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Consumer priorities for the Greek Presidency

In this Memorandum for the Greek Presidency of the Council of Ministers, The European Consumer Organisation (BEUC) presents its consumer policy priorities and urges policymakers to strengthen efforts to pass important consumer files before the end of the current European Parliament’s remit.

In particular, the Memorandum draws attention to the following issues:

- **Product safety and market surveillance**: Consumers’ exposure to unsafe products need to be minimised and market surveillance improved;
- **Package travel**: The legal protections for holidaymakers who book travel packages need to be modernised;
- **Common European Sales Law**: This so-called ‘optional’ regime is not needed but will make cross-border trade more costly and complicated for consumers and business alike;
- **Data Protection**: An update of EU’s personal data protection rules should strengthen citizens’ protection and control over their own data;
- **Key Information Document (KID) for retail investment products**: Consumers need to be able to easily compare different kinds of products before deciding how to invest their savings;
- **Payment accounts**: Bank account fees should become more transparent, switching of accounts made easier and all EU consumers given access to a basic bank account;
- **Official controls of food**: Transparent controls, independent inspections and tougher enforcement can help restore consumer trust in food and the food chain;
- **Medical devices**: The revision of the current laws on medical devices should lead to improving the quality and safety of the medical devices sector, thereby restoring consumer trust.

Other important initiatives concern the telecoms market, air passenger rights, meat origin labelling, and bank deposit guarantee schemes.

We hope that under the Greek Presidency progress will be made on all these initiatives with the aim of delivering clear benefits to European consumers.

We wish Greece a most successful Presidency.
A proposal for a Common European Sales Law regulation (CESL) introducing a ‘28th regime’ of law, covering business to consumer (b2c) contracts was adopted by the European Commission in October 2011. It consists of a set of rules which co-exist alongside national law and which can be “chosen” by the parties as the legal basis for the contract.

It would set aside the consumer specific regime of Private International Law (the Rome I Regulation) and circumvent the application of the relevant national, mandatory consumer protection provisions.

BEUC is not in favour of the introduction of an ‘optional’ regime for consumer contracts. There is no need to deviate from the traditional means of regulating consumer contract law. This 28th contract law regime would rule out the application of national mandatory consumer rules and prompt lower standards of protection than those currently enjoyed in key consumer law areas in many countries. It would give the trader the choice as to what level of protection the consumer benefits from.

Importantly, it would be confusing for consumers and businesses to deal with different regimes of contract law (national and European) thereby rather than facilitating cross-border commerce, it would become more complicated and costly for consumers and businesses alike.
Because consumers are much better protected by solid legal rights enshrined in national law than by an ‘optional’ measure offered or withheld from them by the trader, BEUC is in favour of reviewing and further harmonising the few remaining consumer contract law elements relevant for the Single Market, i.e. the rules for legal guarantees and for digital content products, instead of pursuing an ‘optional’ approach.

In the European Parliament, the Legal affairs Committee proposed to reduce the scope of the Regulation to e-commerce contracts (more precisely to distance selling contracts) only. BEUC believes such a reduction in scope would not help make this optional instrument more acceptable. Rather it underlines its redundancy because of the imminent application of the 2011 Consumer Rights Directive which significantly increases harmonisation of the most important elements of consumer contracts and online contracts in particular. This will be implemented by the end of the Greek presidency.

Currently, the Council is continuing to examine the provisions of Annex I of the proposed Regulation.

We urge the Greek presidency to ensure that the examination of the proposal and in particular the deliberations on the question of the necessity of such an instrument for business-to-consumer contracts will continue in detail in order to ensure that no decision will be taken in a rush.

**Our demands**

- European legislators should reconsider the need at all for this costly and time-consuming initiative, whether its objective of facilitating cross-border business for consumers cannot be met by much more effective, cheaper, swifter, less intrusive measures such as a European code of conduct for e-commerce transactions and the speedy implementation of the Consumer Rights Directive.
- The European Parliament’s ‘health check’ of the Commission’s Impact Assessment confirmed the Commission’s methodology to be dubious and in the most essential parts the quality and credibility of the data is questionable. We hope the Council will consider its results too.
- The proposed CESL, which aims to override EU private international law, is incompatible with Article 6(2) of the Rome I Regulation which aims to guarantee the application of higher consumer protection standards.
BEUC’s analysis shows that the level of protection in the proposal’s annex is not truly high. It does not match higher standards in numerous Member States on issues such as unfair contract terms or legal guarantees (e.g. the burden of proof or payment use).

- Digital content is an area in which the current situation is causing detriment to consumer rights, as clearly shown by two recent Commission studies. More legal certainty and modern consumer protections are needed at EU level. The CESL proposal includes modern rules in this field, but they will only be applicable if businesses deem them self-advantageous. Instead, BEUC calls for a non-optional legislative Directive to harmonise contract laws for digital products.

- In case the proposed CESL would not be rejected by the EU legislators, BEUC supports the European Parliament’s Internal Market and Consumer Protection Committee’s position to turn the Regulation into a normal non-optional Directive limited to legal guarantees and including rules for digital content. This would continue the successful harmonisation process for consumer contract law elements useful for the development of the Single Market. Instead of introducing a new era of optional regulatory EU tools inappropriate for consumer contracts, we call on the Commission to continue modernising consumer law by traditional methods – using full and minimum legislative harmonisation as appropriate – and completing the review of the consumer law acquis as originally envisaged.
Air Passenger Right’s Regulation

In March 2013, the European Commission presented a new proposal amending Regulation 261 from 2004 on compensation and assistance to passengers denied aeroplane boarding, affected by cancellation or long flight delays.

The proposal aims to clarify and extend some of the existing rights to situations of flight disruptions such as long delays not fully or clearly covered by Regulation 261/04. In addition, the proposal strengthens the enforcement of passengers’ rights and the right of redress of passengers in case of disputes.

The European Commission’s proposal contains a number of improvements to Regulation 261/04 such as the right to financial compensation for delayed passengers and the protection of passengers who miss a connecting flight due to a previous delay.

However, the proposal weakens consumer protection levels in some areas and does not codify the rulings of the EU’s Court of Justice in relation to long delays as it should.

The proposal also lacks the protection for passengers necessary in cases of airline insolvency. BEUC has long called for the introduction of the obligation for airlines to guarantee refund and repatriation of passengers in the advent of insolvency, emboldened by a 2012 European Commission study which identified significant passenger detriment.

Furthermore, the proposal does not tackle the longstanding problem of widespread unfair contract terms used by airlines and condemned by many national courts across the EU.

Thus major improvements remain necessary. We are concerned that the Council of Ministers will weaken the Commission’s plans and so we call on the Greek Presidency to place high importance on this proposal and resist weakening future or existing consumer rights.
• No reduction of existing legal protection levels when flights are cancelled or delayed.
• Protection extended to flights coming into the EU and operated by non-EU carriers; this is crucial for code-sharing with airlines based outside the EU.
• Passengers’ right to assistance in ‘extraordinary circumstances’ should not be restricted, as it is precisely in such cases passengers are most in need.
• Passengers’ right to compensation for long delays should follow the Court of Justice Sturgeon judgment. It ruled that flight delays of 3 hours or more triggers the right to compensation and was confirmed in two recent judgments of October 23, 2012 and February 25, 2013 (cases C-581/10, C-629/10 and C-11/11).
• Airline’s “technical problems” should not be considered “extraordinary circumstances” as is often done to exempt from paying compensation obligations. The ECJ judgment in the Wallentin-Hermann case should be duly incorporated.
• Ban “no-show” clauses which deny boarding and/or require additional cost if the outgoing or ongoing flight of their ticket is unused.
• Create a ‘blacklist’ of air transport unfair contract terms (based on existing court cases). The European Parliament has also called for such a list.
• Compensation levels should not be based on the price of the ticket – passenger loss when their flight is cancelled or lengthily delayed is related to the waiting time and other inconveniences, not the price of the ticket.
• The right to re-routing by other means of transport should be granted as soon as possible (the 12 hour timescale should be deleted).
• An EU-wide guarantee scheme to protect buyers of seat-only tickets against airline insolvencies should be established.
• Passengers should have the right to transfer their tickets to another person if they are prevented from travelling.
• Airlines should be obliged to adhere to Alternative Dispute Resolution (ADR) systems in order to solve consumer complaints.
Documents

- Air Passengers Rights – Revision of Regulation 261/04 – Presentation by Ursula Pachl at the hearing of the Transport Committee (X/2013/038)
- Revision of Regulation 261/04 on the rights of air passengers in the event of denied boarding, cancellation and long delays – BEUC’s position paper (X/2013/056)
- Public consultation on passenger protection in case of insolvency – BEUC response (X/2011/048)
- Protection of air passengers in case of insolvency of airlines (X/2011/105)
Revision of the Package Travel Directive

In July 2013, the European Commission proposed a revision of the Package Travel Directive 90/314. This was long overdue and intends to extend the rights of purchasers of travel combinations to situations not covered by the Directive of 1990. It aims to address the major changes in the travel market and consumer expectations since 1990. There has been a dramatic increase in internet sales, online travel agencies have emerged and low cost airlines have fundamentally changed the market.

BEUC welcomes the proposal’s extension of protection particularly to tailor-made and dynamic packages bought online. Yet the approach taken risks not serving the revision’s purpose by being inadaptable to a market in continuous movement. The proposed scope is too narrow. The focus is on the business models traders deploy rather than the expectations of the consumer when buying travel combinations. The proposal creates a new category of travel combinations called “assisted travel arrangements” (ATAs). These are not clearly distinguishable from the category of “packages”, yet, the seller of assisted ATAs (unlike “packages”) will not be liable for the performance of the additional services included in the arrangement.

This would mean traders who currently sell dynamic or traditional packages could easily change their business model to shed seller liabilities for “real” packages. The proposal to extend protection to ATA passengers in case of insolvency is welcome. However, the proposal is unclear about fundamental aspects of this new element. Contrary to the current Directive, the new proposal seems based on full harmonisation – which is highly problematic. Our preliminary evaluation shows in many Member States the review would reduce national protection standards, particularly contract law provisions (which are numerous in the proposal). Thus major changes are necessary to the Commission’s proposal to ensure it will provide for a save and efficient consumer protection measure.

We thus hope that the Greek Presidency will give high priority to this proposal, but we call on the EU legislators to take the time necessary for a thorough examination and assessment and not to rush into any premature agreement due to the upcoming changes in the European Parliament.
Our demands

- Ensure that the current Directive’s minimum harmonisation approach remains valid as the basic principle, but allow for some exceptions where necessary, provided the level of consumer protection is high enough.
- The definition of “packages” should be amended to ensure all so-called “click-through” contracts, which are concluded on the internet via linked websites, are covered.
- The information obligations in article 4 should include important items such as information on the right of withdrawal, protection against insolvency, formal requirement for information provision and sanctions for non-compliance.
- Package sellers’ information obligations should also apply to sellers of ATAs (assisted travel arrangements).
- Price increases after contract conclusion should be prohibited. Alternatively the upper limit for increases should be 3% and the consumer be informed at least 30 days before departure.
- The right of the consumer to be compensated for lack of conformity should not be undermined by an obligation of the consumer to notify such “on the spot”.
- Joint liability for the performance of the package vis-à-vis the consumer should rest with the organiser and the retailer.
- The prescription period for introducing complaints to the organiser/retailer should not be shorter than 3 years (article 12.6).
- Consumers should be able to withdraw from early booking contracts without penalty if concluded or negotiated off-premises or at a distance (including online).
- The sale of standalone services (only hotel, only accommodation etc.) via an agent or intermediary (online agency, online portal, airline) should also be covered by the Directive and establish information obligations, requirement to confirm the booking and liability for booking errors of the seller.
Antitrust damages actions

Background

Competition infringements which result in consumer detriment can occur every day – but the consumer victims are rarely compensated. Since its creation in 2004, the European Competition Network (network of European national competition authorities) has tackled more than 600 cases of competition law infringements; more than half of these cases related to cartels and certainly had a direct impact on consumers’ pockets.

However, almost no compensation claims have been taken by private individuals or consumer organisations. This is despite the jurisprudence of the European Court of Justice which has acknowledged the right of any person to obtain redress before national courts if they suffered harm because of an infringement of European competition rules.

The Commission published its proposal on antitrust damages actions in 2013. Its aim is to facilitate access to justice and compensation to the victims of anticompetitive behaviour. However, as it does not contain any provisions on collective redress, its impact can be totally lost on consumers, who are unlikely to claim compensation individually.

The Recommendation on collective redress, adopted by the Commission in 2013 is likely to be of limited impact and will leave consumers on very uneven grounds throughout the EU. Binding rules on the availability of collective actions are badly needed in order to make it possible for consumers to claim damages of anticompetitive behaviour.

We have high expectations for the Greek Presidency to conclude the negotiations – not only overcoming the various legal and procedural national differences, but also ensuring consumers benefit from this new legislation.
Our demands

- Consumer associations should be recognised, across the EU, as qualified entities to bring damages claims on behalf of the victims of anti-competitive behaviour.
- Member States should be obliged to introduce collective redress procedures for damages claims.
- Final decisions of national competition authorities shall be considered irrefutable proof of the infringement and be binding on the courts.
- There should be a rebuttable presumption that end-consumers (indirect purchasers) have borne the overcharging generated by unlawful practices.
- Access to evidence is indispensable: the victims must have access to the files held by the competition authorities and by the liable party under certain conditions.
- The cost of actions needs to be driven down, namely by the creation of a ‘fund for group actions’ and by other systems such as recourse to insurance.

Documents

- BEUC position Paper on Damages Actions (X/2013/067)
Cross-border enforcement of consumer rights

Background

Giving European consumers new or better rights is not much worth if those rights cannot be enforced properly. Enforcement is one of the major consumer policy priorities for the EU, as attested by the EU Consumer Programme and the European Commission’s Consumer Agenda.

The European Commission is rightly seeking ways to improve enforcement throughout the EU. The review of the Consumer Protection Cooperation Regulation which creates a network of national enforcement authorities and gives them powers to investigate cross-border infringement will be an important future step within this new policy.

Due to national divergences in enforcement approaches, cooperation is not always easy and needs to be developed further. In addition, European consumers increasingly face infringements of a pan-European nature and tackling such Europe-wide unfair commercial practices via separate national strategies is no longer an adequate option.

BEUC calls for a shift in enforcement perspectives from cross-border infringements to genuine enforcement without borders in the EU. If the Single Market is to deliver for consumers, modes must be found to effectively tackle both cross-border and pan-European infringements and guarantee coherent results.

Another way of making enforcement more efficient, the European Commission has announced an ‘enforcement dialogue’ with stakeholders, among them consumer organisations. We hope that under the Greek presidency this enforcement dialogue will be the subject of further discussion amongst ministers and enforcement authorities and that consumer organisations will be duly involved in this important process.
Our demands

- Valuable, constructive relationship building and information sharing between consumer organisations and national enforcers is a prerequisite for developing a new European enforcement culture.

- The European Commission’s enforcement dialogue should not be just a unilateral flow of information from consumer organisations towards enforcers. A crucial aspect here is that in order to enable real dialogue and information sharing which identifies and tackles infringements most effectively, consumer organisations need to be considered a genuine partner on a national level and be involved in co-ordination work at EU level.

- In order to fight European infringements, a discussion on the European Commission’s powers in the enforcement of consumer rights should be launched.

Documents

- Letter to European Commissioner Neven Mimica on cross-border enforcement (X/2013/084)

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Payment account package

In May 2013 legislation was proposed by the European Commission to give all EU citizens access to a basic payment account, ensure payment account fees are transparent and comparable and make switching payment accounts easier.

This initiative is highly important for several reasons – the Commission’s 2012 monitoring report of the implementation of the code of conduct on bank account switching revealed numerous shortcomings confirming BEUC’s own findings; 2011’s attempt to adopt another self-regulation measure on transparency and comparability of personal current bank account fees failed due to banks’ incapability of meeting the requests by both consumers and the European Commission. In addition, according to recent data, 10% of all EU consumers, i.e. 58 million Europeans aged 15 or above, do not have a bank account.

We ask the Greek Presidency to give high priority to the Commission’s proposal in order to finalise it prior to the European elections.
Our demands

- Ensure every consumer has the right to a basic payment account both nationally and at cross-border level, free of charge or for a nominal fee. Consumers legally resident in the EU should be able to open payment accounts in any Member State.
- Ensure consistency between the Anti-Money Laundering Directive (AMLD, adopted April 5, 2013) and the EU legislative proposal on payment accounts so that the AMLD provisions are not used by financial institutions as a means to exclude less financially valuable consumers; harmonise national interpretations of AMLD at national and cross-border level within the EU.
- Ensure information on payment account fees is transparent and comparable across financial institutions to enable consumers to shop for better deals and spur competition in the market by:
  - Developing glossaries of terms covering all the terminology linked to current accounts;
  - Fully standardising the terminology and presentation of fee lists;
  - Preventing banks from levying any fees and charges not stated in the fee lists;
  - Developing regularly updated independent price comparison websites, accessible to all consumers;
  - Providing annual and monthly fee statements to consumers and ensuring appropriate enforcement and monitoring.
- Remove all technical and legal obstacles to bank account switching to enable consumers to easily switch their bank accounts from one bank to another. In particular:
  - Provide better information and training of staff to ensure a smooth consumer switching experience across financial institutions;
  - Provide a system for automated redirection of payments from the transferring payment service providers (PSP) to the account held by the consumer with the receiving PSP during a period of 13 months;
  - Ensure that switching is free of charge for consumers;
  - Conduct a feasibility study on account number portability with a view to elaborating a technically feasible and efficient way to introduce it in the coming years.

Documents

- Transparency and comparability of payment account fees (X/2011/054)
- BEUC response to the public consultation on payment accounts (X/2012/042)
Deposit Guarantee scheme

The financial crisis and the recent decisions restructuring the Cypriot banking industry have shown that protecting consumers’ deposits is essential to restore consumer confidence in the banking sector and ultimately ensure its stability. Proposals to utilise deposits when banks fail have added to this uncertainty.

The Deposit Guarantee Schemes (DGS) legislation serves a crucial function – to ensure the protection of deposits while providing financial systems with the security to prevent bank runs. The European Commission’s Directive proposal of July 2010 contains many advances on the current legislation. In addition, the European Parliament who voted on DGS in February 2012 has adopted key provisions on high temporary balances and pay-out periods.

Trilogue negotiations have started recently after a long delay at Council level. Therefore, we call upon the Greek Presidency to finalise negotiations prior to the European elections.
Our demands

- BEUC supports the European Commission proposal to abolish compensation mechanisms between the liabilities of the depositor and his deposits; protection of the accrued, but not credited, interests; compulsory ex ante funding of the DGS.
- The guarantee limit should be per depositor and per brand, not per bank license.
- Protection for temporary higher balances is needed and the circumstances which lead to protection should be extended.
- Repayment of depositors should not be privileged over interventions to permit deposit transfers to another institution or to prevent failure.
- If the repayment does not occur within 7 days, the depositor should be entitled to early repayment.
- There should be no time limit on claiming repayment. Each DGS should settle a provision for all depositors whose identity is known, but who have not yet contacted the DGS.

Documents

- BEUC position paper on Deposit Guarantee Schemes (X/2010/083)
Enhance saver and retail investors’ protection: KID (PRIIPs)

Background

The complexity and long-term nature of investments make it difficult for the saver and retail investor to assess their suitability before a lengthy period of time has passed after deciding to invest.

The lack of comparability between different retail investments makes it impossible for the non-expert investor to make an informed decision regarding their investments. The mis-selling of long-term investment products is very harmful to consumers who, for instance, will not have sufficient revenue upon retirement.

The Regulation on Key Information Documents (KID) released in July 2012 has been the only legislative proposal since the beginning of the financial crisis whose unique purpose is to better protect savers and retail investors.

BEUC welcomes that the European Parliament in its plenary vote in November 2013 widened the scope of the law considerably by including life insurances and private pension products. It also obliges sellers of KID-products to disclose their commission as well as allow for products to be taken off the market if deemed unsuitable for their target buyers.

Now that the European Parliament has voted, we ask the Greek Presidency to initiate the trilogue negotiations without delay in order to finalise this dossier on the basis of the outcome of the EP vote prior the European elections.
Our demands

- BEUC welcomes the consumer protection improvements stipulated in the proposed Regulation on KID and asks for the following:
  - A highly standardised Key Information Document is essential to better inform consumers and make comparing easier. In order to achieve this, the KID should be compulsory for all savings and investment products and not only for packaged investment products;
  - Consumers need information from the distributor and not only from the manufacturer of a financial product. In order to make an informed choice and compare investment products, consumers must receive information on the real costs of their investment which includes the remuneration of the financial intermediary and the tax regime applicable to the investment products being recommended.

Documents

- BEUC brochure on retail investments ‘A good investment – How the EU can better protect consumer finance’ (X/2011/102)
- BEUC position paper on KID (X/2012/009)
The existing Insurance Mediation Directive contains principles that each Member State has implemented in substantially different ways and some important matters do not fall within its current scope: insurance products directly sold by insurance undertakings and insurance products sold on an ancillary basis are not regulated; lower standards for the sale of life insurance products with investment elements (e.g. unit-linked contracts) than to non-insurance investment products (regulated under the Markets in Financial Instruments Directive (MiFID), which leads to cross-sectoral inconsistency as market participants are offering insurance-based investments in place of other investments.

In 2012 the Commission adopted a proposal for a revision of the Insurance Mediation Directive (IMD2). The goal of the Commission’s proposal is to upgrade consumer protection in the insurance sector by creating common standards across insurance sales and ensuring proper advice. In the European Parliament, the leading ECON committee has still not voted on the file.

We ask the Greek Presidency to finally initiate deliberations on the issue and put it on the agenda of the Council.
BEUC welcomes the IMD proposal, as the harmonisation of sales rules for all types of insurance (including life insurance) is necessary to avoid loopholes in consumer protection and avoid regulatory arbitrage from the financial industry. This proposal needs to be improved in the following ways:

- All intermediaries selling insurance on an ancillary basis should fall under the Directive’s scope and should comply with all consumer protection provisions;
- Information about the insurance product should be given through a standardised information sheet;
- Ensure full consistency between the rules under MiFID and IMD as regards investment products;
- Avoid conflicts of interest and in particular ban contingent remuneration linked to any targets related to the activities run by the intermediary including sales volume and number of claims reported by clients;
- Not only should remuneration linked to a contract be disclosed, but all remuneration (including that in kind) linked to the mediation activity.

Documents

- BEUC position paper on IMD (X/2012/026)
Payment Services Directive (PSD) and Regulation on Interchange Fees (cards)

Background

Retail payment services are ubiquitous in consumers’ daily lives. There are several ongoing initiatives in the payments area. Following the Commission’s Green Paper ‘Towards an integrated European market for card, internet and mobile payments’, in July 2013 the Commission published two legislative proposals to achieve a competitive and efficient single payments market: the revision of the Payment Services Directive and a proposal for a Regulation on interchange fees for card-based payment transactions.

The European Parliament has taken up its work on both the Directive and Regulation. Votes in the leading Economic and Monetary Affairs committee are planned for February 2014. We ask the Greek Presidency to initiate deliberations within the Council and focus on consumer protection aspects and more effective competition rules.
Our demands

- Ensure all payment service providers are efficiently regulated and supervised.
- Ensure all payment services are accessible to all consumers and are secure, efficient and as cheap as possible. When paying, consumers should always have several payment options both for physical and remote transactions.
- Ensure the business model(s) for card payments do not constitute a barrier to competition in the payments market or entry to the market for new providers and new products.
- Ensure the Regulation on interchange fees does not harm cheap and efficient national card schemes.
- Ban payment surcharges on any means of payment at EU level: surcharging has been proven harmful to consumers and inefficient.
- Provide direct debit users with an unconditional refund right for authorised and unauthorised transactions, in line with recital 32 of Regulation No 260/2012 on SEPA direct debits and credit transfers.
- Reduce consumer liability for unauthorised payment transactions and provide a clear definition of ‘gross negligence’; ensure the Payment Services Provider refunds the payer with the amount of unauthorised payment transaction on the day it is made aware of the transaction.
- Ensure the host supervisory authorities are given supervision powers over payment services providers who originate from other countries.
- Ensure that Payment Services Providers have a data breach notification obligation and regularly provide data on fraud related to different means of payment to competent authorities.

Documents

- Factsheet on Multilateral Interchange Fees (X/2013/025)
- BEUC response to the Commission Green Paper consultation ‘Towards an integrated European market for card, internet and mobile payments’ (X/2012/022)
- BEUC position paper on the revision of the Payment Services Directive (X/2013/079)
- BEUC position paper on proposed Regulation on interchange fees (X/2013/077)

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In January 2012, the European Commission adopted a proposal for a Regulation on Data Protection which will replace the current 1995 Directive. The proposal aims to ensure a uniform set of rules across Europe, while strengthening the rights of individuals and facilitating the flow of personal data across borders. We welcome the numerous positive elements of the proposed Regulation.

The European Parliament’s leading Committee has already adopted its report almost unanimously, together with the mandate to start negotiations with the Council. The outcome of the vote is positive with MEPs strengthening key provisions of the proposal further.

In particular, the definition of personal data remains broad, while the new rules will apply to all companies offering services to EU consumers or monitoring their behaviour. The principles for processing, including transparency data minimisation and purpose limitation, have been strengthened, and the rights to data portability and erasure have been maintained. The European Parliament has also introduced strong safeguards with regards to transfer of data to third countries and has established multiple means for consumer redress.

BEUC calls upon the Greek Presidency to intensify the work on the proposed Regulation to ensure that the new rules are adopted in the current legislative term. The report of the European Parliament provides a good basis for an inter-institutional agreement to be reached. Europe can become the global leader by adopting strong and future-proof data protection rules.
Our demands

- The definition of personal data should remain broad and flexible in light of the rapidity of ICT developments. Pseudonymised data is, by definition, personal data as it relates to an identifiable individual and therefore falls within the scope of the draft Regulation.
- The scope of ‘legitimate interests’ as a ground for processing should not become a catch-all category. It can only be used as a last resort, i.e. when no other legal grounds are available and the data controller should prove that its interests override those of the data subject.
- As regards the principle of ‘purpose limitation’, the European Data Protection Board should be entrusted with the task of defining criteria to assess the compatibility of further processing with the original purpose for which data was collected.
- When subject to profiling measures, consumers should be informed of the possible consequences or effects this could have on them. Consumers should also be able at all times to object to the processing of their personal data for profiling purposes. Furthermore, the legitimate interests of the controller cannot be accepted as a legal ground for profiling.
- A dual system of notification of data breaches needs to be maintained, according to which all breaches must be notified to the data protection authorities while only those breaches which adversely affect the protection of personal data and privacy should be notified to individuals.
- The appointment of a lead Data Protection Authority and the establishment of a ‘one stop shop’ should not result in forum shopping. To mitigate this risk, the powers of the lead authority should not be exclusive.
- Judicial collective actions for compensation for harm suffered from data protection infringements should be introduced.

Documents

- BEUC key demands on the Proposal for a General Data Protection Regulation (X/2013/027)
- BEUC position paper on Data Protection (X/2012/039)
On 12 September 2013, the European Commission adopted a proposal for a Regulation that aims to establish a Telecoms Single Market. The proposed Regulation supplements the current regulatory framework, adding additional regulatory layers to the telecoms market and modifying existing legislation in some specific cases.

The proposal offers a good opportunity to remove barriers in the telecoms market by creating a true Single Market for European consumers. However, it carries the risk of significantly impacting the degree and quality of competition across Europe, both in fixed and mobile markets. Therefore, it is crucial the proposed measures are carefully analysed as regards their impact on consumers.

For consumers to reap the benefits of the digital era, access to telecoms networks and services needs to be guaranteed. Yet, many of the draft Regulation’s provisions fail to safeguard consumers’ interests: the provisions on users’ rights are below the current level of consumer protection in several Member States; the articles related to net neutrality do not sufficiently safeguard the openness of the internet against abuses by companies for their own commercial interests and the proposed new roaming regulatory mechanisms do not eliminate roaming altogether and are therefore far from satisfactory.

The Greek Presidency should ensure that the proposal is amended to protect the interests of consumers as a condition without which the proposed measures will not achieve the goal of a true telecommunications Single Market.
• Cross border services within the EU, such as international long distance calls and roaming services, should be offered at the level of domestic prices. The phase out of roaming charges can be gradual, but it should happen at a faster pace than is envisaged and be applicable to all European mobile customers.

• A thorough analysis of the impact of the proposed measures on domestic retail markets must be carried out, as companies will naturally tend to increase prices to balance decreases in revenue. Measures to avoid or reduce the impact of this increase must be included.

• The provisions on end-users’ rights, such as termination of contracts or notice periods on compensation for subsidised equipment for example, must be significantly improved because, as they stand, they effectively reduce the level of consumer protection in some Member States as compared to the current legislative framework.

• The articles that guarantee access to an open and neutral internet must be significantly improved. The definition of specialised service needs to be modified and the provisions which aim to shield the “best efforts” internet from unwarranted impact from specialised services need to be strengthened.

• Further analysis is needed on how the proposed Regulation affects investments in broadband infrastructure and how it can be ensured that sufficient broadband investments are dedicated to services that offer access to the internet.

• It must be ensured that the single EU Authorisation Regime does not entail a risk of “forum shopping” where operators will be able to pick and choose their home market, to the potential detriment of consumers.

Documents

- BEUC position paper on the Telecoms Single Market (X/2013/081)

For more information: digital@beuc.eu
Revision of the Regulation on Official Controls

Background

On May 6, 2013 the European Commission published a package of measures to strengthen the enforcement of health and safety standards for the whole agri-food chain. This package included the proposal on official controls. While the proposal aims to reduce the administrative burdens on industry by abolishing information obligations, it also calls for a more risk-based approach to controls across the chain. Although BEUC agrees with this approach, it is vital for transparency and clear communication when evaluating risk.

It is clear that, in recent times, consumer confidence in food and the food chain has, once again, been seriously dented. The horsemeat scandal demonstrated just how long and complex the food chain has become and, while this time it was not a food safety issue, highlighted just how costly this can be for consumers, the food industry and Member States. The current review provides an opportunity to take steps to prevent such a scandal from occurring again.

An important issue up for discussion is the financing of official controls. While up to now, only certain parts of the chain were subjected to fees, the intention is to require all food operators to pay, with the exception of micro-enterprises. BEUC supports the proposal, however, it must be ensured that the costs are not passed on to the final consumer. In addition, we do question the exemption of micro-enterprises to fees. It is essential that the risk posed by business is taken into account as small businesses can pose high risks.
We support provisions to permit increased transparency on inspection reports, whether it be by publishing inspection reports or providing information to consumers on the performance of food operators via schemes such as ‘score on the door’ or ‘smileys’. Not only is this providing useful information to consumers, but we also believe it can act as an incentive to food businesses to perform better.

We ask the Greek Presidency to do its utmost to finding an agreement which takes consumers concern fully into account and to ensure that the adoption of the proposal can advance quickly after the European Parliament elections.

**Our demands**

- More unannounced independent inspections looking at food authenticity in addition to food safety.
- Tougher enforcement with clear disincentives for illegal practices and tough penalties for those prosecuted.
- A requirement for the food industry to improve traceability and regularly test its products.
- Greater transparency on how and who decides on risk.
- Greater transparency to the public on how food businesses are performing through publication of inspection reports (e.g. on the internet), adoption by more Member States of schemes such as ‘score on the door’ or smileys.

**Documents**

- BEUC position paper on the Official Controls review (X/2013/050)
Recent years have seen a growing interest on the part of European consumers to know the origin of the food they buy. In response, some industry operators have recognised the marketing potential this provides and communicate the origin of their products. Indications such as ‘made in’, ‘product of’, etc. are multiplying on food labels as well as the use of flags, symbols or pictures which can indirectly imply or suggest a particular food’s origin (though sometimes in a confusing way).

While the origin must always be labelled for some foods – olive oil, fish (unless it is canned or prepared), beef (fresh, chilled, frozen or minced), fresh or frozen poultry of non-EU origin, wine, most fresh fruit and vegetables, honey and eggs – for all other foods origin labelling is only voluntary. This means that currently origin information is largely missing on foods such as meat products (e.g. ham and sausages), yoghurts and cheese, kitchen staples (e.g. oil, flour, sugar and pasta), biscuits and confectionery, or ready-meals. BEUC research showed that consumers want to know the countries where the animal was reared, slaughtered and where the meat was further processed into e.g. sausages or ready-meals.

Some issues related to origin labelling have already been addressed in the new EU food labelling legislation which will apply as of December 2014. Origin labelling will become mandatory on fresh, frozen and chilled meat of pig, poultry, sheep and goat. A Commission proposal governing the content of the information to appear on the label is currently being discussed with Member States, which suggests that the country of rearing and slaughter of the animal shall be labelled.

The European Commission is also due to produce a series of reports and studies looking at the feasibility of extending mandatory origin labelling to meat used as an ingredient in food, milk, milk used in dairy and single ingredient foods. When it comes to voluntarily declarations of origin by food manufacturers, new rules will ensure consumers are informed about whether a food’s primary ingredient(s) have a different origin to that stated on the packaging. However, what should be considered as the ‘origin’ of these primary ingredients is still open for discussion (place of farming or country of last substantial processing).

Following the horsemeat scandal, we call on the Greek Presidency to ensure that consumer demands for information on the origin of meat food ingredients are not ignored.
Our demands

- The Commission’s proposal for origin labelling on fresh meat (whereby the countries of rearing and slaughter would have to be labelled) is a step in the right direction even though we would have preferred the beef model (which requires labelling of the countries of birth, rearing and slaughter). However, it should not result in changes being made to current origin labelling rules for beef (for which the country of birth is also required). Moreover, the “rearing” stage should cover a sufficiently long period of time in order not to mislead consumers and the latter should know if the animal was reared in several countries.
- The origin of a food’s primary ingredients should be defined as the place of farming of the raw materials (e.g. wheat for flour used in a cake; sugar beets/canes for sugar used in chocolate; milk for cheese or pig for ham used on a pizza). It should be given at least at the same level of precision as for the food itself.
- Origin labelling should also become mandatory for milk (including when used as an ingredient in dairy), unprocessed foods (e.g. pre-cut fruit and vegetables), single-ingredient foods (e.g. flour, sugar, oil) and ingredients that represent more than 50% of a food.

Documents

- Where does my food come from? – BEUC consumer survey on origin labelling of food (X/2013/006)
- Origin labelling on food – BEUC factsheet (X/2013/005)
Review of the food hygiene package

The European Commission is currently reviewing the EU’s hygiene laws on provisions related to meat inspection, mechanically separated meat (MSM), good food safety practices and cold stores, amongst others. Following on from the impact assessment carried out on the current hygiene package, the Commission is expected to publish proposals related to the review during early 2014. While it has been determined that no fundamental overhaul is required, a number of improvements have been suggested.

From a consumer perspective, the most pertinent points relate to meat inspection, mechanically separated meat and the application of specific hygiene rules at the retail level and we encourage the Greek Presidency to support these aspects in Council discussions.
Our demands

- Consumer perceptions of mechanically separated meat is further examined and taken into account in any future proposals in this area especially regarding the definitions and labeling of such products.

- Meat inspection is a very sensitive issue amongst consumers and any proposal to delegate certain tasks to slaughterhouse staff could severely undermine consumer confidence in meat safety (as controls would be perceived as less independent and transparent). Any proposal on delegating certain tasks should only be made once the Commission is in a position to specify the exact tasks which would be concerned. Also, following on from the current horsemeat scandal, it is clear there is a need for more unannounced inspections at abattoirs, meat processing plants etc. This would go some way to regaining consumer trust in this sector.

- In the interest of consumer safety and consistency, the specific hygiene requirements of Regulation 853/2004 should be applied at the retail level as it is increasingly common for retail to cut, slice and re-wrap meat that is then sold at a ‘self-service’ counter.

Documents

- BEUC response to the Commission questionnaire on the Revision of Meat Inspection (X/2011/088)
- BEUC comments on the review of the Hygiene Package (X/2012/036)
New technologies in food rearing and production processes may have an impact on food safety. Although consumers can benefit from innovation, competitiveness and innovation must not be allowed to take priority over public health and safety. With specific regards to the use of the cloning technique for food production, BEUC has expressed concerns. Indeed, an overwhelming majority of EU consumers do not want cloning to be used for food production purposes. Also, given the lack of traceability and labelling, consumers have no means of knowing whether or not their meat or milk has been produced from clones or their offspring. Furthermore, the European Food Safety Authority itself has recognised that scientific uncertainties remain when they stated that all the issues were not “satisfactorily addressed”.

We regret the negotiations in conciliation between the European Parliament and the Council on the novel food proposal failed back in 2011, leaving a loophole in the regulation of marketing of food products from offspring of clones and dropping the positive provisions achieved, for instance improved authorisation procedures for foodstuffs from third countries.

BEUC understands that the European Commission is now due to put forward separate proposals on cloning and novel food during 2014. We hope that the Greek Presidency will quickly start to work on the new proposals.
Our demands

- The European Commission’s proposal on cloning should tackle the issue and loopholes of food derived from cloning technique as a matter of urgency.
- Should the current moratorium on cloning be removed in the future, there should be a full, compulsory traceability system of clones and their offspring as well as labelling rules for derived food.
- There should be a definition of nanotechnology included in the new novel food regulation for risk assessment purposes.

Documents

- BEUC comments on the European Commission report on cloning for food production (X/2010/087)
Health and nutrition claims are used as a major marketing tool by the food industry in order to entice consumers into buying products. Due to the huge number of exaggerated or unsubstantiated claims currently on the market, it is very difficult for consumers to know which ones to trust and ultimately make an informed choice. Too often claims stress only one positive aspect of a product, claiming for example a low level of sugar, but not mentioning the high levels of salt or saturated fat.

In response to the proliferation of food products claiming health and/or nutrition benefits to appeal to consumers, an EU regulation was adopted in 2006 laying down harmonised rules for the use of claims.

The purpose of regulating claims is to eliminate unsubstantiated and misleading claims and only allow claims which are scientifically proven and that consumers can trust. It also ensures that companies which make scientifically substantiated claims can benefit from their investments. The adoption of the ‘Article 13’ list of general function health claims goes some way to achieving this objective.

The list of permitted claims came into force in December 2012. We urge Member States to ensure the list is enforced in order that consumers can begin to trust in the claims used on food products.

We also ask the Council to encourage the Commission to give the green light to the European Food Safety Authority (EFSA) to continue with its assessment of claims relating to botanicals. We would be very concerned if the Commission were to make a special case for these products and allow them to bear claims based on ‘traditional use’ rather than providing the sound scientific evidence to justify their claims (as has been the case for all other claims). Such a move would result in consumers continuing to be misled about the purported benefits of these products and also risks opening the door to challenges from other companies whose claims have already been rejected by EFSA.

We ask the Council to maintain pressure on the European Commission to restart their work on nutrient profiles and to move forward on the assessment of botanicals.
• Claims relating to the botanical substances should be assessed by EFSA as a matter of urgency in the same way as all other general function health claims.

• Nutrient profiles, a vital and a necessary part of the Health Claims Regulation, will help consumers to make an informed choice as they should ensure that claims only appear on the healthiest products. They were due to be developed by the European Commission by January 2009. However, almost five years later we are still awaiting a proposal. BEUC therefore calls for the European Commission to come forward with its proposal for nutrient profiles as soon as possible. We ask that such profiles be robust, scientific and fit for purpose i.e. they prevent consumers from being misled about the qualities of a food through the use of claims.

• Member States should ensure the enforcement of the Article 13 list and make sure rejected claims have been removed from the market.

Documents

- Brochure: No Special Treatment for Botanical Claims (X/2012/038)
- BEUC factsheet Nutrition & Health Claims (X/2011/025)
- BEUC factsheet on Nutrient Profiles (X/2011/024)

For more information: food@beuc.eu
Unsafe consumer products, including products bearing the ‘CE’ mark, are often found on the EU market and so require recall. They pose an avoidable risk to health and safety.


Many of BEUC’s demands have been addressed by the European Parliament Internal Market and Consumer Protection’s report and vote on 17 October 2013. The committee reintroduced the precautionary principle into the CPSR and the MSR, called for a pan-European injury database, ensured the safety of child appealing products, clarified that all channels of distribution are covered including online sales and decided that consumers should be immediately warned about products which pose a risk.

This package will feature highly on the agenda of the Council and the European Parliament during the Greek Presidency as a first reading agreement is being aimed at by spring 2014. We hope the Greek Presidency will do its utmost to ensure consumer protection will be the top priority during the Council negotiations.
Our demands

- BEUC calls the precautionary principle to be made a cornerstone of both the regulations on consumer product safety and market surveillance. Policy makers need to be able to act to prevent dangers or in the absence of absolute scientific proof. We insist that in terms of risk management, the final decision on an “acceptable” level of risk must remain a political responsibility. This principle should be clearly re-introduced in the regulation.
- The adoption should not be delayed because of controversies among Member States on mandatory ‘country of origin’ labelling as it will be pivotal for the Council to focus on the most effective traceability instruments such as indicating a batch, type or serial number; indicating the full address of the manufacturer and importer on the product or packaging; implementing the ‘one-up-one-down-principle’ as exists with food and empowering the Commission to adopt additional traceability requirements in certain justified cases.
- Equipment on which consumers ride or travel e.g. amusement park rides should be included in the scope of the CPSR.
- Product-specific legislation which addresses environmental issues such as the EU Ecolabel Regulation, the EU Ecodesign Directive and the EU Energy Label Directive should be included in the scope of the MSR.
- Business secrets cannot prevail over the need to inform consumers without delay of serious risk. Market surveillance authorities need to adequately warn consumers without delay and publish all relevant information needed to identify a product and the risk involved.
- Penalties need to be proportionate to the infringement, not the size of the company.
- An EU-funded accident statistics system and a European complaint handling/reporting point should be established.
- Products with child-appealing characteristics must be safe for children to use or come in contact with, under all conditions of use.

Documents

- BEUC/ANEC position paper – Market surveillance of products (X/2013/033)
- BEUC/ANEC position paper – Consumer Product Safety Regulation (X/2013/034)
Chemicals which disturb the hormonal system

**Background**

Every day we come in close contact with an enormous range of man-made chemicals. We use skin creams with parabens, computers with brominated flame retardants and plastic kitchen tools with bisphenol A (BPA).

Many of these chemicals found in consumer products are known to disturb the hormonal system, in particular when exposure takes place during crucial stages of development such as the pre-natal phase.

Endocrine disrupters (EDCs) are associated with common diseases such as obesity, diabetes, cardiovascular diseases, cancer and infertility.

Exposure to multiple chemicals in everyday life is of particular concern, as the EU regulatory framework largely neglects this ‘chemical cocktail effect’ and assesses safety on a chemical-by-chemical approach.

The issue has been recognised at EU level. In spring of 2012, the Environment Council called for hormone disrupting chemicals to be made a priority in the 7th Environment Action Programme, which is also supported by the European Parliament.

In May 2012, the Commission published a Communication on the combination effects of chemicals. The European Parliament adopted an own initiative report on protecting public health from endocrine disrupters in March 2013, yet the Commission’s on-going review process of its EU strategy on endocrine disrupters has still not been finalised.

We call on the Greek Presidency to ensure that as soon as the Strategy is published an in-depth discussion, taking into account the EP report, will take place as to how consumers can effectively be protected from hazardous endocrine disrupters.
• Exposure to endocrine disrupting chemicals should be reduced. To this end, chemicals with endocrine disrupting properties must be subject to restriction and phased out. Safe alternatives must be used where they exist.

• A scientifically-based definition for ‘endocrine disruptor’ which is coherent and applicable to all existing and future EU legislation is needed.

• Under REACH, the role of authorities is to evaluate registered substances and propose appropriate risk management measures. When screening the registrants’ chemical safety assessments, authorities should not only consider the information of the REACH dossier, but also take into account other available information to assess if the substance is (potentially) endocrine disrupting.

• EDCs which have been identified as Substances of Very High Concern (SVHCs) should be included in Annex XIV of the REACH regulation. Consequently these substances would need authorisation.

• As part of the EU strategy on endocrine disruptors, the European Commission identified a priority list of substances for further evaluating their role in endocrine disruption. However, this list was established several years ago and should be updated taking into account REACH registration dossiers and newly available data.

• Risk assessment and risk management methods have to be updated to take into account low-dosage effects of EDCs as well as the combined effect of different chemicals.

• More EU-funded research is needed to better understand the complexity of the endocrine system and the effects of endocrine disrupting chemicals on human health and the environment.
Energy

Internal energy market

Background

Energy is one of consumers’ main concerns in every European country. Consumer trust in the energy industry is at a historic low. Although liberalisation is at widely differing stages among Member States, a general trend can be observed across Europe and that is markets are still largely, and unacceptably, imbalanced. In several Member States, energy consumers still cannot choose between different suppliers as there is no real market competition. In many other countries, even if there is choice of providers, this does not result in genuine competition which benefits consumers.

By and large, European consumers lack the appropriate tools to examine the market and gain access to affordable and reliable energy suppliers. Moreover, our member associations consistently report that consumers often experience difficulties in effectively exercising their energy rights. The basic characteristics of a well-functioning retail market – comparability, ease of switching and complaint handling – are still to be achieved.

To accomplish an internal energy market which also benefits European consumers, the complete transposition of the Third Energy Package is a fundamental step. That is why both the European Commission and the Council of the European Union need to keep national energy retail markets under close supervision and act promptly where needed.

The Commission’s Communication ‘Making the Internal Market Work’ adopted in November 2012 was an important step towards creating an internal energy market by 2014. However, it unfortunately failed to thoroughly analyse the situation facing EU energy consumers.
Therefore, we hope the Greek Presidency will ensure in-depth discussions on existing gaps and challenges related to retail energy markets, the development of energy prices for households as well as on the state of competition in the energy sector. At the same time, we call on the Greek Presidency to encourage European policy makers to put forward concrete actions so that energy prices are affordable for all and consumers can enjoy truly competitive energy market.

**Our demands**

- Member States should urgently transpose the consumer relevant provisions of the Third Energy Package.
- National markets need strong and proactive national regulators, sufficiently empowered to monitor billing, switching and consumer complaints.
- Energy companies need to move away from the monopolistic mentalities of the past and realise that in a competitive market they need to gain and retain consumers by providing more affordable and reliable services which extend value for money. In this respect, consumer rights need to be strengthened and guaranteed.
- Consumers need to be able to make well-informed choices between the products and services offered by various energy suppliers. There must be sufficient choice without overburdening them with a wide variety of incomparable tariffs. Furthermore, switching needs to be facilitated and consumers have independent advice available so they can decide what is best for them.
- Consumers need to be given the choice of whether or not they participate in new programmes and schemes, for example smart metering or demand response.

**Documents**

- ‘Making the Internal Energy Market Work’ - A BEUC reality check on the European Commission Communication (X/2013/016)
- BEUC and CEER Joint Vision for Europe’s Energy Customers (X/2012/106)
- BEUC response to CEER’s discussion paper on a 2020 Vision for Europe’s Energy Customers (X/2012/057)
- BEUC presentation on Energy Retail Markets – A Snapshot From a Consumer Perspective (X/2012/079)
- BEUC response to CEER’s public consultation on Advice on Price Comparison Tools (X/2012/003)
- BEUC position paper on consumer rights in the energy sector (X/2013/083)
Energy bills are high and rising, a cause of serious concern for many European consumers. The problem is likely to increase in the future with the continual rising of prices pushing lower income households to heat their homes less and enduring cold homes. The consequences of fuel poverty and cold homes include poor health and quality of life, social exclusion, financial debt to energy companies and energy supply disconnection etc.

Energy efficiency can be considered one of, if not the most, cost-effective way of reducing energy bills. To make this work, any measure which promotes energy efficiency must look at the consumer benefit and the price tag that comes with it.

EU legislators should focus not only on the benefits that energy efficiency can bring to consumers, but also clearly communicate about the costs. Transparency about the cost-effectiveness of the investments when making our homes more energy efficient as well as the impact on fuel poverty is crucial.

The EU is in the driving seat to shape national energy policies. We believe it is essential that when the Council will discuss the upcoming 2030 Framework for Climate & Energy Policies, it will focus on the most long-term and cost-effective solutions, while including the principle of affordability and avoiding discrimination against vulnerable consumers.
Our demands

- Energy services need to be affordable and reliable.
- Future policies need to include the principle of affordability and avoid discrimination against vulnerable consumers, particularly those on low-income.
- Distributional impact assessments of EU and national policies distinguishing between various consumer groups are needed to tailor different initiatives.
- Regulators should monitor and oversee effectively the wholesale and retail markets by way of the powers assigned to them.
- The circumstances and conditions that lead to vulnerability in the energy sector need to be better understood.
- Investments in energy efficiency solutions should be made in a cost-effective way and schemes be transparent and properly audited so that energy savings are indeed delivered to consumers.
- Greater transparency and efficiency is required to manage the costs and the risks to consumers of investment in the development of innovative new technologies and networks.

Documents

- BEUC and CEER Joint Vision for Europe’s Energy Customers (X/2012/106)
- BEUC response to CEER’s discussion paper on a 2020 Vision for Europe’s Energy Customers (X/2012/057)

For more information: energy@beuc.eu
Medical devices

Medical devices – from contact lenses to pacemakers to pregnancy test kits – are features of many consumers’ daily lives and this broad range of products contribute significantly to people’s health and wellbeing.

On September 26, 2012, the European Commission presented its proposals to revise the EU’s medical devices legislation with the aim of simplifying and strengthening the existing rules to the benefit of consumers and healthcare professionals. The package includes regulations on medical devices and in vitro diagnostic devices, as well as a Commission Communication on safe, effective and innovative medical devices.

The amendments voted by the European Parliament in its plenary session on 22 October 2013 introduced significant improvements to the Commission proposals especially with regard to consumer information, post-market surveillance, ethics and transparency.

The proposal is now in the hands of the Council and we hope the Greek presidency will do its utmost to contribute to strengthening the requirements for pre-market assessment and ensure that the improvements adopted by the European Parliament will be accepted.
Our demands

- The initial European Commission proposal fell short in terms of pre-market assessment requirements. We ask for more thorough pre-market assessment for high risk devices and more clarity on borderline products (e.g. food supplements, medicines, herbal preparations).
- Other demands include:
  - All medical devices on the market must have a positive risk/benefit ratio and bring therapeutic benefit to patients;
  - The definition of “performance” should be adapted to include assessment of clinical effectiveness;
  - Manufacturers should be required to produce more and better clinical data and conduct randomised controlled trials whenever possible to demonstrate a medical device is safe and effective before being placed on the market;
  - A centralised pre-market assessment for a limited number of high-risk devices done by a new medical devices committee within EMA;
  - Improve the functioning of the notified bodies promoting specialisation and excellence;
  - Apply a consistent risk-based approach for the classification of all devices;
  - Set up a multidisciplinary expert group with binding power for a consistent classification of borderline products across the EU;
  - Provide consumers with high quality, complete, understandable and user-tested information for all devices;
  - Guarantee the meaningful involvement of consumers in market surveillance;
  - Provide competent authorities with adequate resources to ensure proper enforcement.

Documents

- BEUC updated position on medical devices (X/2013/031)
- BEUC position on the revision of the EU legislation on medical devices (X/2012/058)
Clinical trials

In July 2012 the European Commission adopted a proposal for a Regulation on clinical trials with the aim of simplifying administrative procedures and promoting clinical research following a decrease of 25% in clinical trials conducted in Europe.

In June 2013 the European Parliament adopted a series of amendments which improve the Commission proposal – especially with regard to transparency, informed consent and ethics committees.

Publication of clinical trial data remains one of the most controversial issues, also due to the ongoing debate on the European Medicines Agency policy on access to documents and to pending ECJ cases brought against EMA by pharmaceutical companies.

According to the Helsinki Declaration of the World Medical Association, all authors have a duty to make the results of their research on human subjects publicly available and are accountable for the completeness and accuracy of their reports. Nonetheless, only half of clinical trials results are published at present and some trials are not even registered. Information on what was done and what was found in these trials could be lost forever to doctors and researchers, leading to bad treatment decisions, missed opportunities for evidence-based medicine and trials being repeated.

The proposal is now being discussed in trialogue. We hope the Greek presidency will guide the Council to stand for transparency and ensure that all clinical trials are registered and that all results are published.
Our demands

- The volunteers who take part to clinical trials put their lives at risk of unexpected adverse drug reactions. They do so in the spirit of altruism to contribute to scientific progress for the benefit of society. Therefore the results of the trials belong to them and to society at large.
- All clinical trials should be registered and all results (positive and negative) should be published.
- Data included in clinical trial study reports should not be considered commercially confidential once a marketing authorisation has been granted.

Documents

- Clinical trials: open the data vault (X/2013/086)
- Clinical trials and medical devices: restore public trust (X/2013/087)

For more information: health@beuc.eu
The Consumer Voice in Europe
- AT - Verein für Konsumenteninformation - VKI
- AT - Arbeiterkammer - AK
- BE - Test-Achats/Test-Aankoop
- BG - Bulgarian National Association Active Consumers - BNAAC
- CH - Fédération Romande des Consommateurs - FRC
- CY - Cyprus Consumers’ Association
- CZ - Czech Association of Consumers TEST
- DE - Verbraucherzentrale Bundesverband - vzbv
- DE - Stiftung Warentest
- DK - Forbrugerrådet - FR
- EE - Estonian Consumers Union - ETL
- EL - Association for the Quality of Life - E.K.Pi.ZO
- EL - Consumers’ Protection Center - KEPKA
- ES - Confederación de Consumidores y Usuarios - CECU
- ES - Organización de Consumidores y Usuarios - OCU
- FI - Kuluttajaliitto - Konsumentförbundet ry
- FI - Kilpailu- ja kuluttajavirasto (KKV)
- FR - UFC - Que Choisir
- FR - Consommation, Logement et Cadre de Vie - CLCV
- HU - National Association for Consumer Protection in Hungary - OFE
- HU - National Federation of Associations for Consumer Protection in Hungary (FEOSZ)
- IE - Consumers’ Association of Ireland - CAI
- IS - Neytendasamtökin - NS
- IT - Altroconsumo
- IT - Consumatori italiani per l’Europa - CIE
- LU - Union Luxembourgeoise des Consommateurs - ULC
- LT - Alliance of Lithuanian Consumers’ Organisations
- LV - Latvia Consumer Association - PIAA
- MK - Consumers’ Organisation of Macedonia - OPM
- MT - Ghaqda tal-Konsumaturi - CA Malta
- NL - Consumentenbond - CB
- NO - Forbrukerrådet - FR
- PL - Federacja Konsumentów - FK
- PL - Stowarzyszenie Konsumentów Polskich - SKP
- PT - Associação Portuguesa para a Defesa do Consumidor - DECO
- RO - Association for Consumers’ Protection - APC Romania
- SE - The Swedish Consumers’ Association
- SI - Slovene Consumers’ Association - ZPS
- SK - Association of Slovak Consumers - ZSS
- UK - Which?
- UK - Consumer Futures