. It applies to all forms of supply, including distance selling.

Obligations of economic operators (manufacturers, importers, distributors): all economic operators intervening in the supply and distribution chain must take appropriate measures to ensure that they make available on the market only PPE which is in conformity with the Regulation.

In particular, manufacturers must ensure that PPE has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II. They must:

- implement the conformity assessment procedures established by the Regulation. These procedures are linked to the degree of risk involved;
- keep the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the market;
- carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring;
- ensure that the PPE which they place on the market bears a type, batch or serial number or other element allowing its identification;
- indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the PPE;
- ensure that instructions and safety information, as well as any labelling, is clear, understandable, intelligible and legible;
- further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE with the Regulation, in a language which can be easily understood by that authority;
- immediately take the corrective measures necessary to bring PPE into conformity, to withdraw it or to recall it, as appropriate.

For their part, importers must make sure that they do not place on the market PPE which does not comply with requirements or which present a risk. They must also make sure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection by the competent national authorities.

CE marking: the CE marking shall be affixed before the PPE is placed on the market and affixed visibly, legibly and indelibly to the PPE or affixed to the packaging and to the accompanying documents. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect. Member States shall take appropriate action in the event of improper use of that marking.

Notifying authorities: the Regulation sets requirements for notifying authorities responsible for conformity assessment bodies. These bodies must apply the conformity assessment procedures without creating unnecessary burdens for economic operators. Interested parties have the right to appeal against the result of a conformity assessment carried out by a notified body.

Market surveillance: in the context of aligning the legislation on PPE with the new legislative framework for the marketing of products, and in order to ensure legal certainty, the rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to PPE covered by this Regulation.

The new Regulation also contains provisions regarding procedures at national level for dealing with PPE presenting a risk, Union safeguard procedures, and compliant PPE which presents a risk to health and safety.

Transitional provisions: Member States shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in conformity with that Directive and which were placed on the market before 21 April 2019.

ENTRY INTO FORCE: 20.4.2016.

APPLICATION: from 21.4.2018, with the exception of certain provisions which apply from

21.10.2016 or from 21.3.2018.

DELEGATED ACTS: the Commission may adopt delegated acts in respect of amending the categories of risks against which the PPE is intended to protect users. The power to adopt delegated acts shall be conferred on the Commission for a period of 5 years (which may be tacitly extended) from 21 April 2018. The European Parliament or the Council may raise objections to a delegated act within two months from the date of notification (which may be extended by two months). If the European Parliament or the Commission raise objections, the delegated act will not enter into force.