

The Consumer Voice in Europe

PROPOSAL FOR A DIRECTIVE ON REPRESENTATIVE ACTIONS

BEUC position paper



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Why it matters to consumers

Too often consumers suffer damages from a trader or company without any realistic possibility of getting compensation. The *Dieseltgate* scandal is a painful reminder that consumers are not in a position and do not have the resources to sue a company in court alone. Having the ability to band together with other consumers who have suffered the same or similar damages would change that. It is high time that all EU consumers are given this right of taking collective action for redress. It would create a better enforcement system of consumer law and give consumers more power when things go wrong.

Summary

BEUC welcomes the Commission proposal on representative actions. The proposal is crucial to strengthen private enforcement of consumer law and give consumers a realistic chance of obtaining redress for damages caused by mass infringements of the law.

Collective redress actions by qualified entities would plug a huge gap in the enforcement of EU consumer rights. Once adopted, with certain amendments as proposed below, the law would mean that EU consumers will no longer be helpless in the face of a future *Dieseltgate* or similar scandal.

The European Commission has been closely looking at this issue for many years. It has issued multiple studies and public consultations. Unfortunately, the debate has often been dominated by exaggerated fears of abuse and damage to business that collective redress actions might cause. Various safeguards have been discussed to prevent this potential abuse.

However, it is rarely highlighted that collective redress is needed because and in case when traders abuse consumers and cause damage to their interests. Unfortunately, in most countries, consumers remain empty-handed, while there are various mass breaches of consumer rights in the Single Market.

BEUC strongly supports this proposal. The European Commission has come up with a balanced system with procedural norms and safeguards to ensure that both the interests of consumers and of traders can be taken into account. Unfortunately, several elements of the proposal could undermine the added value of the new procedure to European consumers. Those elements concern:

- The level of harmonisation;
- The requirement for the injunction to be final before the qualified entity can ask for redress measures (article 5);
- The possibility to derogate from collective redress (article 6 paragraph 2);
- The designation of qualified entities (article 4);
- The financing of cases (articles 7 and 15);
- The scope and the review clause for passenger rights (the annex and article 18 paragraph 2);
- Cross-border representative actions (article 16)

1. Level of harmonisation

Member States must have wide options about how the new provisions of this law would work with their own procedural and substantial laws. The new directive should allow EU countries with currently higher standards to retain them. It should also allow EU countries to introduce national procedures that grant qualified entities more extensive rights to file representative actions, creating a higher level of protection of collective consumer interests than those provided for in this directive.

The provision (Article 1.2) which states that the Directive does not prevent adopting, or maintaining in force, provisions concerning other procedural means to bring actions to protect the collective interests of consumers at national level is not enough Recital 24, indicating that national mechanisms need to comply with the modalities of this directive complicates the understanding of the relationship of the proposed procedure with national laws.

This could have the result that EU countries where collective redress mechanisms currently exist and are being used (for example, Belgium, France, Italy, Portugal or Spain) will have to change their procedures in a way that will weaken the situation for consumers – for instance, if there will be a requirement to wait for the final injunction order (no such requirement in those countries currently). Or if the wide scope of the current mechanism, for example, in Belgium or in Portugal is limited to the list of EU legislation. There is no reason to downgrade well-established and relatively well-functioning systems. Another unwanted consequence would be that these countries are able to keep their current system but nevertheless would need to transpose this directive. This would result in there being two parallel procedures to be used for the same type of cases. Such a situation would create confusion both for consumer representatives and businesses.

To address these problems, it is essential to clarify, that the directive is of a **minimum harmonization** character. The text (Article 1 paragraph 2) needs to be amended to include a clear provision on minimum harmonisation, allowing Member States to make the procedure more favourable to consumers and to maintain their own systems This will also help avoid the above-mentioned problem of parallel procedures in the countries where collective redress already functions well.

BEUC policy demands:

BEUC calls for a clear indication in Article 1 that the directive is of minimum harmonization. This Directive should not prevent Member States from adopting or maintaining in force provisions designed to grant qualified entities more extensive rights to bring representative actions (both actions for injunction orders and redress measures) ensuring higher level of protection of collective consumer interests, than those provided for in this Directive.

2. The link between injunctions and redress actions (Article 5)

The proposal establishes a very close link between an injunction and a redress action. This comes from the fact that the initiative is based on the REFIT review of the Injunctions Directive.¹ However, this link is artificial, as the procedures are of a very different character and objective:

- The injunction action is in principle preventive, as it aims to stop the appearance or the continuation of an infringement.
- The injunction is usually brought to stop the action that harms collective consumer interests in abstract and does not refer to the agglomeration of individual interests/rights of a group of people.
- The collective redress action is about repairing the harm done to a number (whether defined or not) of individual interests.

The precondition of having an injunction order (let alone the final injunction order, as in Article 5.3) to be able to launch redress proceedings is not a requirement in any of the EU countries where there are functioning national collective redress procedures (Belgium, Italy, France, Spain or Portugal).

The requirement of having an injunction order which is final is particularly problematic. It can take many years before a decision is final - in most cases consumers will no longer have either the evidence of the damage or even the product in question anymore. It may incentivise defendants to drag the litigation out as long as possible with the hope that redress actions will become impractical. In addition, there are a lot of cases where the infringement has already stopped or is no longer evident, so there is no need to go through the injunctions procedure at all².

BEUC policy demands:

BEUC calls for the separation of the injunction and redress procedures. If they are brought together (which should certainly remain an option), it should be possible to introduce claims for the declaration of the infringement and for redress at the same time in a single action, without waiting until all the possibilities to appeal the injunction are exhausted.

¹ Directive 2009/22 on injunctions for the protection of consumers' interests (OJ L 110, 1.5.2009).

² For example, a company, when selling their products, was deliberately misleading consumers in relation to the legal guarantee, pushing the customers to buy the commercial warranty. Even if the company changes the practice after a while, the consumers, who bought the commercial warranty due to the previous misleading practice, might still want to launch a case for compensation.

3. Redress actions (Article 6)

The proposal foresees the obligation for EU countries to ensure that qualified entities can bring representative actions seeking a redress order. It leaves it up to Member States to define the procedure. We agree that Member States need to be given enough discretion to be able to take into account national legal traditions and procedural specificities. However, the provisions outlined below go too far in that respect.

3.1. The possibility to derogate from the collective redress procedure

3.1.1. Complex quantification of consumer harm

Article 6 paragraph 2 foresees the possibility for Member States to derogate from the proposal in cases where individual redress is complex to quantify, leaving consumers to act only individually.

This possibility, if used by Member States, might have the effect of seriously undermining the usefulness of the new procedures.

First of all, it is not clear what this complexity entails. The complexity of damage calculation is a regular element of lawsuits, especially of collective redress cases. This provision would exclude an entire range of redress cases, and in particular the ones where collective redress is most needed, such as for instance Volkswagen Dieselgate fraud, mis-selling of various financial services or product liability cases. The possibility of derogation in those cases impedes the entire idea of collective redress.

Recital 19 lists two requirements for the use of this derogation: i) where the quantification of the harm is complex and ii) where it would be inefficient to carry the action as a representative action. It is not clear what this inefficiency means and how could it be more efficient to bring individual actions, especially in the mass damage cases as indicated in the paragraph above. Hundreds of thousands or even millions of consumers can suffer damage because of one breach of law. If the derogation is used, even if those consumers could rely on the declaration of the infringement, they would still have to prove both their individual damage and the link between the illegal behaviour and the damage. Both of those elements are likely to require expensive legal, technical or expert opinions, which will be huge barriers for individuals.

The possibility of the derogation from collective redress procedure in cases where individual redress is complex to quantify should therefore be removed from the proposal. If there are specific rules under Member State's laws on the exact quantification of damages suffered by consumers concerned by the representative action, Article 1 should make clear that national rules on *how* to quantify or calculate consumer harm stay untouched by the Directive. As stated in general in Article 1 para 2, the Directive the Directive does not impair other procedural means to bring actions aimed at the protection of the collective interests of consumers at national level³.

³ Including declaratory judgements in situations where according to the national rules on damage calculation consumers will not be able to obtain full redress as a result of a redress order.

3.2. Cases of small damages

Another category of collective redress is described in Article 6 paragraph 3b and concerns cases where consumers have suffered a small amount of loss and it would be disproportionate to distribute the redress to them. In these situations, the redress should be directed to a public purpose serving the collective interests of consumers.

BEUC supports this provision. Indeed, even if the individual consumer harm might sometimes be very small (for instance, several euros), the aggregated amount of damage can run into the hundreds of thousands of euros. It makes a lot of sense that this kind of redress does not stay in the pockets of the infringer and can at least reach consumers indirectly, by being diverted to certain specific causes or projects serving consumers. It is very important to avoid that the money is simply directed towards the state treasury, as that would not result in effective compensation to consumers.

Some important clarifications are nevertheless needed:

- i) Collective redress is a mechanism first and foremost for compensating consumers, so even in small amount cases there should be an investigation into whether there is a possibility to direct the redress to individual consumers;
- ii) In situations where it is too disproportionate or impossible to directly compensate consumers, the judge or the authority should be allowed to estimate the aggregated amount of the compensation/amount of profit from the infringement, as the exact calculation will not always be possible;
- iii) It should be very clearly defined where to the collected funds go and for what purpose;
- iv) Even if this type of action should not require a prior mandate from consumers, the court or the authority should nevertheless ensure that there is sufficient information and time for consumers to 'opt out', if they feel they do not want their part of compensation to go to a public purpose or are thinking of pursuing their rights via an individual action.

4. Qualified entities (Article 4)

We strongly support the provisions that Member States designate consumer associations as qualified entities. Experience in the EU countries which have a national collective redress procedure clearly shows that consumer associations successfully make use of this possibility.

We believe the requirements for qualified entities are clear and sufficient and will ensure that only well-grounded cases are taken forward.

The national experience in the EU also shows that it is not enough if only public bodies are entitled to bring collective actions. For various reasons they often do not act. In addition, some countries⁴ traditionally rely on private enforcement rather than on public enforcement. It could therefore be problematic for them to be obliged to find public bodies for all areas covered by the Annex. The result of this Directive should not be that those countries are obliged to change their well-established enforcement systems just to be able to nominate public bodies as qualified entities for representative actions.

⁴ Austria and Germany.

This requires an amendment, in Article 4 paragraph 3, clarifying that Member States must ensure that in particular consumer organisations and, **where applicable** public bodies, are eligible for the status of qualified entity.

We strongly support the provision in Article 4 paragraph 3 giving the option to Member States to designate as qualified entities consumer organisations that represent members from more than one Member State. Umbrella organisations may in future have an important role in dealing with EU-wide infringements.

5. Financing of cases (Articles 7 and 15)

Even in the most legally promising cases, the decision on whether to launch a collective case involves financial risks and depends on the financing that is available. Such actions can be very expensive and are highly risky as a result. Most Member States do not allow qualified entities to require any, even symbolic, payments from consumers or to ask them to become members of that association as a pre-condition to be represented. In addition, even when consumer organisations win the case, they are often not able to recover all the costs within the action.

In this situation, even the biggest associations can struggle to find the necessary funds to bring collective actions.

The proposal foresees, in Article 15, that Member States should ensure that the procedural costs do not prevent qualified entities from bringing cases. In this respect, EU countries should look into setting a threshold on applicable court or administrative fees, granting qualified entities access to legal aid or providing them with public funding for this purpose.

Given the public interest of collective actions which consumer organisations usually take, we also suggest an adaptation of the court costs. For instance, Portugal has a very effective system where the application of the 'loser-pays' principle is limited to qualified claimants in collective actions. Under the Portuguese Consumers Rights Law, consumer claimants who launch a 'popular action'⁵ are exempted from the preliminary costs of bringing a case. When the case is successful they do not pay the court fees, and when they lose, they only pay between 10% and 50% of these fees at the discretion of the judge (the plaintiff association might pay more only when the claim is considered abusive). In contrast, the defendant will have to pay the court fees whatever the issue of the case. This system is excellent to guarantee full access to justice for collective claims.

The Portuguese rules on costs are reproduced in the Maltese collective redress procedure.

In France and Italy, the judge can decide not to apply the 'loser pays' rule when the claim brought was not unfounded and the defendant has enough financial means to cover the expenses.

No abuse or inflation in the number of collective cases has been observed in these countries.

⁵ Portuguese collective redress system, in place since 1995, with a very broad scope and an opt-out principle.

Business representatives often raise concerns about the use of third-party funding. But when third - party funding is used - the proposal includes several safeguards in Article 7. Various Member States use third party funding in different ways. In some countries, for example Austria, it is in use for many years already with very positive experiences and results. In fact, collective consumer cases would not even be possible in Austria without third-party funding. In other countries it is known less and there is more apprehension about using it.

Due to these different situations, we suggest that the provisions in Article 7 paragraph 2 are deleted. Member States should be obliged to make sure that there are adequate safeguards that they deem necessary taking into account the need for such funding and other national legislation in place. Member States would be better placed to take into account national needs and sensitivities.

6. The scope

6.1. Scope of application (Annex)

This new instrument could make a real change in areas where there is mass consumer harm.

Unfortunately, the material scope of the proposal (both for injunctive and redress actions) is based on a list of EU legislation. The Commission has proposed quite a comprehensive list, much wider than in the previous Injunctions Directive. However, some important elements are still missing.

In principle we believe the **closed list** approach is not the best option, as it is not future-proof and leaves no space for courts to act when there is a recognised consumer interest, but the specific law is not included. A number of Member States have open clauses. The 2013 Recommendation on collective redress also followed an 'open clause' approach.

If it is made clear that the directive is of minimum harmonisation, as we suggest in *Section I* of this paper, the minimum harmonisation nature should also apply to the annex.

Alternatively, there could be an amendment to ensure the list is of an open nature:

"Qualified entities may bring actions according to this [Directive] to protect consumers interests against violations of Union law. Such interests may consist in, but are not limited to, the enforcement of rules of consumer protection, competition, environment protection, protection of personal data, protection in energy and telecommunications markets, passenger rights, for product and food safety and information, health and medical services, financial services and investor protection."

We strongly suggest including damages resulting from infringements of competition in the scope of this directive. Consumer harm is often massive in this area but can be too dispersed for consumers to pursue it individually. Many EU countries where collective redress systems function efficiently also allow private damages claims resulting from competition infringements to be brought using the same collective procedures.

If the above-mentioned approaches to make the list in the Annex open or non-exhaustive should fail, there is a need to add a number of important pieces of EU legislation, especially relating to potential infringements in areas of health, product safety and connected products.

Please see the annex of this position paper for the exact list of legislation we propose to be added.

6.2. Review clause for passenger rights (Article 18.2)

BEUC finds it crucial that the wide scope of the proposal is preserved, and that it includes passenger rights.

The re-evaluation clause in Article 18.2, opening the door to removing air and rail passenger legislation from the scope of the directive in the future, is unacceptable and should be deleted. Otherwise consumers facing mass harm situations in this area, e.g. last-minute mass flight cancellations, would be stripped of a possibility to collectively enforce their rights before the courts.

The enforcement mechanisms set up by EU legislation on air and rail passenger rights⁶ do not ensure a comparable level of redress possibilities to those offered by the proposal on representative actions.

The claim procedures set up in Regulation 261/2004 on air passenger rights in the event of denied boarding, long delays and cancellations and Regulation 1371/2007 on rail passenger rights result in **non-legally binding opinions** of the relevant national enforcement bodies (NEBs) as to the application of the Regulation in an individual case. This means that if the airline or the railway company does not agree with the enforcement body's interpretation of the regulation, the passenger is still obliged to engage in legal proceedings before the court in order to enforce his/her rights. There is no way to do it collectively if a Member State in question does not provide a national collective redress procedure that includes passenger rights in its scope.

The pending proposals on air⁷ and rail⁸ passenger rights do not foresee any rights for consumers to get compensation collectively neither.

⁶ Regulation (EC) No 261/2004 establishing common rules on compensation and assistance to passengers in the event of denied boarding and of cancellation or long delay of flights (OJ L 149, 11.6.2005) and Regulation (EC) No 1371/2007 on rail passengers' rights and obligations (OJ L 315, 3.12.2007).

⁷ Proposal for a Regulation amending Regulation (EC) No 261/2004 establishing common rules on compensation and assistance to passengers in the event of denied boarding and of cancellation or long delay of flights and Regulation (EC) No 2027/97 on air carrier liability in respect of the carriage of passengers and their baggage by air (COM/2013/0130 final).

⁸ Proposal for a Regulation on rail passengers' rights and obligations (recast) (COM/2017/0548 final).

Learning from past experiences, we know that thousands of passengers can be affected by similar incidents, for example mass last-minute flight cancellations by Ryanair in September 2017 and the pilot strikes in autumn 2018. In such cases, , passengers will only be able to go to court individually to fight for their rights. A possibility to seek collective redress in such situations would significantly increase enforcement levels and lower litigation costs.

It should be kept in mind that adhering to the Alternative Dispute Resolution (ADR) bodies is currently not mandatory for the airlines. This means many passengers are unable to use ADR procedures. Moreover, many ADR bodies that do solve individual passenger claims do not deal with collective cases.

BEUC asks to delete the revision clause in Article 18 paragraph 2.

6.3. Definition of damages

The proposal does not define damages – this is left to Member States. However, it is very important to at least harmonise that **both economic and non-economic damage can be subject to redress measures** in representative actions. For example, if a collective case is brought based on data protection⁹ or e-privacy¹⁰ legislation (for instance, based on the Facebook/Cambridge Analytica data scandal) non-economic damages resulting from the data breaches should also be covered. The same should be true in cases of other infringements resulting in moral damages.

We suggest clarifying, in Article 6 paragraph 1, that redress measures can be requested both with respect to economic and non-economic damages.

7. Information to consumers

We strongly support the provisions in Articles 9 and 15.2 obliging the trader, against whom the injunction was issued, to cover the costs of informing consumers. It is crucial for the effectiveness of actions and for their deterrent effect on the infringer that the cost of informing consumers both about the decisions establishing the infringements and about any further redress measures are borne by the trader.

Article 9 paragraph 2 already mentions some safeguards that are needed to ensure that the infringing trader will inform consumers in a clear and intelligible way. However, we strongly **suggest adding that the information note from the trader to consumers, as well as the timeframe to inform, has to be approved by the judge or by the authority overseeing the case.**

⁹Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (OJ L 119, 4.5.2016).

¹⁰ Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector (OJ L 201, 31/07/2002).

8. Evidence

We strongly support the provisions on obtaining evidence in Article 13. There is usually a big asymmetry in the information available to consumers (or their representatives) and to traders. The judge or the authority needs to be able to request the trader to disclose certain pieces of evidence.

We want to underline that access to evidence that is in the possession of the defendant is a normal evidence procedure, and not particular to collective actions, so it should not raise any specific concerns.

For comparison, Article 5 of the EU Directive on Rules governing Actions for Damages for Infringements of Competition Law¹¹ goes much further in terms of access to evidence.

9. Cross-border representative actions

The Injunctions Directive lacks effectiveness when it comes to cross-border cases. In sharp contrast to the intention of the lawmaker, the directive has rarely been used by qualified entities to seek an injunction in front of the court of another Member State. As national courts apply their domestic procedural law to such disputes, it is expensive to litigate in foreign countries and the outcome of proceedings is unclear.

It is positive that the proposed new directive tries to make cross-border actions easier. It does this by providing Member States with the option to designate as qualified entities consumer organisations which represent members from more than one Member State. However, the directive does not address the problem that in many cases a qualified entity will be reluctant to sue traders before the courts of another Member State.

In general, problems of international jurisdiction and applicable law are not addressed by the proposal. Art 2(3) makes clear that rules on private international law stay untouched. Regarding the competent court, the Regulation 1215/2012 on International Jurisdiction and Enforcement of Judgments (Brussels I Recast Regulation) sets out the basic rule that persons are to be sued principally in the courts of the respective Member State where they are domiciled (Art 4). Only by virtue of special jurisdictional grounds, litigation against foreign traders is possible before domestic courts.

In this context, the Court of Justice already showed reluctance to give consumer organisations privileges. As they are not considered 'consumers', they cannot use the jurisdictional privilege under Article 16 and sue a foreign trader before their home court. This provision does not apply to proceedings that involve multiple claims assigned to a consumer organisation by consumers.¹² Consumer organisations may rely on the special jurisdiction tort law matter (Art 7(2)), according to which they can represent domestic consumers by bringing a preventive action against a foreign trader before the courts where the harmful event occurred, which is the Member State where the consumer organisation is domiciled. This option cannot be used when it comes to consumers domiciled in other Member States. In this case, courts from different Member States would be competent for different consumer-related representative actions. It is also unclear to what extent this

¹¹ Directive 2014/104/EU of 26 November 2014 on certain rules governing actions for damages under national law for infringements of the competition law provisions (OJ L 349, 5.12.14), Article 5.

¹² Case C-89/91 *Shearson Lehman Hutton*; Case C-167/00 - *VKI v Henkel*.

option can be used to seek redress measures under Article 6 of the proposed directive. Those measures may relate to concrete contractual obligations and may require “the mandate of the individual consumers” (paragraph 1, last sentence).

Applicable law also remains unclear especially if, in the country of the consumers, a certain contract term would be considered unfair but would be legal in the country where the trader is established.

From all this follows that consumer organisations face many difficulties when suing a trader who is domiciled in another Member State. The objective of the representative actions’ proposal should clarify that consumer organisations can take the measures prescribed in the proposal before a single court which is the Member State where they are based. Only then can legal uncertainty be avoided, and the new rules be deemed effective.

10. Effects of final decisions

We strongly support Article 10 on the effects of final decisions. It would be very helpful for qualified entities if they could rely on the earlier final decisions regarding infringements (both nationally and cross-border) when bringing subsequent redress cases.

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Annex to the position paper

EU legal acts to be added to the Annex of the Proposal for the EU directive on representative actions for consumers:

1. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002).
2. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014).
3. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (OJ L 157, 9.6.2006)
4. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016).
5. Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011).
6. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014).
7. Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014).
8. Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (recast) (OJ L 178, 28.6.2013).
9. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (OJ L 396, 30.12.2006).
10. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009).
11. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009).
12. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004).
13. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014).

14. Directive on security of network and information systems (NIS Directive) 2016/11/48 (contains security obligations for special types of economic actors regarding the security of their networks, includes cloud service providers, online marketplaces and search engines).
15. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017).
16. Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004).
17. Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (OJ L 263, 9.10.2007).
18. Regulation (EC) 1924/2006 of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006).
19. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002).



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