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*(Resolutions, recommendations and opinions)*

OPINIONS

# EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

**454TH PLENARY SESSION HELD ON 10 AND 11 JUNE 2009**

## Opinion of the European Economic and Social Committee on the Trans-Atlantic relations between the EU and North American countries in the air transport sector — a true regulatory convergence (exploratory opinion)

(2009/C 306/01)

On 15 December 2008, the Czech presidency of the European Union wrote to the European Economic and Social Committee under Article 262 of the Treaty establishing the European Community requesting an exploratory opinion on

*'Trans-Atlantic relations between the EU and North American countries in the air transport sector — a true regulatory convergence'*.

The Section for Transport, Energy, Infrastructure and the Information Society, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 20 May 2009. The rapporteur was Jacek KRAWCZYK.

At its 454th plenary session, held on 10 and 11 June 2009 (meeting of 11 June 2009), the European Economic and Social Committee adopted the following opinion by 143 votes to 3 with 2 abstentions.

### 1. **Conclusions**

1.1 For intercontinental air passenger traffic, the relation between the EU and North America is by far the most important. More than 60 million passengers and over 3.1 million tons of freight were carried in 2007. This makes it by far the most significant air traffic flow between the world regions.

1.2 EU — Canada and EU — US have entered into negotiations on creation of Open Aviation Areas (AOO). The Open Aviation Area concept extends full freedom of the air to both parties.

1.3 On 30 April 2007, the Commission signed the text of a comprehensive first stage Air Transport Agreement (first stage agreement) with the United States of America.

1.3.1 Even though the first stage agreement was a tremendous success it did not accomplish its prime objective — the creation of an OAA.

1.4 On 30 March, 2009, the Transport Council adopted a political position approving the signature of the EU — Canada Agreement. On 6 May 2009 at the EU-Canada summit in Prague the final text of this agreement has been marked.

1.4.1 The EU — Canada Agreement is the first agreement of the EU which achieves a complete opening of the markets, for traffic rights and investment, and, at the same time, reaching an unprecedented level of regulatory convergence and cooperation between the authorities.

1.4.2 EESC welcomes the EU — Canada Air Transport Agreement as the first fully following new development of the EU external policy in line with the Council conclusions of 2005.

1.4.3 EESC strongly supports an effort of the Commission to achieve similar results with the EU — US second stage negotiations.

1.5 EU — US second stage negotiations, which started in 2008, shall by virtue of Article 21 of the first stage agreement include the following items of priority interest to

one or both parties: further liberalisation of traffic rights, additional foreign investment opportunities, effect of environmental measures and infrastructure constraints on the exercise of traffic rights, further access to the Government-financed air transportation, and provision of aircraft with crew. There is an expectation from the European stakeholders, that second stage negotiations should enhance further regulatory convergence.

1.5.1 The EESC wishes to remind that time is of the essence and empowered representatives from the EU and US side should restart the negotiations as soon as practically possible. If no substantial progress is made by November 2010, the EU can decide to suspend certain rights granted to US airlines.

1.5.2 Labour issues should receive a special attention as important part of the second stage negotiations. Support of the employees is very important. EESC encourages the second Labour Forum, which will be held in Brussels in June 2009, to produce tangible results in a form of recommendations concerning important social issues.

1.5.3 Implementation of an Open Aviation Area will increase traffic between EU and US what may cause some negative consequences to the environment. EESC recommends to the Commission to undertake strategic environmental impact analysis of the potential agreement.

1.6 The EESC priorities for the second stage agreement — it should deliver the essential ingredients of an OAA:

— removal of restrictions on the ownership and control,

— removal of all discriminatory market practices,

— the right of establishment, so as to permit cross-border mergers, acquisitions and new entry,

— as much regulatory cooperation, and convergence, as can sensibly be achieved,

— removal of unnecessary travel difficulties for the EU citizens due to excessive security measures enforced by the US.

1.7 The EESC strongly encourages TEC to support second stage negotiations by giving them high political priority and enabling consultations through Transatlantic Labour Dialog (TALD) and Transatlantic Environmental Dialog (TAED) as well as other dialogues officially affiliated with TEC.

1.8 The UE — Canada Aviation Agreement should be the reference for the second stage EU — US Agreement. Change is possible — that is the main message from EU — Canada negotiations.

## 2. **Introduction**

2.1 According to EUROSTAT data for intercontinental air passenger traffic, the relation between the EU and North America is by far the most important. More than 60 million passengers were carried in 2007 (5,6 % growth in relation to 2006; 22,3 % of extra EU-27 traffic).

2.2 According to IATA on the North Atlantic route between North America and Europe (including Russia), passenger traffic increased in 2007 by 7,6 % to 57,3 million passengers (in relation to 2006). This makes it by far the most significant air traffic flow between the world regions.

2.3 In 2007 between North America and Europe over 3.1 million tons of freight was carried, which made it one of the three main global transport routes.

2.4 The reasons for the scale of the EU — US aviation market are: geographical, cultural, as well as economic. In 2007 EU and US alone counted for 40 % of the global trade and 60 % of the global FDI. No doubt that aviation has contributed to the development of this largest trade and investment relationship in the world. The relationship between EU and Canada is also very strong (EU being the second largest direct investor in Canada).

2.5 Broad economic relationship between EU and North America is supported by closer regulatory cooperation. Transatlantic Economic Council (TEC) established in 2007 provides high-level forum for EU — US discussions on strategic economic matters with the aim for more regulatory convergence and enhancement of trade and investment. Preliminary talks on the possibility of a comprehensive EU — Canada trading agreement are currently under way.

2.6 This is in the context of such regulatory and economic cooperation, that EU — Canada and EU — US have entered into negotiations on creation of Open Aviation Areas (AOO). Study undertaken on behalf of the Commission (conducted before the current crisis) concluded that an EU — US Open Aviation Area would, over the first 5 years, stimulate more than 25 million additional EU — US passengers' growth, generate more than EUR 15 billion benefits for consumers and create 80 000 new jobs in the EU and the US combined. It would be possible due to:

— removing output constraints (existing at the time of bilateral air services agreements),

— facilitating improved cooperation between airlines through deeper alliances,

— reducing airline costs due to the increased pressure of competition.

2.6.1 Implementation of an Open Aviation Area will increase traffic between EU and US what may cause some negative consequences to environment including: higher emissions, additional waste, increased noise. These and other environmental issues have been addressed in the past but not very successfully.

2.7 An Open Aviation Area concept extends full freedom of the air to both parties, removes restrictions on investment by foreign entities and permits wet leasing of aircraft under non-discriminatory, transparent conditions. It embodies a general commitment to regulatory convergence and to harmonisation of air transport standards in the field of safety, security and environment.

## 3. EU — US first-stage negotiations

3.1 The Commission has initially started negotiating new EU — US aviation agreement on the basis of a mandate agreed at the Transport Council of 5 June 2003.

3.2 On 30 April 2007, the Commission signed the text of a comprehensive first stage Air Transport Agreement (first stage agreement) with the United States of America which is applied since 30 March 2008. This agreement replaced the existing bilateral agreements concluded by Member States.

3.3 The main elements of the EU — US air transport agreement are as follows:

### 3.3.1 Market Access

— 'Community carrier' concept permitting EU airlines to operate to the US from any point in the EU;

— Removal of all restrictions on international routes between EU and US;

— Removal of all restrictions on pricing on all routes between EU and US;

— Unlimited code sharing between EU, US and third country airlines;

— Creation of new opportunities for EU airlines to wet-lease aircraft to US airlines for use on international routes between the US and any third country.

### 3.3.2 Regulatory Cooperation

— Security: US has accepted the EU's demand that, it shall take account of the security measures already applied in the EU;

— Safety: procedures for consultation in the event of safety concerns and recognition of the development of safety responsibilities at EU level;

— Joint Committee: establishment of a Joint Committee which would be responsible for resolving questions relating to the interpretation and implementation of the Agreement, including social issues;

— Competition: commitment to promote compatible regulatory approaches;

— Government subsidies and support: recognition that government subsidies can distort competition; Joint Committee should maintain an inventory of issues raised by the two sides;

— Environment: recognition of the possibility that US airlines may be subject to taxation of aviation fuel on routes between Member States should two Member States exercise their rights under Community law to withdraw the existing tax exemption.

### 3.3.3 Ownership and Control

— US airlines: guarantees concerning permissible percentage ownership by EU nationals, including possibility to exceed 50 % of total equity, guarantee of fair and expeditious consideration of transactions involving EU investment in US airlines;

— EU airlines: right to limit US investments in EU airlines reciprocally to 25 % voting equity, acceptance by US of any EU airline owned or controlled by EU or ECAA citizens;

— 3rd country airlines: unilateral acceptance by US of EU ownership and/or control of any airline in the EEA, ECAA, and 18 African countries.

### 3.3.4 Other issues

— Ground handling: traditional provisions guaranteeing access to ground handling services;

— Doing business issues: provisions relating, for example, to the right to establish offices, to maintain staff, and to engage sales agents in the territory of the other Party;

— Computer reservation systems: the US has accepted provisions guaranteeing European CRS providers the right to operate in the US, on which the US has yet to make commitments in the context of the GATS/WTO.

3.4 First stage agreement was an important step towards an OAA. It established important principles for regulatory co-operation, and set up the Joint Committee to oversee its progress. It contributed to the removal of some barriers to market access.

3.5 Even though the first stage was a tremendous success it did not accomplish its prime objective — the creation of an OAA. In particular the first stage agreement is imbalanced in terms of market access granting US airlines unlimited 5th freedom rights within the EU, without EU airlines enjoying reciprocal rights within the US market (5th freedom rights grant airlines right to take traffic from their home country to the other Party and further to third countries). Selected market practices still favour US airlines, (i.e. the Fly America program). Finally it permits US investors to own a greater share of the voting stock of EU airlines (49 %) than EU investors can of US airlines (25 %).

3.6 Both sides agreed to carry on the second stage of negotiations beginning 60 days after first agreement coming into force.

4. **EU — Canada Air Transport Agreement**

4.1 After concluding the first-stage agreement with the US, Commission received a negotiating mandate from the Council in early October 2007 to launch negotiations on the EU — Canada Air Transport Agreement. After four rounds of negotiations, and following the instruction given by the 2008 EU — Canada summit in Quebec, the draft EU-Canada aviation agreement was initialled by the Commission on 30 November 2008. On 30 March 2009, the Transport Council adopted a political position approving the signature of the EU — Canada Agreement. On 6 May 2009 at the EU-Canada summit in Prague the final text of this agreement has been marked.

4.2 The main features of the draft agreement are as follows:

4.2.1 Regulatory cooperation:

— one-stop security and close cooperation,

— strong article on environment cooperation: agreement on the importance of cooperation in this field and the freedom of the parties to take measures,

— explicit agreement on the importance of social issues, cooperation on social matters through the Joint Committee,

— role of the Joint Committee to oversee implementation of the agreement,

— mutual recognition of safety standards and close cooperation,

— trade mechanism allowing for measures to be taken in case of discriminatory practices and unfair treatment.

4.2.2 Traffic rights and investment: agreement foresees a gradual opening of the traffic rights limitations and the investment and control system in four phases in:

— in the first phase, all limitations existing for traffic between the EU and Canada will be lifted,

— in the second stage Canadian side opens investment in its airlines up to 49 % and then Canadian airlines will receive further traffic rights,

— in the third stage both sides allow airlines of the other party to establish in their respective territories, the airlines will receive the right to take traffic from their home country to the other Party and further to third countries (full 5th freedom rights),

— the fourth stage — right to own and control 100 % of airlines of the other Party and right of Cabotage.

4.3 The EU — Canada Agreement is the first agreement of the EU which achieves a complete opening of the markets, for traffic rights and investment, and, at the same time, reaching an unprecedented level of regulatory convergence and cooperation between the authorities.

4.4 EESC welcomes the EU — Canada Air Transport Agreement as the first fully following new development of the EU external policy in line with the Council conclusions of 2005.

4.5 EESC strongly supports an effort of the Commission to achieve similar results with the EU — US second stage negotiations.

5. **EU — US second stage negotiations**

5.1 Second stage negotiations shall by virtue of Article 21 of the first stage agreement include the following items of priority interest to one or both parties:

— further liberalisation of traffic rights,

— additional foreign investment opportunities,

— effect of environmental measures and infrastructure constraints on the exercise of traffic rights,

— further access to the Government-financed air transportation, and

— provision of aircraft with crew.

5.2 As consultation process shows, there is an expectation from the European stakeholders, that the second stage should enhance further regulatory convergence.

5.3 It is possible that the parties might be able to achieve more progress in the second stage in the fields of cooperation initiated in the first stage such as:

— Security Cooperation: in this field more work is necessary to achieve full mutual acceptance of each party's security measures,

— Safety: separate draft EU — US agreement has been agreed, but delayed due to the US concerns about foreign repair stations and EASA fees and charges,

— Environment: both sides shall explore much closer alignment on environmental issues during the second stage,

— Competition: further progress is very important, but it might be difficult because of the different procedures in place in the EU and US,

— Joint Committee: in the light of the experience of the first stage agreement the Joint Committee should be given more powers to take action on regulatory matters associated with issues such as: 'doing business' or government subsidies and support.

6. **Labour issues**

6.1 Labour issues should receive a special attention as important part of the second stage negotiations. In particular, the promising 'EU — US Aviation Forum on Liberalisation and Labor: past, present and future' held in Washington DC in December 2008 should be further elaborated and its outcome taken into account as much as possible in areas such as: collective agreements, individual rights as regards contracts, working time, vocational training, social benefits and trade union representation.

6.2 EESC encourages the second Labour Forum, which will be held in Brussels in June 2009, to produce tangible results in a form of recommendations concerning important social issues related to future implementation of an OAA. Support of the employees is very important for the successful implementation of second stage negotiations.

6.3 Transatlantic Labour Dialog (TALD) should become involved in the second stage negotiations. The EESC in its opinion on 'Transatlantic relations: How to improve the participation of civil society' ([1]) expressed strong support for re-establishment of the TALD as a part of institutionalised dialogue between the EU and US. The EESC also recommended enlarging the advisory group to the TEC by adding TALD and Transatlantic Environmental Dialog (TAED).

7. **The challenge of timing**

7.1 As it was initially agreed by the parties of the first stage agreement there is a timetable for the second stage negotiations to be concluded:

— PHASE 1. (May 2008 — March 2009). Start of the negotiations;

— PHASE 2. (March 2009 — November 2010). Formulation of a functional US administration decision on the possible suspension of rights;

— PHASE 3. (November 2010 — March 2012). Decision on the possible suspension of traffic rights — possible implementation in March 2012.

7.2 If no substantial progress is made by November 2010, the EU can decide to suspend certain rights granted to US airlines. The EESC wishes to remind that time is of the essence and empowered representatives from the EU and US side should restart the negotiations as soon as practically possible.

8. **EESC priorities for the second stage agreement**

8.1 The second stage agreement should deliver the essential ingredients of an OAA:

— removal of restrictions on the ownership and control of EU and US airlines by EU and US investors. Removing the current restrictions would be entirely consistent with the Framework Agreement concluded at the EU/US summit in April 2007 which called for the removal of unnecessary investment barriers between the EU and US;

— removal of all discriminatory market practices, in particular the Fly America program;

— the right of establishment, so as to permit cross-border mergers, acquisitions and new entry;

— as much regulatory cooperation, and convergence, as can sensibly be achieved,

— addressing labour issues arising as a result of the first stage agreement implementation,

— removal of unnecessary travel difficulties for the EU citizens due to excessive security measures enforced by the US.

8.2 Second stage negotiations — because of its importance — should be given the highest attention by including into the agenda of TEC. The EESC strongly encourages TEC to support second stage negotiations by giving them high political priority and enabling consultations through TALD and other dialogues officially affiliated with TEC.

8.3 EESC recommends to the Commission to undertake (at the beginning of second stage negotiations) strategic environmental impact analysis. Strategic impact analysis identifying potential negative consequences to the environment would help to eliminate or minimize those negative effects throughout the EU — US negotiations.

8.4 The UE — Canada Aviation Agreement should be the reference for the second stage EU — US Agreement. Change is possible — that is the main message from EU — Canada negotiations.

8.5 Successful implementation of the EU — Canada agreement and successful completion of the EU — US second stage negotiations may have positive influence on further developments of EU-Latin America's countries air transport agreements.

9. **The international aspects of the possible agreement**

9.1 Because of the weight of the two respective markets, EU — US Agreement has the potential to lead to a new, post-Chicago, era in aviation.

([1]) OJ C 228 of 22.9.2009, p. 32.

9.2 By forming an 'oasis' of regulatory convergence and openness, also open to newcomers, the EU — US Agreement has the potential to substitute the 1944 Chicago Convention by spreading to other, like-minded, States, eventually encouraging more and more countries to revise their policies in order to benefit from the principles of this agreement.

Brussels, 11 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

III

*(Preparatory acts)*

# EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

**454TH PLENARY SESSION HELD ON 10 AND 11 JUNE 2009**

## Opinion of the European Economic and Social Committee on the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee — An Industrial Property Rights Strategy for Europe

*COM(2008) 465 final*

(2009/C 306/02)

On 16 July 2008 the Commission decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the

'*Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee — An Industrial Property Rights Strategy for Europe*'

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 19 May 2009. The rapporteur was Mr RETUREAU.

At its 454th plenary session, held on 10-11 June 2009 (meeting of 10 June), the European Economic and Social Committee adopted the following opinion by 98 votes to three with one abstention.

### 1. **Summary of the EESC's conclusions**

1.1 The EESC supports the Community industrial property rights strategy proposed by the Commission. It reiterates a number of points already made in previous opinions.

1.2 It calls first and foremost on Member States to support the strategy, both as regards the future Community patent and the current international talks, particularly in the WIPO. The discussions on distribution of patent fees, which continue to hold up the adoption of the Community patent, are not appreciated by civil society, which is concerned with long-term progress and wants to see effective, practical conclusions which significantly reduce the cost of obtaining and maintaining patents.

1.3 The EESC stresses in particular the need to facilitate access to industrial property titles, for effective protection thereof and to combat — very often mafia-type — counterfeiting which is a burden on the economy and businesses and can expose consumers to serious risk (medicinal products, toys, household appliances etc.).

1.4 This requires a more effective dispute resolution system, circulation of final judgments handed down in a Member State (abolition of exequaturs), and better-organised, closer cooperation on police and customs matters.

1.5 More active involvement of organised civil society in international talks should help to strengthen European negotiators' positions and encourage technology transfer to the least-developed countries with a view to development of sustainable technology.

### 2. **The Commission's proposals**

2.1 The Communication concerns the European strategy for industrial property rights, given their growing importance in value creation and innovation and their role in industrial development, in particular for SMEs.

2.2 While the majority of intangible industrial assets are covered by harmonised Community protection, the same does not apply to one key asset: patents. Although there is an EU-wide system based on the Munich Convention, under this system there is neither a unified judicial authority nor uniform case law among the national courts, which have jurisdiction in the area of patents. The cost of EU-wide patents is deemed to be too high, owing, in particular, to the cost of translation into national languages.

2.3 The London Agreement, which reduces translation costs, came into force on 1 May 2008, but language issues and the amounts to be paid to national industrial property offices continue to make it difficult to find a definitive solution.

2.4 The Commission feels that major progress has recently been made towards a Community patent paving the way for a coherent system protecting intangible industrial assets, as can be seen from the Recommendation from the Commission to the Council to authorise the Commission to open negotiations for the adoption of an Agreement creating a Unified Patent Litigation System ([1]).

2.5 In the Commission's view, 'the intellectual property system should continue to act as a catalyst for innovation and contribute to the overall Lisbon strategy'. Lastly, the Communication sets forth measures which could be taken to achieve a European industrial property system of this kind, which would also make it possible to combat counterfeiting more effectively.

## 3. **The EESC's comments**

3.1 The Communication is one of a series of proposals, reflections and analyses which have been developed over the years since the failure of the Luxembourg Convention on a Community patent system in the early 1970s. The EESC, which has always supported the creation of the Community patent, welcomes the news that substantial progress has been made recently.

3.2 The language-related points cited by certain Member States in opposition to the Commission's proposals have never convinced the EESC. Indeed, it firmly believes that industrial property issues should be governed by private law. The question of official languages should be governed by the constitutional law of each country, which should not in principle be concerned with private agreements or disputes or hinder the application of property law on intangible industrial assets at Community level.

([1]) SEC(2009) 330 final of 20.3.2009.

3.3 Over and above the legal and political debates, it is the interests of the European economy, businesses, inventors and holders of an indisputable property right which should prevail, so as to encourage the creation of value and jobs, especially in SMEs, which are in practice left quite defenceless against piracy and counterfeiting of their industrial property. The successive EESC opinions on patents, combating counterfeiting ([2]) and the Community patent ([3]) continue to apply and to reflect a considerable social demand for jobs and industrial development.

3.4 This Communication should be seen as supplementing Communication COM(2007) 165 final on Enhancing the patent system in Europe.

3.5 *The changing innovation environment*

3.5.1 The EESC endorses the Commission's views on the growing importance of innovation as a driver of competitive advantage in the knowledge-based economy; knowledge transfer between public research, businesses and private R&D is essential for Europe's competitiveness. The Committee is very interested in the call to set up a European framework for knowledge transfer and supports in particular the proposal for harmonised definition and application of the research exemption to patent infringement.

3.5.2 This Community framework should make it easier to bring together fundamental research, R&D and the development of innovative applications, and to enforce the rights of each stakeholder more effectively with due regard for the autonomy of fundamental research, as it is often impossible to predict the practical applications of research programmes, which cannot, therefore, be guided solely by demand for industrial applications; moreover, research is a key pillar of the knowledge-based economy and the Lisbon Strategy.

3.5.3 Under this approach, Member States should continue to take the Better regulation programme as a basis and other stakeholders (inventors, universities, businesses and end-users) must be put in a position to make informed choices about the management of their industrial property rights

3.6 *Quality of industrial property rights*

3.6.1 The EESC shares the view that the European industrial property system must encourage research, innovation and dissemination of knowledge and technology, which paves the way for new research and applications.

([2]) OJ C 116 of 28.4.1999, p. 35 (rapporteur: H. Malosse) and OJ C 221 of 7.8.2001, p. 20 (rapporteur: H. Malosse).

([3]) OJ C 155 of 29.5.2001, p. 80 (rapporteur: J. Simpson) and OJ C 112 of 30.4.2004, p. 76 and p. 81 (rapporteur: D. Retureau).

3.7 *Patents*

3.7.1 At the same time, access to industrial property must be facilitated with the Community patent, preventing patents from being used to hijack the protection system through 'patent trolls', who use poor quality patents (cross-references, overlaps, excessively complex — not to say incomprehensible — drafting of claims) in order to appropriate others' inventions; they thus obstruct the lodging of new patents or cause confusion which ultimately leads to breaches of competition rules, clogs up the courts and makes it difficult to find clear information and case law.

3.7.2 The Community patent should only be granted for genuine inventions which represent a real technological advance and are likely to be used in real industrial applications. Applications without a genuine, tangible inventive step must not be accepted, and the creation of genuine pools of patents which are complementary and can be used in a number of different applications should be encouraged. Claims should be strictly confined to the technical innovation made by the invention: their interpretation should be restricted in respect of use of the patent and disputes between patent owners.

3.7.3 The use of expertise and codes of good conduct to enhance the quality of patents lodged is essential, as it should be borne in mind that holders have exclusive rights for a relatively long period of time. This is the trade-off for publication, which, to encourage demand for licences from industry, allows knowledge to be disseminated but also exposes inventions to reproduction.

3.7.4 The EESC also feels that the quality of the patent is an essential guarantee for licence applicants and encouraging innovative applications. It therefore endorses the Commission's proposals in this area, such as the importance of the quality of the scientific and technical mechanism for examining patents and cooperation between national and European examiners, and the importance of recruiting qualified examiners, as they are the pillar of Community expertise in technology and applications. Examiners and other highly-competent experts make up the pool of human resources which is essential for the quality of the Community patent, and the Commission should give more consideration to this question so as to be able to give the best professionals the ethical and material conditions which are essential for high-quality examinations, to the benefit of applicants and industry.

3.7.5 Member States which grant patents without an examination, and therefore without a guarantee, should, as the Commission proposes, reflect on the quality of the patents they issue. The EESC believes in this connection that, in certain complex cases which are not clear-cut, these countries should call on the expertise of examiners or other national or even foreign experts to improve the quality of the national patents they issue.

3.7.6 Patent offices should also ensure strict respect for fields which are not patentable under the Munich Convention such as software and methods, algorithms and parts of the human body such as genes [4], which are unpatentable scientific discoveries.

3.7.7 Although the lifespan of the Community patent is 20 years in theory (TRIPS agreements), the actual average varies between five to six years for ICTs and 20 or 25 for medicinal products, giving an overall average of 10 to 12 years. Utility models have even shorter actual lifespans.

3.8 *Trade marks*

3.8.1 The EESC endorses the Commission's proposal to carry out an in-depth evaluation of the Community trade mark system, and also calls for cooperation to be developed between the European and national trade mark offices.

3.9 *Other rights*

3.9.1 The EESC also endorses the proposed evaluation on obtaining plant varieties, not to be confused with GMOs. It welcomes the public consultation planned on the possibility of introducing protected geographical indications for typical non-agricultural products.

3.9.2 The EESC will carefully monitor arrangements for PDOs and PGIs and protected designations for agricultural products and spirits. It believes that protected designations could also be extended to typical products other than foodstuffs — craft products for example — and would also like other information increasing a product's value such as the fact that it is organic or sustainable to be displayed on designation labels as well, where appropriate, even if the qualities described are not necessarily a requirement for the designation to be granted.

3.9.3 As regards the aftermarket in spare car parts, which the Commission wants to liberalise, the EESC notes that there is some conflict between this liberalisation policy and protection of designs. Despite this, the EESC has adopted an opinion supporting this approach [5]. However, it should be pointed out that the principle of exclusive rights is being breached and that car manufacturers are required to supply original spare parts for a mandatory length of time, while other manufacturers are not. Logically, the principle of a mandatory licence should apply, and it should be mandatory to use the same materials where parts contribute to the vehicle's structural solidity.

[4] As discussed in Directive 98/44/EC with regard to certain isolated genes.

[5] OJ C 286, of 17.11.2005, p. 8 (rapporteur: V. Ranocchiari).

4. **Industrial property rights and competition**

4.1 Like the Court of First Instance, the EESC feels that in more and more situations, owing to inflation of low-quality titles from certain countries, the best way to resolve certain conflicts between applicable rights is usually to apply the theory of abuse of rights. This should result in a genuine principle of mandatory licensing, which could lead to a rebuttable presumption of a requirement to issue a licence at a reasonable price under fair, non-discriminatory conditions. In all cases, foreign patents relating to fields excluded by Community law or which are very poor quality should not be recognised as valid, enforceable titles.

4.2 The Commission believes that standard-setting helps achieve a better industrial environment. For the EESC, standard-setting, which benefits consumers and SMEs, must be carried out in an open and transparent manner. The EESC endorses the view that the owner of an essential proprietary technology, which is then taken as a standard, extracts an over-inflated value for his title if they conceal their patent during the standard-setting process. A penalty system should apply in the event of this behaviour.

4.3 The future Community patent should require a higher level of quality, in line with the criteria set out by the Commission in respect of the European strategy, and also a specialised jurisdiction system, in particular to avoid 'patent ambushing' and other distortions of competition, which are very often based on poor-quality titles. Good patents are ousted by bad ones.

4.4 The EESC welcomes with interest the proposal for a study to analyse the interplay between industrial property rights and standards in the promotion of innovation; it will also take part in the planned consultation on standard-setting in ICTs, which will touch on this interplay.

4.5 In the current period of development of new, complex technology where manufacturing a product involves numerous discoveries and a large number of inventions and patents, a cooperation strategy is needed, maybe involving cross-licensing systems or patent pools. A balance should be ensured between stakeholders, to avoid potential distortion of competition and the rights of 'small inventors' being breached, in view of the huge patent portfolios of large businesses, some of which lodge thousands of new patents each year in the field of ICTs.

5. **SMEs**

5.1 In a globalised market SMEs and VSEs [6] have great difficulty in protecting their trade marks and patents (where they have them) as many of them are involved in subcontracting. However, a large number of businesses are reluctant to lodge patents, often because of a lack of information or fear of a system which is known to be complex and costly. Sometimes the exclusive rights granted in certain countries are circumvented by counterfeiting in other countries where patent owners' rights are not protected.

5.2 Thus, manufacturers often rely on trade secrets, but these secrets are not always safe, thanks to chemical analysis of products and the development of industrial espionage. For example, in perfume manufacturing, there used to be no patents as that would have meant publishing the chemical formula of components. Today, current analysis techniques mean that trade secrets no longer provide protection, and proper legal protection should be established for complex products, perhaps a form of copyright.

5.3 Reluctance to lodge patents, even if only because of the lodging and renewal fees associated with the current European patent, has had the effect of holding back technology transfer as the investors concerned have been unable to obtain licences; this is a loss for the European economy. SMEs and VSEs should therefore be supported and encouraged to obtain industrial property rights and to use them in business strategies involving several businesses which own titles and operate in the same sphere of activity, with a view to implementing inventions combining several different discoveries. In any case, industrial property title owners are in a better position to interest investors or obtain credit for developing their activities.

5.4 As the EESC has often stressed, European industry needs affordable, high-quality patents which are valid throughout the Community and stimulate the internal market.

5.5 An inexpensive, rapid dispute-resolution system is also needed; mediation should be encouraged to resolve certain disputes. Arbitration is also an alternative. The judicial system for patents should, for its part, be specialised, easy to access and expeditious so as not to hold back economic progress.

5.6 These are questions of public interest, and it is hard to understand why they have remained on hold for so long; it is true that very large businesses are able to lodge patents under the current system, thereby generating large amounts of income for the European Patent Office and national member offices. The purpose of the system is not that, however: it is to encourage industrial innovation and development, benefiting businesses and generating new skilled jobs, although expenditure will be needed to ensure effectiveness and extension of titles issued to innovative businesses and individuals.

[6] Very Small Enterprises (VSEs) and micro-businesses.

5.7 The EESC firmly believes that individuals working in a business who contribute directly to innovation and lodging of patents should be entitled to part of the income generated by their inventions (the issue of the employee inventor, or 'work for hire'); this happens in some countries but the practice should be extended to give innovation a greater boost.

## 6. **Enforcement of IPRs**

6.1 The EESC has already commented in detail in a number of opinions on enforcement of IPRs and combating piracy and counterfeiting, notably in one Opinion ([7]) to which the reader is referred in particular.

6.2 It is up to Member States which have issued intellectual property titles to enforce the exclusive rights they have granted, notwithstanding the general principle of exclusion of abuses of rights. Counterfeiting is a serious offence against the economic interests of innovative businesses, as well as the image of Community industry, and exposes consumers to serious risks. Moreover, it is difficult for SMEs to defend themselves on their own and they need tangible help.

6.3 High-quality legislation, jurisdiction systems and customs controls at the EU's borders are essential to combat counterfeiting.

6.4 The EESC therefore advocates strict compliance with the Brussels I Regulation and developing judicial and customs co-operation to this end. Final judgments handed down in a Member State should be accepted without an exequatur in all the other Member States.

6.5 Under Community law, the zero-tolerance approach advocated by the Commission to infringement of industrial property rights and copyright should target offenders who produce imitations or copies commercially, as the EESC has already stated in previous opinions. Industrial property rights cannot be protected by clamping down indiscriminately. Mafia-type counterfeiting rings and large producers should be targeted to put an end to an industry which is a burden on growth and jobs in the Member States.

6.6 Education and information also have a key role to play as regards consumers, who must be aware of what is involved in the production of imitations, including child labour or forms of forced labour. They must be warned of the risks entailed in buying certain items such as medicinal products on websites selling for the most part highly-dangerous imitations.

## 7. **International dimension**

7.1 At international level, it is essential to implement a strategy to ensure respect for European IPRs both within and outside Europe in order to tackle counterfeiting and piracy. At the same time, Europe should endeavour to encourage sustainable-technology transfer to developing countries.

7.2 International agreements on trade marks, patents and copyright follow old rules on treaty law (Vienna Convention). The EESC condemns the regrettable lack of transparency. It is not just a question of involving the best experts in national delegations, but also of adopting a European approach, especially when it comes to the quality requirement for protected titles. Civil society and its organisations should be more involved in these talks so that the European Union's economic partners know that 'European delegations' have wide support based on prior consultation and involvement in following talks — which could drag on for years.

7.3 The requirements of sustainable development and international cooperation to achieve this should take precedence in the global economic area. All talks must aim to find solutions which meet the public's expectations and serve the interests of the organisations concerned.

## 8. **Final comments**

8.1 The EESC supports the Commission's strategy, subject to some reservations and the suggestions made above.

8.2 It is fully aware of the obstacles and difficulties in the way of reforms, which will be problematic and costly, but it firmly believes that the sustainable growth generated by a European protection system will result in tax revenue.

8.3 The Community patent will boost investment in innovative technology.

([7]) OJ C 116, of 28.4.1999, p. 35 (rapporteur: H. Malosse).

8.4 In this area the EESC will continue to support all tangible Community initiatives seeking to improve applicable law, dispute resolution and protection of IP title owners in the fight against mafia-type organisations responsible for counterfeiting. It stresses once again the urgent need for solutions, which have been too long awaited by businesses and the public.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

# Opinion of the European Economic and Social Committee on the Communication from the Commission to the Council and the European Parliament: A strategic European framework for international science and technology cooperation

*COM(2008) 588 final*

(2009/C 306/03)

On 24 September 2008, the European Commission decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the

*'Communication from the Commission to the Council and the European Parliament: A strategic European framework for international science and technology cooperation'*

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 19 May 2009. The rapporteur was Mr WOLF.

At its 454th plenary session, held on 10-11 June 2009 (meeting of 11 June), the European Economic and Social Committee adopted the following opinion by 111 votes to none, with one abstention:

## 1. **Summary and recommendations**

1.1 International science cooperation has a broad — and invariably favourable — impact both on scientific and technical progress among the stakeholders involved, and also on understanding between nations. This is true not only within the European Research Area (ERA), but also right across the world.

1.2 Hence the Committee welcomes the Commission communication and endorses its basic objectives. Similarly, it welcomes and supports the relevant decisions [1] of the Competition Council of 2 December 2008, including the tone to set up a high-level group of experts (dedicated configuration of CREST).

1.3 The Committee backs the Commission in its bid to achieve a coordinated approach by the Member States to securing international framework agreements, and to incorporate in an appropriate way the thematic targets of international cooperation into the joint research programming and the preparatory work for the 8th Research Framework Programme.

1.4 At issue here are basic questions such as researcher mobility and intellectual property agreements, as well as moves to foster personal initiative and promote conferences as a conduit for knowledge-sharing and communication, and the need to boost the attractiveness of the ERA.

1.5 The Committee feels that, even with due regard for subsidiarity, the Commission has a key role to play in international agreements on major scientific and technical infrastructure projects, since the costs these entail (for building and operation) and the effort involved in using them are, generally speaking, beyond the wherewithal of individual Member States and are thus a typical task for the Community. The Committee therefore also endorses the objective of pursuing international research infrastructure projects (as has already been done with the ITER) or of involving international partners in European research infrastructure projects.

1.6 The Committee supports the Commission proposal to highlight ICT (information and communication technologies) as an issue for international cooperation, and at the same time recommends that the new category of ICT for Science and Research be introduced. However, the Committee would recommend that similar importance should also be attached to other key global questions such as energy, climate, the environment and health, though this should not mean ruling out other issues, particularly fundamental research, from international cooperation.

1.7 The Committee stresses that the success of international cooperation is very much dependent on the attractiveness of the European Research Area and on the performance of European universities and research institutes. The measures needed to achieve this are key elements of the Lisbon strategy. It is therefore all the more important, in the light of the current economic and financial crisis, to implement an anti-cyclical policy and to use all available financial and structural means to support the European Research Area and the foundations on which it is built, including its international dimension, and to make it attractive.

## 2. **Communication from the Commission**

2.1 The communication presents a strategic European framework for international cooperation in science and technology (S&T). Its purpose is to:

[1] 2910th COMPETITIVENESS Council meeting Brussels, 2 December 2008. Conclusions concerning a European partnership for international scientific and technological cooperation.

— strengthen the coordination of Member States' and EC actions aimed at reinforcing strategic S&T cooperation and information society dialogues with partners worldwide;

— create additional synergies between public authorities, industry and civil society to make EU action in these policy fields more efficient;

— facilitate access to knowledge, resources and markets worldwide;

— have a positive influence on the global S&T agenda by pooling of resources;

— improve framework conditions under which international research is conducted;

— make it easier for Europe's researchers and universities to work with the best scientists and research infrastructures in the world;

— strengthen the global position of the European industry in electronic communications and other advanced technologies.

2.2 The Commission communication responds to the Council conclusions of February 2008, and is one of the five Commission initiatives on the future of the European Research Area (ERA). The proposed framework is designed to contribute to the free circulation of knowledge — 'the EU's fifth freedom' — at global level, to raising the S&T profile of Europe worldwide and to disseminating European ICT (Information and Communications Technology) know-how in the world.

2.3 Mobility of researchers is an essential feature here.

2.4 Cooperation with scientifically advanced partners will differ in nature from that with countries which are developing their science base; but both types of cooperation are needed.

2.5 Policy dialogues on S&T are to be launched with countries which signal an interest in becoming associated to the 7th framework programme for research and technological development (FP7).

2.6 By far the biggest share of publicly funded R&D investment comes from the Member States. Thus, the EU can effectively contribute to international cooperation across the world only by strengthening the partnership between the Member States and the European Community.

## 3. **The Committee's comments**

3.1 **Preliminary remarks**. In its 2000 opinion [2] on the Communication from the Commission Towards a European research area, the Committee noted as a key hallmark of scientific research that 'its methods and the related scientific terminology are the same in all countries and languages', continuing: 'Thus there is a single scientific "global culture" and a single scientific "technical language", and associated common values. (…) Only this allows a global international exchange of knowledge and worldwide cooperation.'

3.2 **Point of departure**. It is encouraging to note that, for many decades now, a wide range of international (i.e. extra-EU) scientific and technical cooperation projects have been in place in many Member States — both between companies (global players) and between publicly supported research-performing organisations and their research groups. The various science and technology associations [3] also give a key fillip in this area, as do specific international organisations including the International Energy Agency (IEA) [4], the World Health Organisation (WHO), the International Union of Pure and Applied Physics (IUPAP), the International Panel on Climate Change (IPCC) and also, among others, the European Space Agency (ESA) and the European Organisation for Nuclear Research (CERN). Overall experience to date has shown that those countries that openly exchange and cooperate in this area also reap cultural and economic benefits in the medium and long term.

3.3 **Basic endorsement**. The Committee thus endorses the basic objectives of the communication. Cooperation between countries across the world saves resources and disseminates new knowledge faster. Generally speaking, it has a broad — and invariably favourable — impact both on scientific and technical progress and also on understanding between nations. In this way, it also in particular helps build up good relations with the EU's neighbours. However, cooperation must not become an end in itself, as it requires additional expense that must in each case by justified by the expected added value.

3.4 **Tension between competition and cooperation**. The issue of international R&D cooperation under discussion here also touches on the tension between competition and co-operation [5]. In basic research, competition is, in the main, considered only in terms of setting priorities for scientific findings and garnering the associated prestige. Competition issues take on growing economic importance, however, as R&D starts to produce marketable processes and products that bring economic benefits in their wake.

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[2] OJ C 204/5.70, 18.7.2000.

[3] Academic associations organised by academic discipline at national, European or indeed international level are financed largely by membership fees from their members and are thus typical representatives of organised civil society.

[4] Known as Implementing Agreements.

[5] OJ C 218, 11.9.2009, p. 8.

3.5 **Promotion and recognition of personal initiative and mobility:** The most important initiators and players in international cooperation are researchers themselves (scientists and engineers). It is thus vital to promote and recognise the importance of personal initiative and mobility. To that end, individual support is required, as is encouragement for mobility through measures similar to those in place — or still being aimed at — within the European Research Area.

3.6 **Promotion of international conferences and science and technology associations.** Specialist conferences are the main forum for publicising and evaluating findings, pooling knowledge and ideas, launching cooperation initiatives and developing new or improved concepts. Such conferences are generally organised by science and technology associations, which are typical civil society organisations. The Committee therefore recommends that there should be greater awareness and recognition of their value and that their efforts to disseminate knowledge, evaluate findings and coordinate research should be drawn on and encouraged ([6]).

3.7 **Promotion and recognition of self-organisation**: In addition to individual researchers, research institutes and universities are the prime movers in initiating and cultivating international cooperation — and in establishing the requisite contractual arrangements — with selected partner bodies, often on a number of different fronts within their own specific spheres of competence. That should be encouraged and supported, not least by putting in place reliable legal, financial and staffing parameters that also offer a sufficient degree of continuity.

3.8 **Additional support:** In order to facilitate or initiate the action outlined above, government-level framework agreements between Member States and non-European third countries are helpful, if not essential. The Committee feels that this is the key coordinating task, i.e. to ensure that there is policy coherence in international R&D cooperation (research policy, but also neighbourhood policy, development policy, industrial and economic policy) — using both European and national instruments — towards third countries.

3.9 **Role of the European Commission:** While, on the one hand, the Committee would stress that research bodies and businesses must act under their own responsibility to initiate and flesh out those aspects of international cooperation — and the attendant programmes — that may be useful to them, it does on the other hand feel that the Community and the Member States have important tasks to perform on basic, overarching questions such as the following, which should be discussed in a spirit of partnership between the European Commission and the Member States:

— Basic mobility issues such as visa matters, tax issues, personal legal protection, insurance, pension rights etc., whereby the primary aim should be to safeguard the interests of European research and European researchers and also to secure two-way arrangements with international partners.

— The possible association of other, non-EU (and especially neighbouring) countries in FP7, including two-way access agreements.

— Basic issues in international agreements on the protection on intellectual property ([7]) in research and development ([8]). This again highlights Europe's weakness: the absence of a Community patent and of any grace period.

— Support for cooperation by working groups from third countries on projects supported under the RTD framework programme, and equivalent arrangements for EU working groups to cooperate on projects supported by the third countries concerned. The access rules must be adapted accordingly.

— Efforts under the initiative for joint programming in research to ensure that the Member States make sufficient resources available for international cooperation.

— Coordination of these objectives with the preparatory and drafting work for the 8th Research Framework Programme. Strengthening international cooperation by further expanding existing measures and, where appropriate, preparing new ones.

3.10 **Key message of the Commission communication:** Accordingly, the Committee feels that the Commission communication's key message is to bring the ever-growing importance of international cooperation to the attention of the Council and the Parliament, to put in place a coordinated approach by the Member States and the Community to securing international framework agreements, and to explore the thematic and regional targets of international cooperation and take appropriate account of these in the joint research programming and the preparatory work for the 8th RTD Framework Programme.

3.11 **European Research Infrastructure**. The Committee feels that, even with due regard for subsidiarity, the Commission should play a stronger, direct role in international cooperation on large apparatus and other projects that fall under the heading of European research infrastructure, since the costs these entail (for building and operation) and the effort involved in using them are, generally speaking, beyond the

([6]) Point 3.10.1 (alt'd), EESC opinion published in OJ C 44, 16.2.2008, p. 1.

([7]) This is not, however, meant to limit room for manoeuvre in such agreements, where, among other things, account has to be taken of the balance, or otherwise, of partners' existing knowledge and skills.

([8]) OJ C 218, 11.9.2009, p. 8.

wherewithal of individual Member States. This applies in particular to those programmes supported and coordinated by the Commission in which the EU is a direct partner (e.g. the ITER fusion programme) or plays a key coordinating role, for instance the European Strategy Forum on Research Infrastructures ([9]) (ESFRI) and the additional measures taken under it. The Committee is thus particularly supportive of the Commission's objective of 'tackling scientific challenges through global research infrastructures'. This may also involve the participation of international partners in European research infrastructure projects. The geographical aspect and the available scientific potential should also be taken into consideration in this context.

3.12 **Strategic Forum for International S&T Cooperation — Crest Group:** The Committee welcomes and supports the setting up of a Strategic Forum (dedicated configuration of CREST) in accordance with the preliminary recommendation of the Competitiveness Council of 14 November 2008 and its corresponding decision of 2 December 2008. ([10]) It also welcomes and supports the corresponding aims, i.e.:

— a long-term partnership between the European Commission and the Member States for improved coordination of aims, instruments and activities of international cooperation in science and technology. This also includes greater international cooperation under the RTD framework programme;

— further development of the international dimension of the European Research Area;

— Coordination of activities and positions vis-à-vis third countries so as to speak with a single European voice in international fora.

3.13 **International dimension of the European Research Area**: The Committee wishes to place special emphasis on the international dimension of the European Research Area. This involves both greater cooperation between the Member States ([11]) on the basis of 'variable geometry' ([12]) and the coordination of R&D activities at international level.

3.14 **Convergence of humanities and natural sciences**: The Committee recommends that international cooperation be expanded beyond the area of science and technology into areas where these have discernable links to the humanities and the related ethical issues.

3.15 **Shortcomings in the communication:** The Committee regrets, however, that the communication does not draw sufficient attention to the many existing instances of cooperation and to the agreements in place (see point 3.2) or to the initiators or tools involved, thus giving the uninformed reader an overly negative picture of the current situation. Moreover, past experience gained in this way should be the basis for any further moves forward. Better use should also be made of initiatives such as those of the specialised associations.

## 4. **Specific comments**

4.1 *Choice of topics: some observations*

4.1.1 **ICT including 'ICT for science and research':** Among the areas of key importance for international cooperation, the Commission draws particular attention to ICT as a key cross-cutting technology for science and industry, including the goal of disseminating European ICT know-how in the world. The Committee fully supports this, but would nonetheless point out that, as an issue, ICT must not be interpreted too narrowly, but should encompass the entire area of activity — from the harmonisation of differing standards to communication networks and high-performance computers and their increasingly sophisticated software. The wide-ranging discipline of scientific computing ([13]) has now developed into a very significant additional pillar of scientific and technological method. This might be achieved best by introducing a subcategory 'ICT for science and research'. The Committee also notes the significant potential benefits of cooperation with groups of experts in international partner countries.

4.1.2 **Energy, climate, environment and health**. However, there are other equally important global issues — including the energy and climate question and research in the fields of environment and health — that should also have an appropriate profile in the proposed strategy.

4.1.3 **Remaining open to other issues:** It is true that, at certain times, particular questions and issues do take on special importance and urgency — as is currently the case for energy and climate questions, for instance — and that there is also a need to pool scare resources. However, given the unpredictable nature of new findings, and of the timeframes involved in transforming those findings into technical applications, the Committee recommends that the range of issues to be addressed in international framework agreements should not be limited from the outset but should remain open to other thorny questions that may arise and take on new currency in the future. International cooperation is, moreover, also a particularly important element of pure research.

([9]) OJ C 182, 4.8.2009, p. 40.

([10]) 2891st COMPETITIVENESS Council meeting Brussels, 2 December 2008. Conclusions concerning a European partnership for international scientific and technological cooperation.

([11]) OJ C 182, 4.8.2009, p. 40.

([12]) In this context, the concept of variable geometry describes the possibility of cooperation and/or involvement of individual Member States that takes different forms in each case (see Article 169 of the Consolidated Treaties).

([13]) Often called simulation science of numerical modelling. This method makes it possible to investigate complex questions in a way that was impossible in the past.

4.1.4 **Pure research** (or basic research): The Committee recalls the contribution of pure research to the discovery of the laws of nature on the basis of which almost all modern technologies were developed and medical discoveries were made. The Committee recommends that the advice of the European Research Council (ERC) be sought regarding implementation.

4.2 **European self-interest and differing categories:** It is in Europe's own interest to make a clearer distinction between different categories of international cooperation, i.e.:

— Association arrangements with the EU RTD framework programme. In addition to countries such as Norway and Switzerland — EU neighbours already associated with the RTD framework programme — the Committee particularly supports moves to open association negotiations with countries such as Russia and ([14]) Ukraine.

— Cooperation with highly developed non-neighbouring countries, i.e. countries with top-class training facilities and a highly developed R&D infrastructure, such as the USA, Japan and, increasingly, China, Brazil and India. This is a particularly important aspect of the issue.

— Cooperation with other countries where the key goal is, in the first instance, to realise, promote and draw mutual benefit from their potential capabilities.

4.3 **The language question — a problem, but not a taboo**. The international language of science is English. Thus those EU countries where English is the native language or is mastered by most R&D stakeholders have a natural advantage in terms of attracting students — as future decision-makers in scientific cooperation — and of engaging in scientific exchanges. The other Member States should also seek appropriate solutions that are of benefit both to themselves and to the European Research Area.

4.4 **Mobility and avoiding brain drain**. The mobility of scientists, i.e. researchers, teaching staff and students, is vital to knowledge-sharing and cooperation and is, nowadays, also a virtual prerequisite for anyone wishing to take a research career further. However, in the long run, mobility can also mean that a country's best talents move to wherever they find the best and most attractive research environment and opportunities for their own personal development. This is a problem both for the EU as a whole — in relation to its neighbours and to the USA for instance — but also between individual EU Member States.

4.5 **Providing opportunities**. Since it is simply not an option to prevent mobility and thus deprive talented young people of opportunities for development, it is vital for the EU that all the Member States — and indeed the Community itself — should, as part of their research policy, work to develop centres of excellence and/or other attractive models, and thus to strike an appropriate overall balance in the desired mobility flow (brain circulation). Resources from the Structural Funds should be used for this purpose.

4.6 **Making Europe more attractive — the European Research Area:** The same is also true of the relationship between the EU as a whole and its international partners. A crucial factor in the success of international cooperation and in the EU's negotiating position on the various agreements is the attractiveness of EU research and development, including training facilities/university infrastructure, and the individual career opportunities of its researchers. Strengthening the European Research Area is thus one of the most effective means of avoiding a brain drain out of the EU, attracting the world's best scientists to Europe and being able to negotiate international agreements from a position of strength.

4.7 **Lisbon strategy, current crisis and anti-cyclical policy:** The success of international cooperation is thus very much dependent on the attractiveness of the European Research Area and from the performance of European universities and research institutes. The measures needed to achieve this are key elements of the Lisbon strategy. It is therefore all the more important, in the light of the current economic and financial crisis, to implement an anti-cyclical policy and to use all available financial and structural means to support the European Research Area and its foundations, including its international dimension, and to make it attractive. At the same time, the Committee calls on the Commission and the Member States to adopt an anti-cyclical staffing policy in order to counteract the threat of unemployment for young graduates that may arise from a reduction in R&D activities in the private sector. ([15])

Brussels, 11 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

([14]) This is a recommendation of the EESC that goes beyond the Commission proposal.

([15]) See CESE 864/2009, point 1.7 (not yet published in the Official Journal).

# Opinion of the European Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use

*COM(2008) 663 final — 2008/0256 (COD)*

(2009/C 306/04)

On 23 January 2009, the Council of the European Union decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the

'*Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use*'

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 19 May 2009. The rapporteur was Ms HEINISCH.

At its 454th plenary session, held on 10/11 June (meeting of 10 June), the European Economic and Social Committee adopted the following opinion by 94 votes with 4 abstentions.

## 1. **Conclusions and recommendations**

1.1 The Committee takes note of the plan to improve information to the public on prescription-only medicines and wishes to express its reservations about individual points in the proposal for a directive. A harmonised legal framework would help to ensure legal certainty and clarity within the Community. The EESC has doubts about the proposal for a Directive COM(2008) 663 final, which would authorise the pharmaceutical industry to communicate directly with patients.

1.2 With the same aim in mind, the EESC considers that the significant variations from one Member State to another in rules on the legal status of medicines with regard to prescription and dispensing are an obstacle to good, understandable information on medicines. Accordingly, the EESC calls on the Commission to continue working towards harmonisation of the setting of rules on the prescription and dispensing of medicines.

1.3 Every citizen (patient) has the right to comprehensive and comprehensible information in their own language. This also applies to online information about prescription-only medicines. This information should relate to the illness in question, i.e. the information on the medicine concerned should also give patients an explanation of the illness it may be used to treat ([1]). In view of demographic changes, it is particularly important to provide older patients with the means of accessing information ([2]).

1.4 The EESC recommends setting up an independent body to provide information alongside market authorisation holders. Such a body would be able to provide information on medicines from different manufacturers used in a particular indication. The EESC therefore urges that the proposal for a directive be amended accordingly to advocate such independent bodies.

1.5 Under Article 100h(1) of the proposed directive, websites have to be registered in advance with the national competent authorities. This would ensure that public concerns, including in relation to online material, can be more easily and effectively met.

1.6 It is difficult to distinguish between advertising and information in a given case, as the dividing line between these two areas is often blurred. The EESC considers that the directive should define authorised information on the basis of quality criteria on independent, comparative and comprehensible information, without waiting for the Commission to draw up 'guidelines'.

1.7 The EESC urges that information on non-interventional scientific studies not be considered as information which can be disseminated to the public, and that the relevant sections of the proposal be deleted.

1.8 'Health-related publications' are not an appropriate means of disseminating information on prescription-only medicines. This could constitute 'push' information, whereas the scope of the directive should be confined to information which patients are actively looking for. The option of disseminating information by means of 'health-related publications' should therefore be deleted from the proposal for a Directive.

([1]) See the EESC opinion on the Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, OJ C 175, 28.7.2009, p. 116.

([2]) See the EESC opinion on Taking into account the needs of older people, OJ C 77, 31.3.2009, p. 115.

Conversely, websites can be an appropriate information channel, but the new Article 100c (b) must specify that it is referring to websites exclusively devoted to medicines and approved by the European agency and the national agencies.

1.9 The proposal for a Directive also reflects the need to make officially approved information more readable, especially in the package leaflet. The EESC strongly supports such efforts, also outside the context of proposal under discussion. Patients must be given full and comprehensible information, especially concerning the side-effects of medicines and patient lifestyle factors. Doctors and healthcare professionals should also be given further training in this regard.

1.10 The EESC calls on the Member States to set up an industry-independent online portal, soon after the entry into force of the Directive, which can be used to disseminate information on prescription-only medicines. For this to happen, conferences and forums must be organised in the Member States in cooperation with patient organisations and social security bodies including complementary sickness insurance bodies.

1.11 The directorates-general are advised to inform patients of the possibilities and dangers of online options for finding information on medicines.

1.12 The EESC endorses the methods for monitoring information set out in Article 100g. Wherever prior checks on information appear necessary, they should be carried out. However, if the content of the publication has already been approved by the competent authorities or if there is a different mechanism in place to ensure equally adequate and effective monitoring, no prior checks are needed. Member States must have scope to decide whether a mechanism is in place in their territories to ensure equally adequate and effective monitoring. Article 100g thus regulates the issue in a balanced way.

1.13 Communication between patients and healthcare professionals — in particular doctors and pharmacists — must remain the top priority. Personalised advice from healthcare professionals is vital to ensuring that prescription-only medicines are used safely.

## 2. **Introduction**

2.1 The proposal for a Directive is intended to create a clear framework for provision of information by marketing authorisation holders about their prescription-only medicines to the general public with a view to enhancing the rational use of these medicines.

2.2 The aim is to ensure the high quality of information provided by coherent application of clearly defined standards across the Community.

2.3 The Directive is to allow the provision of information through channels that address the needs and capabilities of different types of patients.

2.4 Marketing authorisation holders are to be allowed to provide in an understandable way objective and non-promotional information about the benefits and the risks of their medicines.

2.5 The directive is also intended to make sure that monitoring and enforcement measures are in place to ensure that information providers comply with the quality criteria, while avoiding unnecessary bureaucracy.

## 3. **Background**

3.1 Directive 2001/83/EC on the Community code relating to medicinal products for human use [3] provides for a harmonised framework for the advertising of medicines at Community level. This legislation prohibits the advertising to the general public of medicines subject to prescription. However, the Directive does not include detailed provisions on information on medicinal products, and only provides that certain information supply activities are exempted from the advertising provisions.

3.2 On the basis of Article 88a of Directive 2001/83/EC [4], a Communication from the Commission to the European Parliament and the Council concerning the Report on current practices with regard to the provision of information to patients on medicinal products was adopted and submitted to the European Parliament and the Council on 20 December 2007 [5]. The report notes that rules and practices on what information can be available vary significantly among Member States. While certain Member States apply very restrictive rules, others allow for several types of non-promotional information to be made available.

## 4. **Commission proposal**

4.1 The proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use envisages exempting certain types of information from the scope of the provisions on the advertising of medicines (Title VIII) and regulating information on prescription-only medicines in a new Title (VIIIa).

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[3] OJ L 311, 28.11.2001, p. 67, as last amended by Directive 2008/29/EC (OJ L 81, 20.3.2008, p. 51).

[4] Introduced by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

[5] COM(2007) 862 final.

4.2 The types of information on authorised medicinal products subject to medical prescription which marketing authorisation holders may disseminate to the general public or members thereof are listed in Article 100b of the proposal for a Directive. These include the summary of product characteristics, labelling, and package leaflet of the medicinal product, as approved by the competent authorities. Medicinal product-related information on non-interventional scientific studies is also to be allowed.

4.3 Information may only be disseminated through health-related publications, internet websites on medicinal products, and written answers to requests for information of a member of the general public (Article 100c).

4.4 Article 100d sets out general quality standards for information and required content.

4.5 Article 100g sets out provisions for the monitoring of information. The methods used should be based on the control of information prior to its dissemination, unless the content of the information has already been approved by the competent authorities or an equivalent level of adequate and effective monitoring is ensured through a different mechanism.

4.6 Websites with information on prescription-only medicines are to be registered and may not contain web-TV.

## 5. **General comments**

5.1 The aim of improving information to the public on prescription-only medicines gives rise to numerous reservations in that it authorises the pharmaceutical industry to communicate directly with patients.

5.2 As well as rules on information provided to the general public, accompanying measures are needed, particularly in terms of ensuring that information is accessible and comprehensible. It is especially important to take account of demographic change, by also informing older people and other groups with particular information needs about possibilities for using the Internet in a way which is comprehensible to them.

5.3 However, after the directive is transposed, the problem also arises of differences between the status of particular medicines in the Member States. As a result, advertising of a medicine may be permitted in one Member State, while another Member State only allows information to be provided in accordance with the provisions of the Directive. Differences in the type and quality of information available in individual Member States will therefore remain.

5.4 The proposal for a Directive also responds to heightened EU public interest in information on existing medicines and treatment options. Patients have become responsible consumers of healthcare, increasingly seeking information about medicines and treatments. However, the image of the 'empowered consumer' is an idealised picture.

5.5 More and more people are searching online for information about medicines, including those which are available only on prescription. The growing importance of the Internet must be taken into account by approaching it as a key source of information which the public can use to find out about medicines. In this context, it should be noted that action is also needed to enable those social groups that have hitherto been less frequent users of the Internet to make better use of the possibilities this medium affords (see point 5.2).

5.6 Another reason that a framework had to be established in Community law for the provision of information on prescription-only medicines is the dubious quality of some of the information available online. We must ensure that high-quality information is made available. Article 100h)(5) of the proposal requires registered websites to be clearly identified so that the public can distinguish them from suspect ones.

5.7 Since the information which market authorisation holders are allowed to disseminate on prescription-only medicines is to include the package leaflet, the EESC supports ongoing efforts — outside the context of the proposal under discussion here — to improve the readability of such leaflets. This can only happen if patient organisations are involved. The EESC recommends that a working group be set up to look into this issue.

5.8 The EESC recommends setting up an independent body to provide information alongside market authorisation holders. Such bodies could provide information on medicines from different market authorisation holders and, for instance, also present different medicines (especially generic medicines) available for a particular indication.

## 6. **Specific comments**

6.1 The EESC welcomes the continued ban on advertising prescription-only medicines to the public.

6.2 The proposal for a Directive is rightly based on the principle that officially approved information such as the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities should be classified not as advertising but as information. It should be permissible to make such information available to the general public.

6.3 If the presentation of the criteria set out in point 6.2 above differs from the officially approved form, compliance with the quality criteria set out in Article 100d must be ensured. Article 100b(b) should explicitly refer to the requirements of Article 100d, to ensure clarity. Presentation of officially approved information in a different form may be necessary due to the fact that at present officially approved information such as package leaflets and specialised information may sometimes be difficult for patients to understand. The EESC therefore reiterates that such information in the officially approved form must be made easier to read and more readily comprehensible (see point 5.7).

6.4 Information on non-interventional scientific studies should not be disseminated to the public. There are considerable doubts as to whether patients are capable of correctly evaluating information on non-interventional scientific studies and drawing the conclusions that are relevant for them, irrespective of the quality of such information. Information about such studies should continue to be provided by healthcare professionals on a case-by-case basis

6.5 'Health-related publications' are not an appropriate means of disseminating information on prescription-only medicines. Given that the term itself can be understood in different ways, it is doubtful whether it would be interpreted uniformly in the individual Member States. It may also be asked whether this method of disseminating information crosses the boundary between information sought by patients ('pull' information) to information actively disseminated to patients ('push' information), given that patients who buy health-related publications are not necessarily looking specifically for information on a particular medicine ([6]).

6.6 Under Article 100h(1) of the proposed directive, websites have to be registered in advance with the national competent authorities. This would ensure that public concerns, including in relation to online material, can be more easily and effectively met.

6.7 The costs of registration should not place an unreasonable administrative burden on either authorities or the industry.

6.8 It makes sense for information to include a statement indicating that a health professional should be contacted if the patient requires more detailed explanation of the information provided. While providing information on prescription-only medicines may meet patients' heightened need for information and reflect the changing profile of the 'informed' consumer, the information to be disseminated under the proposed directive cannot take the place of explanations provided by health professionals to individual patients.

6.9 The EESC endorses the methods for monitoring information set out in Article 100g. Wherever prior checks on information appear necessary, they should be carried out. If the content of the publication has already been approved by the competent authorities or if there is a different mechanism in place to ensure equally adequate and effective monitoring, no prior checks are needed. Member States must have scope to decide whether a mechanism is in place in their territories to ensure equally adequate and effective monitoring. Article 100g thus regulates the issue in a balanced way.

6.10 The EESC is wholeheartedly in favour of drawing up guidelines on information permitted under Title VIIIa, as provided for in Article 100g(2) of the proposed directive. These guidelines and the code of practice set out therein could clarify the distinction between unauthorised advertising and authorised information. This is necessary given the impossibility of a drawing an abstract distinction in a general definition.

6.11 The EESC endorses the ban on having web-TV on websites and on disseminating information by TV or radio.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

([6]) Particularly in the case of 'health-related publications' which are actually newspaper supplements.

# Opinion of the European Economic and Social Committee on the Proposal for a Regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, 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

*COM(2008) 664 final — 2008/0257 (COD)*

(2009/C 306/05)

On 23 January 2009 the Council decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the

*'Proposal for a regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, 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'*

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 19 May 2009. The rapporteur was Ms GAUCI.

At its 454th plenary session, held on 10 and 11 June 2009 (meeting of 10 June), the European Economic and Social Committee adopted the following opinion by 92 votes in favour and three abstentions.

## 1. **Summary and recommendations**

1.1 The EESC endorses the Commission's intention to establish a stronger pharmacovigilance system through increased market surveillance by reinforcing monitoring procedures providing for clear roles and responsibilities for the key responsible parties and for a transparent EU decision-making.

1.2 The EESC strongly recommends that the new regulatory framework put the patient at the centre of the EU legislation, providing for sufficient harmonised rules in this area in order to assure to EU citizens, at least on the long run, an equal access to sound information across the EU, and the full availability of safe, innovative and accessible medicines registered in any part of the EEA market at reasonable price.

1.3 Along this line, the EESC is in favour of significant improvements in the present situation, given that the differences emerged between the national legislative, regulatory and administrative provisions on medicinal products have deep repercussions on patients and that these differences could hinder intra-EEA trade and affecting the good functioning of the internal market.

1.4 The Committee, therefore, underlines the importance of involving patients in pharmacovigilance including direct patient interactive reporting of suspected adverse reactions: the responsibility for health care should become increasingly shared with patients taking a more active interest in their own health and care options and in a two-way channel of communication, including a sound use of internet.

1.5 The Committee support clarification and codification of tasks and responsibilities across and between all stakeholders: Member State Competent Authorities, EMEA (including its committees), Commission and Marketing Authorisation Holders, including their Qualified Person for Pharmacovigilance, and patients. The EESC believes that the new elements introduced by the proposals must neither call into question, nor weaken existing structures and procedures at local level, especially those that involve the patient and health professionals, provided that common parameters for comparable data are assured in transparent and rapid procedure.

1.6 The Committee endorses the establishment of a new Pharmacovigilance Committee to replace the existing Pharmacovigilance Working Party within the EMEA and believes that the setting up of such a committee could result in better and faster functioning of the EU system, provided that tasks, procedures and relations with the other existing committees are better clarified.

1.7 The collection and management of pharmacovigilance data in the EudraVigilance database must be fostered with new human and financial resources to become the single interactive point of rapid receipt and fast delivery of pharmacovigilance information for medicinal products together with an effective data management. It is vital for public confidence that there should be a transparent and user-friendly access policy open to all the stakeholders, especially the patients, in an interactive way, respecting data protection and confidentiality.

1.8 The EESC underlines the importance of simplified procedures for small and medium-sized enterprises (SMEs) and asks for the optimisation of the 'SME office', providing financial and administrative assistance to micro, small and medium-sized enterprises.

1.9 As international markets expand and companies operate more and more on an international basis, the EESC recommends to foster the coordination of Member States' and EC actions both at European and international level.

1.10 The EESC requests that within 5 years, the EMEA presents to the EP, the Council and the Committee, an independent external evaluation of its achievements on the basis of its new Regulation and the work programmes together with an evaluation assessment of the working practices and the impact of the new mechanism provided by this proposal, as well of the interactive functioning of the Eudravigilance database.

## 2. **Preliminary remarks**

2.1 Harmonised Community rules on the pharmacovigilance of medicinal products for human use are provided by Regulation EC/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 (EMEA), as regards medicinal products authorised by the Commission in accordance with the centralised authorisation procedure of that Regulation, and by the Directive 2001/83/EC.

2.2 Risk assessment during product development should be conducted in a thorough and rigorous manner even if it is impossible to identify all safety concerns during clinical trials. Once a product is marketed, there is generally a large increase in the number of patients exposed, including those with co-morbid conditions and those being treated with concomitant medical products. Therefore, postmarketing safety data collection and risk assessment based on observational data are critical for evaluating and characterising a product's risk profile and for making informed decisions on risk minimisation.

2.3 The present opinion is dealing with the Commission's proposals on amendments to the present Regulation only, whilst another opinion of the Committee is dealing with the amendments to the Directive 2001/83/EC [1].

2.4 The EESC is strongly in favour of significant improvements in the existing Community legal framework, given that the differences are emerged between the national legislative, regulatory and administrative provisions on medicinal products and that these differences could hinder intra-Community trade and affecting the good functioning of the internal market.

2.5 A lack of coordination would deny the Member States access to the best scientific and medicinal expertise for the evaluation of the safety of medicines and for risk minimisation.

2.6 The Committee has already pointed out that 'a strong pharmacovigilence system is vital and believes that existing systems must be strengthened. All health professionals involved in the prescribing or dispensing processes, as well as patients, should participate in an effective post-marketing surveillance system applied to all medicines' [2].

2.7 The EESC endorses the Commission's intention to establish an increased market surveillance by reinforcing monitoring procedures providing for clear roles and responsibilities for the key responsible parties and for a transparent EU decision-making on drug safety issues in order to deliver measures that are equally and fully implemented for all relevant products in EU.

2.8 The responsibility for health care is becoming increasingly shared with patients taking a more active interest in their own health and care options. The importance of involving patients in pharmacovigilance including direct patient reporting of suspected adverse reactions is recognised and the EESC welcomes the emphasis on creating and supporting ways of ensuring patient involvement at all levels.

2.9 The EESC recognises the benefit to EU citizens and patients of the new provisions for pharmacovigilance which will result in an improved access to health and medicines information and a proactive collection of high quality data on the safety of medicines. This collection and management of pharmacovigilance data in the EudraVigilance database must be fostered with new human and financial resources to become an interactive single point of receipt and delivery of pharmacovigilance information for medicinal products for human use.

2.10 The EESC is dealing with all the different aspects of the Pharmaceuticals Package of Proposals that are treated in various opinions [3] on specific subjects. To this effect an important and fruitful public hearing was held in Brussels under the chairmanship of President Bryan Cassidy with the participation of representatives of firms and of national and European organisations.

## 3. **The Commission proposals for amended regulation**

3.1 The objective of the proposals is to improve the protection of public health in the Community while enhancing the single market in medicinal products, by strengthening and rationalising EU pharmacovigilance and removing disparities between national provisions in order to ensure the proper functioning of the internal market for such products.

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[1] See opinion CESE 1024/2009 (opinion not yet published in the Official Journal).

[2] OJ C 241/7, 28.9.2004.

[3] EESC works on opinions CESE 1022/2009, Rapporteur Heinisch, CESE 1023/2009, Rapporteur Gauci, CESE 1024/2009 (INT/471) Rapporteur Cedrone, CESE 1191/2009 (INT/472), Rapporteur Morgan, CESE 1025/2009, Rapporteur Cedrone and R/CESE 925/2009 (INT/478), Rapporteur van Iersel (opinion not yet published in the Official Journal).

3.2 The proposals aim to contribute to the strategic goals of the Community framework for the authorisation, supervision and surveillance of medicinal products through:

— improving the protection of public health across the Community in relation to the safety of medicinal products;

— supporting the achievement of the internal market in the pharmaceutical sector.

3.3 The specific objectives of the proposals are:

— establishing clear roles, responsibilities and clear standards against which they perform their roles, with regular reporting by the European Commission, pharmacovigilance inspections and EMEA audit;

— rationalising EU decision-making, the timing of the establishment of the new EMEA committee structure and the number of pharmacovigilance referrals to the EMEA;

— establishing medicines safety websites by each Member State and launching of the EU safety web-portal by the EMEA in order to foster transparency and communication on medicines safety and to increase the understanding and trust of patients and health professionals on these questions;

— strengthening companies' pharmacovigilance systems, while reducing their administrative burdens;

— fostering the EudraVigilance database on the safety of medicines through risk management, structured data collection and periodic reporting of suspected adverse reactions;

— strengthening the coordination of Member States' and EC actions aimed at reinforcing strategic S&T cooperation to stimulate innovation in the pharmaceutical sector, through the FP7 programme and the Innovative Medicines Initiative;

— involving stakeholders in pharmacovigilance;

— simplifying the current Community pharmacovigilance procedures.

3.4 The proposals underline the need for adequate funding of activities related to pharmacovigilance by the Agency through the collection of fees charged to marketing authorisation holders, the resources for the EMEA Telematics Master Plan and the overall impact on the EMEA budget.

## 4. **The Committee's comments**

4.1 **Basic endorsement**: The Committee endorses the basic objectives of the proposals of the achievement of the internal market in the pharmaceutical sector, improving the protection of public health as stated above.

4.1.1 In the context of the renewed Lisbon Strategy, the Committee reiterates the concern expressed about the importance of simplification of the regulatory framework to benefit citizen, patients, firms and society, and underlines the need of 'an integrated approach in order to build advantage for the industry and patients as well as to stimulate its continued development as a major contributor to a dynamic knowledge-based, competitive economy in Europe' ([4]).

4.2 **Clear roles and responsibilities**. The Committee underlines the importance that 'all health professionals involved in the prescribing or dispensing processes, as well as patients, should participate in an effective post-marketing surveillance system applied to all medicines. This spontaneous reporting system should be particularly stringent for newly marketed medicines' ([5]).

4.2.1 The Committee is convinced that the norms as they are now can be improved with the participation of all stakeholders since one of the shortcomings is the fact that there is a lack of knowledge or information regarding the different characteristics and risks which marketed medicines have.

4.2.2 The EESC strongly support clarification and codification of tasks and responsibilities across and between all stakeholders: Member State Competent Authorities, EMEA (including its committees), Commission and Marketing Authorisation Holders, including their Qualified Person for Pharmacovigilance. Another EESC opinion is dealing with the new proposals on codification.

4.3 **Rationalising EU decision-making**. The Committee endorses the establishment of a new committee to replace the existing Pharmacovigilance Working Party within the EMEA and believes that the setting up of such a committee, to specifically deal with pharmacovigilance issues across the EU, is a step in the right direction in order to harmonise safety signals across the EU.

4.3.1 The Committee would wish greater clarity and further refinement of some of the proposals, in particular: around the interface between CHMP and the new Pharmacovigilance Committee, patient and public involvement including patient reports of suspected adverse reactions, the role of an intensive monitoring list and the definitions for non-interventional studies.

([4]) See footnote 2.
([5]) See footnote 2.

The EESC would like to refer to the recently established Committee for Advanced Therapies (CAT) which specifically deals with licensing and post-marketing issues including pharmacovigilance and follow-up of efficacy and of advanced therapy medicinal products as defined under Regulation (EC) 1394/2007. This regulation was based on the need to have the required expertise to assess such complex and specialised products.

4.3.2 Therefore, the EESC questions whether a general pharmacovigilance committee will have the relevant expertise to regulate pharmacovigilance issues for specialised products, such as advanced therapy medicinal products. It is thus suggested that for these products, the CHMP through the CAT is consulted during the risk/benefit assessment.

4.3.3 The contribution of the future new Committee on Pharmacovigilance for safety analysis should be reconsidered within the more general framework of risk-benefit ratio analysis which is and should continue to be the responsibility of the CHMP.

4.4 **Patient first**. The patient must be at the centre of the proposed new regulatory framework. Today EU legislation does not provide for sufficient harmonised rules in this area and as a consequence EU citizens have unequal access to information across the EU. Patients must be encouraged to report adverse reactions directly to the national authority for all medicines instead of to the marketing authorisation holder. The Committee is in favour of direct reporting as an essential tool to empower patients and to improve their involvement in the management of their own health.

4.4.1 It is important that clear and transparent safety information, namely a pictogram ([6]) to help consumer distinguish immediately intensively monitored drugs, the conclusions and recommendations of the Periodic Safety Update Reports (PSURs) and medicines consumption data are made public, respecting confidentiality on data protection and commercial interest. Eudravigilance has to be regularly updated and easily and fully accessible by patients.

4.4.2 The Committee believes that the patient information leaflets need to be designed to convey potential adverse reactions more clearly with the introduction of safety information on the package leaflet and the warning for medicines under intensive surveillance. In any case, information dumping must be avoided and information must be tuned on the different audience needs and supported by an appropriate use of internet: on this question the EESC is providing a specific opinion ([7]).

4.4.3 The final aim for the Committee must be the completion of a effective single European market in pharmaceuticals built on the needs and interests of European patients and citizens, in terms of availability of safe, innovative and accessible medicines needed by patients under a unified EU approach that reduce the dependence of the market on the decision-making processes in the 30 different national governments.

4.5 **Transparency and communication**. In supporting the current proposals to enhance communication with healthcare professionals and patients via product information, the Committee strongly suggests that this opportunity is taken to make both PILs and SPCs ([8]) more useful, user friendly and coherent.

4.5.1 Pharmacovigilance information for medicinal products for human use needs an interactive European database network. The EESC is strongly in favour of strengthening the Eudravigilance database as the single point of receipt of information on adverse reactions in human beings arising from use of the product within the terms of the marketing authorisation 'as well as from any other use, including overdose, misuse, abuse, medication errors, and those occurring in the course of studies with the medicinal product or after occupational exposure'.

4.5.2 Transparency should be favoured in acts and decisions at all levels of the agencies and of the EMEA. An important aspect of that is the accurate and timely communication of emerging data on risk as an essential part of pharmacovigilance. Risk communication is an important step in risk management as well as a risk minimisation activity. Patients and healthcare professionals need accurate and well communicated information about the risks associated with both the medicinal product, and the condition for which it is being used. ([9])

4.5.3 The EESC feels that the key message is to bring the ever-growing importance of a transparent policy concerning the public access to the data and that such requests must be provided within the delay prescribed by the legislation. It is vital for public confidence that a transparent access policy is agreed by all Member States. The Committee would like to have a clearer justified reason on the denied public access to the transparent and non-promotional post-marketing studies or to the results of these studies while launching the EU safety web-portal by the EMEA. The EESC underlines its strong support for

([6]) Like the black triangle scheme used in the UK.

([7]) See CESE 1024/2009, Rapporteur Cedrone (opinion not yet published in the Official Journal).

([8]) PIL & SPC = Patient Information Leaflets (PILs) and Summaries of Product Characteristics (SPCs).

([9]) See also: proposed Recommendation on 'Pharmacovigilance Urgent Measures' procedure under Art. 107 of Directive 2001/83/EC; and Directive 65/65/EEC as amended, Council Regulation 2309/93 on Rapid Alert System (RAS) in Pharmacovigilance.

guiding principles and oversight of a subset of Post-authorisation safety studies -PASS ([10]), in line with Articles 24, 26 and Article 57 (1)(d) of Regulation (EC) No 726/2004 ([11]).

4.5.4 The Committee supports the proposal for the EMEA to carry out all literature monitoring, since this would provide a significant reduction in duplication of work. The Agency shall monitor selected medical literature, in cooperation with the Marketing Authorisation holders, for reports of all suspected adverse reactions to medicinal products for human use containing certain active substances to be entered into the Eudravigilance database and in a published list of active substances being monitored.

4.6 **Simplification of procedures**. The EESC welcomes the proposed initiative to reduce administrative burden with respect to ADR reporting and to decrease the current duplicate reporting system that exists across the EU for Individual Case Summary Reports via both paper and electronic copies across different Member States. The Committee believes that it would be useful to introduce a specific legal obligation to follow the requirements of the International Conference on Harmonisation — ICH ([12]) for electronic submission.

4.6.1 Furthermore, it is important to point out that, at present, a lot of precious resources for pharmacovigilance at a National Competent Authority — NCA level are used up acknowledging and dealing with Individual Case Safety Reports — ICSRs — sent by companies with an unuseful duplication of activities. These resources could be better utilised by encouraging a stronger collaboration between the authorities, maximising the expertise available, work-sharing and simplifying the administrative aspects of the activities related to the submission and administration of all the safety reports.

4.6.2 The EESC underlines the importance of simplified procedures for small and medium-sized enterprises (SMEs) and asks for the optimisation of the 'SME office', providing financial and administrative assistance to micro, small and medium-sized enterprises (SMEs) pursuant to Commission Regulation (EC) No 2049/2005.

4.7 **Coordination of Member States' and EC actions**. As international markets expand and companies operate more and more on an international basis, the task of regulatory authorities to assess compliance with legislation and monitor the safety of medicines becomes increasingly important and resource-intensive as 'the EU pharmaceutical industry operates in a global economy' ([13]). In response to this overall situation and to address the challenges of the internal and international market, which can pose potential risks to public health, there is the need of intensified global cooperation on two different levels:

— at Community level, to enhance dynamic coordination between Community institutions and national authorities, including national agencies whose natural mission consists in animation, expertise and decision-making;

— at European and international level, to ensure a stronger voice within the Council of Europe, World Health Organisation-IMPACT, the International Conference on Harmonisation ICH and ICH Global Cooperation Group, EU-US Framework for Advancing Transatlantic Economic Integration on Administrative Simplification in Medicines Regulation ([14]), EU-Russia Common Economic Space & Regulatory Dialogue on Industrial Products, EC Agreements with Switzerland, Australia, New Zealand, Canada, Japan, the EU-China Consultation and Cooperation Mechanism on pharmaceuticals and medical devices.

4.7.1 As the Commission Vice-President Günter Verheugen ([15]) said: 'The pharmaceutical sector makes an important contribution to European and global well-being through the availability of medicines, economic growth and sustainable employment'.

4.7.2 The increasing internationalisation of the sector and the 'shortcomings in the EU pharmaceutical market which affect patients' access to medicines and to relevant information is hampering the competitiveness of the industry' ([16]). On this line, the Committee strongly recommends:

— to foster initiatives finalised to EU pharmaceutical research and international research cooperation;

— to intensify cooperation with major partners (US, Japan, Canada) to improve medicines' safety worldwide;

— to strengthen cooperation with emerging partners (Russia, India, China).

([10]) PASS: The proposed definition is: 'a pharmaco-epidemiological study or a clinical trial with an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard or confirming the safety profile of the medicinal product'.

([11]) The draft proposal of the EudraVigilance Access Policy is published for public consultation on the EMEA website (http://www.emea.europa.eu/htms/human/raguidelines/pharmacovigilance.htm).

([12]) International Conference on Harmonisation, an international organisation that attempts to standardises globally the regulatory and scientific aspects of clinical research, drug development, and pharmaceutical product registration.

([13]) See COM(2008) 666 final of 10.12.2008 and CESE 1456/2009, (INT/478) Rapporteur van Iersel (opinion not yet published in the Official Journal).

([14]) See also the agreement on mutual recognition between the European Community and the United States of America.

([15]) See Commission Vice-President Günter Verheugen, IP/08/1924, Brussels, 10.12.2008.

([16]) See EC Press Release IP/08/1924, 10.12.2008.

4.8 **Independent external evaluation of EMEA achievements**. The EESC requests that, in its report for 2015, the EMEA presents an independent external evaluation of its achievements on the basis of its founding Regulation and the work programmes together with an evaluation assessment of the working practices and the impact of the new mechanism provided for the CHMP, the CAT and the new Pharmacovigilance Committee, taking into account the views of the stakeholders, at both Community and national level.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

# Opinion of the European Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use

*COM(2008) 665 final — 2008/0260 (COD)*

(2009/C 306/06)

On 23 January 2009 the Council decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the

*'Proposal for a Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use'*

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 19 May 2009. The rapporteur was Mr CEDRONE.

At its 454th plenary session, held on 10 and 11 June 2009 (meeting of 10 June), the European Economic and Social Committee adopted the following opinion by 93 votes in favour and three abstentions.

## 1. **Conclusions and recommendations**

1.1 The EESC welcomes the Commission initiative, which aims to improve the pharmacovigilance system and its harmonisation at the EU level, and gives priority to patients and their health needs.

1.2 The EESC emphasises that it is important to base the gradual strengthening of the pharmacovigilance instrument primarily on transparency and the simplification of procedures in an increasingly concrete framework of greater harmonisation between Member States' procedures in order develop a common methodology, since the EESC is convinced of the need to work towards the goal of free movement of medicinal products and the completion of the single market in this sector.

1.3 The EESC is therefore in favour of the improvement to the legislative framework in force, which amends and substantially enhances Directive 2001/83/EC, discussed herein, and Regulation No 726/2004 (on which a specific opinion (CESE 1023/2009) has been drawn up — rapporteur: Sylvia Gauci). These measures take account of limitations encountered during the application of the current provisions and aim to replace existing national rules, which are liable to present — often unnecessary — barriers to the free movement of medicines in the EU and hinder a practical risk reduction process.

1.4 The EESC emphatically endorses the objective whereby all stakeholders are directly involved in the pharmacovigilance process, including not just professionals in the sector and the relevant public sector bodies but also patients themselves, who thus become active partners in the risk reduction process and play an increasingly active part in therapeutic choices that are more in tune with their health needs. The EESC believes that the new elements introduced by the proposals must neither call into question, nor weaken existing structures and procedures at local level, especially those that involve the patient and health professionals, provided that common parameters for comparable data are assured in transparent and rapid procedure.

1.5 The EESC points out that this initiative is fully in line with the renewed Lisbon Strategy, which, in addition to simplifying procedures, seeks to foster continuous development of the pharmaceutical sector in order to create a sector founded on knowledge-based economic growth that can contribute significantly to high-skill employment and fully respond to the healthcare demands put forward with increasing insistence by civil society.

1.6 It considers the establishment of an EMEA committee with pharmacovigilance as its specific and sole task, and the availability of a continuously updated EU database on potential risks (Eudravigilance) that is easily accessible to all citizens to be the strong points of the legislative measure, which follows a request for increasingly simple and more practical instruments for the preparation of the information leaflets that accompany all pharmaceutical products.

1.7 As a result, the EESC's assessment is positive since the initiative will reduce administrative burdens and simplify procedures for reporting adverse reactions, not least by cutting back on the current paper-based procedure for reporting between Member States.

1.8 Given the importance of pharmacovigilance for public safety in ensuring the citizens' right to safe and effective pharmaceutical products, the EESC calls for pharmacovigilance to be included in its own right in EU research programmes, starting with those set up under the Seventh Framework Programme, via programmes directly involving the EU, its Member States, industries, universities and public and private research centres.

1.9 The EESC believes that once the key issue of pharmacovigilance has been dealt with, a number of issues affecting this sector will remain unresolved such as, for instance, the price of pharmaceutical products, the varying availability of medicinal products within the Member States themselves, issues relating to the use of generic medicines and their harmonised distribution, protection against counterfeit medicines and illegal supply chains, the safe importing of active ingredients and excipients, etc. These problems have to be addressed in order to achieve the intended freedom of movement of medicinal products in the European Union and the completion of the single market.

## 2. **Introduction**

2.1 Civil society's consistent calls for 'good health' and a better quality of life place the need to provide an adequate response to healthcare issues at the top of the agenda, starting with prevention and the proper use and monitoring of medicinal products.

2.2 As one of the key tools for protecting public heath, pharmaceuticals are a valuable resource and their discovery and adequate availability are a key aspect of public heath protection. Their proper use is a key contributor to the steady rise in life expectancy while, at the same time, it helps to cut down on healthcare expenditure insofar as it reduces the cost of hospital or specialist care.

2.3 The need to review pharmacovigilance legislation was revealed by a close analysis of experience acquired and an independent study carried out in 2004 by the Commission. This report revealed several shortcomings and the need to better define the rules governing this field. As a result, the Commission decided to review existing pharmacovigilance legislation in order to bring it into line with gradual advances in general legislation on the free movement of medicinal products and making use of medicinal products safer for EU citizens.

2.3.1 Since EU pharmacovigilance legislation was first introduced in 1965, only piecemeal and limited action has been taken. In view of the limitations encountered on a day-to-day basis, we are now faced with the need for a qualitative leap in the definition of pharmacovigilance legislation, not least in order to prevent this issue from creating barriers, which are often unnecessary, to the free movement of medicinal products in the EU, which is absolutely unacceptable.

2.4 The rules currently in force are Regulation (EC) No 726/2004 of 31 March 2004 and Directive 2001/83/EC. The Directive under consideration seeks to amend the latter. Both legislative instruments have made a useful contribution to monitoring the side effects of pharmaceutical products, but the study carried out and a subsequent consultation involving all stakeholders have shown that there is room for improvement through more precise definition of these rules.

2.5 The proposed amendments fall within a strategic framework for marketing authorisations for medicinal products, and subsequent supervision and surveillance to ensure a high level of public health protection and progress towards the completion of the internal market for the pharmaceutical sector, bearing in mind the social dimension of pharmaceutical products, whose purpose should always be to benefit patients and their interests.

## 3. **Context**

3.1 In its earlier opinions, the EESC has systematically stressed the importance of Europe's competitive and highly innovative pharmaceutical industry, which over the last 50 years has been among the most high-tech, high-innovation and high-skill employment sectors, with a corresponding added value and growth rate for the modern industrial framework.

3.2 However, the positive effects of medicinal products are also accompanied by unintended, noxious side effects resulting from their use and from medication errors, including the misuse and/or abuse of the product. Misuse of medicinal products accounts for 5 % of all hospital admissions.

3.3 The responsibilities inherent in such a role are fundamental and warrant considerable attention in order to safeguard public health properly, especially since we are confronted with a marketing process in which the adverse effects of new molecules are only detected after authorisation has been granted and the new medicinal product is therefore already on the market.

## 4. **Definitions**

4.1 The term pharmacovigilance is used to define the pharmacological process dedicated to the detection, assessment, understanding and prevention of the adverse effects of medicinal products, and in particular, of short and long-term side effects.

4.2 Risk assessment during the development of medicinal products should be thorough and rigorous, even if it is impossible to identify all safety risks during clinical trials. Once a medicinal product enters the market, there is generally a substantial increase in the patients exposed to it, including patients who suffer from more than one condition at the same time or who are being prescribed a number of different types of medication.

4.3 Adverse drug reaction (ADR) is an expression that describes the unwanted, negative consequences associated with the use of given medication. An ADR could be identified as any unexpected or dangerous reaction to a drug. The meaning of this expression differs from the meaning of 'side effect', as this last expression might also imply that the effects can be beneficial. An ADR is a 'response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function'.

## 5. **Gist of the Commission proposal**

5.1 The Directive aims to strengthen and rationalise the pharmacovigilance system, especially with respect to clarifying roles and responsibilities, by amending Directive 2001/83/EC, which has served so far as the legal reference framework for medicinal products for human use.

5.2 This is why the Commission has decided to amend the existing EU legislation. The objectives pursued are as follows:

— setting out clear roles and responsibilities for the parties;

— rationalising EU decision-making on drug safety issues;

— strengthening safety transparency and communication to increase the understanding and trust of patients and professionals as regards safety;

— strengthening companies' pharmacovigilance systems;

— ensuring the proactive and proportionate collection of high-quality data relevant to safety and post-authorisation risk management;

— involving stakeholders in pharmacovigilance by enabling patients to report suspected adverse reactions and including them in decision-making;

— simplification of the current Community pharmacovigilance procedures with consequent efficiency gains for both the pharmaceutical industry and medicines regulators.

5.3 The Commission explains that the proposals are consistent with the overall objective of the free movement of medicinal products, which is to remove disparities which still exist between national provisions by reconciling a high level of public health protection with the proper functioning of the internal market for medicinal products.

5.4 All interested parties, i.e. patients, healthcare professionals, the competent authorities of the Member States and the industry, were widely consulted on the proposals. The impact assessment suggested increasing the clarity, efficiency and quality of the current EU system of pharmacovigilance with a view to public health improvements and overall cost savings to the EU pharmaceutical sector.

5.5 In order to establish clearer roles and responsibilities, the new provisions clarify and codify the tasks and responsibilities of the interested parties. Although the pharmacovigilance system will remain the province of the individual Member States, marketing authorisation holders will have to report all available data exclusively to the Community's Eudravigilance database, thereby automatically ensuring an EU-level assessment of any related issues.

5.6 These strengthened safety measures for medicinal products should increase the trust of patients and healthcare professionals by including a new 'key information' section in the summary of product characteristics and the package leaflet which accompany every medicinal product.

5.7 The responsibilities of the agency will be bolstered by the establishment of a new scientific committee responsible for pharmacovigilance, as set out in Article 27 of the new provisions, with the additional role of assessing risk, providing support both to the Committee for Medicinal Products for Human Use within the Agency and the coordination group of Member States.

5.8 Under the new provisions, marketing authorisation holders will have to keep a 'pharmacovigilance system master file' and to provide a risk management system for each new medicinal product authorised, which should be proportionate to both the identified and the potential risks.

5.9 The new proposal makes an additional improvement to pharmacovigilance by strengthening the electronic infrastructure for reporting adverse events connected with medicines (Article 24). The scope of periodic safety update reports sent to the Eudravigilance database will be amended so that they serve to analyse the risk-benefit balance. Provision has also been made for the regulatory follow-up of periodic safety update reports. Thus, Eudravigilance will provide a clear link between pharmacovigilance evaluations and the review and updating of marketing authorisations, while at the same time giving real-time access to all information on the database.

5.10 The new legislative proposal sets out to simplify the reporting of adverse drug reactions, making periodic safety update report submission proportionate to risks. This will facilitate the reporting of adverse and unintended reactions to medicinal products taken in normal doses as well as from overdose or medication errors by both healthcare professionals and patients. It combines rules for reporting adverse reactions, applying the same provisions to medicines authorised under the centralised procedures and those authorised by individual Member States.

5.11 Section 1 of Chapter 3 concerns the recording and reporting of unintended effects. Subsequent sections provide a detailed description of the other procedures for reporting and evaluating pharmacovigilance information and more detailed technical information. The second section covers 'Periodic safety update reports' the third 'Community procedure', setting out in Article 107 the procedure each Member State must follow in order to suspend or revoke marketing authorisation because serious deficiencies have been found, and the fourth section 'Publication of assessments'; this is an important section since it concerns the supervision of post-authorisation safety studies for medicinal products.

## 6. **Legal basis**

6.1 The proposal is based on Article 95 of the EC Treaty, which prescribes the codecision procedure and is the legal basis for achieving the free movement of goods for medicinal products for human use. Moreover, since the Amsterdam Treaty came into force, Article 95 has been intended to remove barriers to intra-Community trade and therefore justifies EU-level action in the area of medicinal products.

## 7. **Subsidiarity and proportionality principles**

7.1 EU pharmacovigilance measures guarantee the best protection of public health through the application of the same standards across the Community. They are also in line with the proportionality principle insofar as they seek to safeguard public health without imposing unnecessary administrative burdens by building on existing structures, procedures, resources and practices. The proposal envisages that the efficiency of the EU pharmacovigilance system will be increased and costs reduced due to the resulting simplification.

7.2 The objective of improving the safety of medicines placed on the Community market can be best achieved by applying the subsidiarity principle as set out in Article 5 of the Treaty. Under this article, the best way to achieve these objectives is at EU level, as the requirements for accreditation and market surveillance relating to the marketing of pharmaceutical products fall within the scope of Article 15(2) of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008.

7.3 Furthermore, since the proposal provides for the simplification of the Community pharmacovigilance system, it falls under Annex 1 of the Commission Legislative and Work Programme for 2008.

## 8. **General comments**

8.1 Recognising the major, positive contribution that medicinal products make to the citizens' quality of life, the EESC has always supported any initiatives liable to increase safety in the use of medicinal products, which is a fundamental aspect of public health protection.

8.2 The EESC's initial assessment of the decision to overhaul existing legislation in the light of previous experience is positive insofar as the objective of such a strategy for improving safety through the proposed amendments has been a key element of earlier EESC opinions on the various aspects of pharmaceutical policy.

Moreover, the EESC takes a positive view of the Commission's efforts towards simplification in the interests of individual patients as well as companies. It also endorses efforts being made to complete the single market in a sector as complex and important as the pharmaceutical sector.

8.3 The EESC endorses the amendments that clarify and improve the definition of terminology previously used in Directive 2001/83/EC. The new wording will help solve problems relating to previous interpretations, which sometimes gave rise to doubt and inconsistencies in application. In particular, with regard to Article 1, the EESC welcomes improvements in defining the meaning of 'adverse reaction', as used in point 11, and the way in which it has been distinguished from the use of 'suspected adverse reaction' in point 14 referred to in the same article. Its definition should take account of the risk of confusion with the International Conference on Harmonisation (ICH) definition.

9. **Specific comments**

9.1 In the same vein, the EESC takes a positive view of clarifications set out in the new point 15 with respect to the definition of 'post-authorisation safety study', and the new definition in point 28 regarding the 'risk management system', followed by a detailed description of the required documentation in the new Article 8(iaa) and point 28c) on the 'pharmacovigilance system' and point 28d) on the proposed master file, which is defined in greater detail in Article 8(3).

9.2 The EESC draws particular attention to Article 21(a) since the new definition contributes to safety by making the marketing authorisation of the new pharmaceutical product subject to the provision of substantial documentation to establish compliance with the key safety measures set out in Article 22, subject to certain conditions established by the competent authorities regarding the safety of pharmaceutical products.

9.3 Article 22(a) requires the national competent authority to require a marketing authorisation holder to conduct post-authorisation safety studies if there are concerns about risks. On the basis of documents submitted by the marketing authorisation holder, the national competent authority may withdraw or confirm authorisation. The EESC welcomes the provisions of Article 23, which, based on the findings of the study, oblige the authorisation holder to immediately inform the national competent authority of any prohibition or restriction imposed by the competent authorities of any other country.

9.4 Article 101 clearly sets out the role of Member States in the direct management of a pharmacovigilance system, making them responsible for the collection of information on the risks of medicinal products as regards patients' or public health in a single database, i.e. Eudravigilance, in accordance with detailed procedures set out in Article 24. A competent authority is to be appointed in each Member State with responsibility for collecting data on adverse reactions relating to medicinal products on the basis of conditions for authorisation and other uses including overdose, misuse, abuse and medication errors.

9.5 The EESC believes that Article 102 contributes to improving patient safety in the use of medicinal products since it enables Member States to impose requirements on doctors, pharmacists and other healthcare professionals in respect of the reporting of suspected or identified adverse reactions.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

# Opinion of the European Economic and Social Committee on the Proposal for a Regulation of the European Parliament and of the Council amending, as regards information to the general public on medicinal products for human use subject to medical prescription, 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

*COM(2008) 662 final — 2008/0255 (COD)*

(2009/C 306/07)

On 12 February 2009 the Council decided to consult the European Economic and Social Committee, under Article 152 (1) of the Treaty establishing the European Community, on the

*'Proposal for a Regulation of the European Parliament and of the Council amending, as regards information to the general public on medicinal products for human use subject to medical prescription, 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'*

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 19 May 2009. The rapporteur was Mr CEDRONE.

At its 454th plenary session on 10 and 11 June 2009 (meeting of 10 June), the European Economic and Social Committee adopted the following opinion by 91 votes with 3 abstentions.

## 1. **Conclusions and recommendations**

1.1 The Committee welcomes the proposed amendment of the regulation in question as it responds to the objectives of simplifying and harmonising information for patients.

However, the EESC considers that the significant variations from one Member State to another in rules on the legal status of prescription and dispensing of medicines are an obstacle to good, understandable information on medicines.

Accordingly, the EESC calls on the Commission to work towards harmonising the determination of the legal status of prescription and dispensing of medicines containing the same active ingredient(s), at the same dosage, for the same therapeutic indications, presented in the same way and under the various registered trade marks in existence in the Member States.

1.2 It has always supported legislative measures aimed at simplifying rules and extending them in a harmonised way to all EU Member States. As well as being advantageous to patients, this also benefits SMEs, which often find their hopes dampened by bureaucracy.

1.3 In order to achieve an ever-higher standard of information for patients, the EESC, in addition to the measures proposed by the Commission, proposes that the package leaflets that accompany every pharmaceutical product should contain information in a simple and direct visual form based on bands of colour for reporting for instance: benefits (green band), contraindications (yellow band), and possible risks (red band).

1.4 It would also be worthwhile having a list of generic medicines (pharmaceutical products with the same active ingredient whose patents have expired). This list could be put together by the Agency and supplied to pharmacies and all distribution centres open to patients.

1.5 Though aware that computer usage is not yet universal among the EU public, the EESC believes it would be useful to launch an additional procedure for providing patients with necessary information on medicines via the internet. This information, complementing rather than replacing that currently available, should be checked and should carry a label of Community recognition, in order to prevent abuses or misinformation.

1.6 While reiterating its call for continued development of the policy of streamlining bureaucratic procedures and patient information, the EESC calls on the Commission to table further legislative measures to cover all those areas of the pharmaceutical sector that still present difficulties in terms of non-harmonised application in individual Member States, as this impedes the achievement of full and free movement of medicinal products in the EU.

## 2. **Reasons for the current proposal**

2.1 The proposal in question amends current practice as provided for under Regulation (EC) No 726/2004 with regard solely to information for the general public on medicinal products for human use subject to medical prescription.

2.2 The amendments concern the rules on direct information for consumers on medicinal products subject to prescription and are aimed at securing the proper functioning of the internal market for medicinal products for human use. While amending the rules on information for the public on medicinal products for human use, the regulation also reaffirms the legislative ban on advertising, in line with the provisions of the Directive published in OJ L 311 of 28 November 2001 and the recent amendment set out in Directive 2008/29/EC.

2.3 The need to adjust the provisions of the existing regulation dates back to the Communication from the Commission to the European Parliament of 20 December 2007. That report on 'current practice with regard to information provision' noted that divergences in Member States' rules and practices regarding the provision of information had in some cases led to disparities and varying public access to relevant information.

## 3. **Gist of the current proposal**

3.1 Draft Regulation COM (2008) 662 final aims to:

— secure a high quality of information;

— ensure that information is provided through channels that address patients' needs;

— enable marketing authorisation holders to provide objective and non-promotional information in an understandable way.

3.2 The proposed amendments are aimed at filling the gaps in the current application of pharmaceutical legislation provided under Regulation (EC) No 726/2004 on information for the public on medicinal products for human use, more specifically:

— enabling marketing authorisation holders to provide the public with information, without prejudice to the prohibition on advertising;

— establishing high quality harmonised conditions on the content of information that marketing authorisation holders are allowed to disseminate;

— determining harmonised channels, in order to exclude unsolicited means of dissemination;

— obliging Member States to establish a monitoring system to be implemented only after information has been disseminated;

— stating that the information must be approved by the authorities responsible for granting marketing authorisations and must extend to information provided on web sites.

3.3 A new Title VIIIa is aimed at addressing disparities by ensuring harmonised, good quality, non-promotional information. The aim is to do away with the unjustified differences in the case of medicinal products authorised under Title II of Regulation (EC) No 726/2004, which provides for a single summary of product characteristics and applies Title VIIIa of Directive 2001/83/EC to those products.

3.4 By way of derogation from Article 100g(1) of Directive 2001/83/EC, medicinal product-related information referred to in Article 100b(d) of that Directive is to be vetted by the Agency prior to its dissemination (Article 20 b), COM(2008) 662 final).

3.5 Therefore, the tasks of the Agency provided for under Article 57 (1) will include a letter u), that of 'delivering opinions on information to the general public on medicinal products for human use subject to medical prescription'.

3.6 The third paragraph of Article 20b states that the Agency may object to the information submitted within 60 days of receipt of the notification. In the absence of opposition, the information may be published, in accordance with the principle of 'silence implies consent'.

## 4. **The Agency's tasks**

4.1 The Committee for Medicinal Products for Human Use (CMPH), which is part of the Agency, is responsible for preparing opinions on all matters regarding the evaluation of medicinal products for human use. All decisions on authorisations are taken on the basis of scientific criteria relating to the quality, safety and efficacy of the medicinal products concerned.

4.2 EMEA is made up of various committees, including the Committee for Medicinal Products for Human Use. The Agency's tasks are to:

— provide Member States and the Community institutions with scientific advice on all matters regarding the evaluation of the quality, safety and efficacy of medicinal products;

— coordinate both the scientific evaluation of medicines subject to the Community marketing authorisation procedure and the scientific resources put at its disposal by the Member States for the evaluation, supervision and pharmacovigilance of medicinal products;

— disseminate information on adverse reactions to medicines authorised in the EU by means of the Eudravigilance database, which can be consulted on a permanent basis by all Member States;

— create a public database on medicines.

4.3 The present EC regulation complements:

— Commission Regulation (EC) No 2049/2005 laying down rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises;

— Commission Regulation (EC) No 507/2006 on marketing authorisation for medicinal products for human use;

— Commission Regulation (EC) No 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations.

## 5. **Legal base, subsidiarity and proportionality**

5.1 According to the Commission, these modifications are in line with the EU's other policies and objectives. Meanwhile, the choice of Treaty Article 95 appears to be appropriate as that is the legal base for Community pharmaceutical legislation. In addition, the content of the proposed modifications responds to the requirements of Article 5 of that Treaty with regard to the principles of both subsidiarity and proportionality.

## 6. **General comments**

6.1 The EESC has always supported legislative measures aimed at simplifying rules and ensuring they are adopted in all EU Member States in a harmonised way.

6.2 It therefore welcomes the proposed amendment of the regulation in question as it responds to the objectives of simplifying and harmonising information for patients while also simplifying matters for business, starting with SMEs.

6.3 The EESC believes it would be worthwhile launching an IT-based procedure for checking information via the internet, complementing the provisions currently available. It would also be useful to improve the visual format of the leaflets that accompany all pharmaceutical products (see point 1.3).

6.4 The EESC calls on the Commission to table further legislative measures to cover all those areas of the pharmaceutical sector that still present difficulties in terms of non-harmonised application in individual Member States, not least regarding the issue of sale price and the legal status regarding prescription and dispensing, where this impedes the achievement of full and free movement of medicinal products in the EU.

6.5 The EESC would like to know why the amendment of Regulation (EC) 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' has required two separate but parallel legislative initiatives. The first Commission document (COM(2008) 664 final) provides for amendments regarding pharmacovigilance, while the second (COM(2008) 662 final) addresses information for the general public on medicinal products for human use subject to medical prescription.

6.6 The EESC takes a negative view of this compartmentalisation by the Commission, as two separate legislative measures constitute a waste of procedural resources and could cause delays in securing a single regulation.

Brussels, 10 June 2009.

The President
of the European Economic and European Committee
Mario SEPI

# Opinion of the European Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)

*COM(2008) 809 final — 2008/0240 (COD)*

(2009/C 306/08)

On 16 February 2009, the Council of the European Union decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the

*'Proposal for a Directive of the European Parliament and the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)'*

The Section for Agriculture, Rural Development and the Environment, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 18 May 2009. The rapporteur was Mr RETUREAU.

At its 454th plenary session, held on 10 and 11 June 2009 (meeting of 10 June), the European Economic and Social Committee adopted the following opinion by 109 votes in favour, with 3 abstentions.

## 1. **The Committee's conclusions**

1.1 Article 95 TEC rightly forms the legal base for the recast directive, which standardises conditions for the production and distribution of electrical and electronic equipment in the internal market. There are two reasons for adopting this legal form for the directive; this is a recast of a directive and it is the Member States that are responsible for implementing and monitoring the directive, in line with the principles of subsidiarity and proportionality.

1.2 The Committee considers, however, that monitoring the application of the recast directive should aim to ensure that harmonisation of its implementation in the internal market is as comprehensive as possible, in order to avoid potential administrative complications in a cross-border context and any distortions to competition that might ensue.

1.3 As regards possible changes to the list of toxic or dangerous substances whose use is prohibited or heavily restricted, the EESC can only accept the comitology method if the stakeholders concerned are consulted and an impact assessment is carried out for each substance added to or removed from the list.

## 2. **The Commission's proposals**

2.1 By proposing to replace the WEEE (Waste Electrical and Electronic Equipment) Directive with a recast directive intended to boost the waste recovery and processing rate, to extend the scope to medical and hospital equipment and monitoring instruments and to promote the re-use of reparable goods, the Commission aims to ensure better environmental protection and a reduction in administrative formalities. The proposal for a directive aimed at restricting the use of dangerous substances in electric and electronic equipment (RoHS), which is the subject of this Committee opinion, is complementary to and interdependent on the recast WEEE directive and must consequently be recast itself.

2.2 Where toxic or dangerous substances are concerned, the Commission's staff consider that this recast will result in modest but clear overall benefits. Furthermore, the options it recommends will have a considerable cumulative effect on clarifying the directive and harmonising its implementation and execution, thus contributing to better regulation.

2.3 The aim is in particular to extend the scope of the two directives by adding medical devices and monitoring and control equipment to the other equipment already covered by the earlier directives. The emphasis is also on the need to re-use some parts of equipment rather than treating them as waste. The appropriate declarations and proof must be provided to make the distinction between recycled equipment and waste.

2.4 The recast RoHS directive retains its legal base (Article 95, concerning the internal market), and the recast WEEE directive retains its own legal base (Article 175, concerning the environment), in line with their respective goals, which remain basically the same.

2.5 The appendices to the recast RoHS directive detail the type of equipment covered (appendices I and II) and form the new reference point for the recast WEEE directive. Toxic or dangerous substances whose restrictions are covered by the RoHS directive remain unchanged as regards their nature and acceptable threshold quantities. Scientific and technical developments, as well as any possible derogations, will be taken into account by the comitology with scrutiny procedure.

2.6 According to the Commission, the environmental benefits will probably be considerable: several tonnes of heavy metals covered by the RoHS directive (> 1 400 tonnes of lead and around 2,2 tonnes of cadmium) are used in medical devices and monitoring and control instruments, which in terms of weight, accounts for 0,2 to 0,3 % of waste electrical and electronic equipment. Where waste is poorly managed, these substances can be released into the environment (only 49,7 %

of medical device waste and 65,2 % of waste from monitoring and control instruments are collected separately); Restricting the use of these substances under the RoHS directive will, in the medium and long term, help to eliminate them from goods and the resulting waste. A more detailed analysis suggests that, even in scenarios indicating higher recycling rates, including this equipment in the scope of the RoHS directive does benefit the environment.

2.7 Harmonised definitions in all related directives will also help to ensure better implementation and the elimination of administrative barriers (see point 3.3 below) and excessively divergent implementing procedures.

## 3. **General comments**

3.1 The technique of recasting instruments such as the WEEE and RoHS directives can, as in the case now under consideration, lead to a thorough overhaul of existing legislation.

3.2 This recast should address all uncertainties regarding scope and definitions and the different practices in the Member States concerning product conformity in addition to the potential obsolescence of the directives as a result of the new REACH regulatory framework. Genuine harmonisation is crucial to limiting the implementation costs of the measures put forward, in addition to the administrative burden.

3.3 The complementarity and coherence of the two directives with other Community legislation (a common framework for the marketing of products [1], REACH [2] and energy-consuming products [3], which concerns equipment design) should be stepped up.

3.4 The Committee is pleased to note that no changes have ultimately been made to the list of prohibited or restricted substances in electrical and electronic products, which upholds an equivalent level of protection for workers and consumers.

3.5 The EESC consequently reiterates the need for vigilance concerning a number of illegal transfers of dangerous waste to countries that are not technically equipped to process them properly, which presents serious environmental and health risks for those countries. The processing of electronic waste already poses serious public health risks in some of these countries and this situation could worsen if the preliminary waste treatment proposed in the WEEE directive is not carried out properly and because extending the scope to categories 8 and 9 adds new risks.

3.6 The Committee notes that the list of prohibited or restricted substances is not changed by the proposed recast. When considering whether to authorise potential replacement products for the most toxic or dangerous substances, it must be ensured that they do not themselves present any risk. Possible exemptions should only apply to substances that are absolutely irreplaceable in the light of current knowledge and technological developments and with all the necessary protection and precautionary provisions in place.

3.7 The scope defined in appendices I and II of the recast RoHS directive can be amended by the Commission under the comitology with scrutiny procedure, but the EESC considers that any substantial changes at a later date should be subject to new impact assessments and to new preliminary consultations. The Committee welcomes the use of the REACH methodology for the possible introduction of new prohibitions on substances.

3.8 The EESC recognises that harmonising definitions horizontally, covering all of the directives concerned (see point 3.3 above) is a measure that will bring clarity and reduce administrative costs.

3.9 The Committee also acknowledges that setting a reasonable deadline for exempting certain substances (four years) is likely to boost the quest for alternative solutions, whilst providing sufficient legal certainty for manufacturers.

3.10 The EESC is aware that the amended regulatory framework has some influence on business growth and employment and welcomes the improved coherence between the two recast directives and the legislative and administrative simplification that they promote.

3.11 The Committee welcomes the extension of the RoHS directive's scope to two additional categories of equipment (categories 8 and 9 covering medical devices and monitoring and control instruments) and the adoption of the principle of partial re-use of the equipment collected), because it considers controls that help to identify the waste from recycled devices, on the basis of the declaration and monitoring, to be proportionate.

[1] OJ L 218, 13.2.2008, p. 82.
[2] OJ L 396, 30.12.2006.
[3] OJ L 191, 22.7.2005, p. 29.

3.12 The EESC is also satisfied with the harmonisation of the definitions of the economic operators concerned with those of the 'product marketing' package and with the new definitions that have been added (concerning medical devices, for example).

3.13 The Committee very much hopes that harmonisation of the Member States' implementation will be much more effective than it has been to date in the context of the previous directives before they were recast. An evaluation in a few years' time would be desirable to ensure that the stated aims have indeed been met.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

# Opinion of the European Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council on Waste electrical and electronic equipment (WEEE)

*COM(2008) 810 final — 2008/0241 (COD)*

(2009/C 306/09)

On 20 January 2009, the Council decided to consult the European Economic and Social Committee, under Article 175(1) of the Treaty establishing the European Community, on the

'*Proposal for a Directive of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE)*'

The Section for Agriculture, Rural Development and the Environment, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 18 May 2009. The rapporteur was Ms Sylvia GAUCI.

At its 454th plenary session, held on 10 and 11 June 2009 (meeting of 11 June), the European Economic and Social Committee adopted the following opinion by 103 votes with three abstentions.

## 1. **Introduction**

1.1 The objective of the review of the WEEE directive should be to provide positive impacts, both environmental and economic. This will benefit the environment, business operators and European citizens.

1.2 Experience has shown that the aim of the WEEE Directive, which is to achieve a functional internal market approach to waste management, has not been realised.

1.3 During the implementation of the WEEE Directive there have been many problems with many differences between member states.

1.4 These differences are partly caused by ambiguous definitions in the Directive but also by the freedom in implementation given to the Member States in Article 175 of the EC Treaty.

## 2. **Conclusions and Recommendations**

2.1 To date, the Committee can summarise the issues that need to be looked at as a result of the review of the WEEE Directive, as follows:

2.2 The WEEE Directive has a simplification potential by reducing the administrative burden on the market operators.

2.3 In reviewing the Directive, the European Union together with national authorities should ensure that the Directive creates a level playing field across all EU countries. A dual legal base of articles 95 and 175 of the EC Treaty would be desirable, whereby provisions related to the scope, definitions, product requirements and producer responsibilities related to the putting on the market of new products should fall under the legal base of article 95 of the Treaty and provisions related to targets and waste treatment under article 175 of the EC Treaty.

2.4 All actors in the chain, including producers, importers, retailers, traders, scrap dealers, should face the same responsibilities when dealing with WEEE.

2.5 The review of the Directive should allow for a better interaction between provisions for the protection of the environment on the one hand and rules that affect the smooth functioning of the Internal Market on the other.

2.6 In particular, the producer definition should not lead to more barriers to the Internal Market. This will be more in conformity with recent case law of the European Court of Justice that requires that the environmental protection does not run counter to the principles of the Internal Market. The definition of producer as proposed in article 3(j) of the WEEE recast proposal should also tie in to the extent possible with relevant definitions provided in Decision 768/2008/EC, while acknowledging the specific obligation that arises from the WEEE Directive, namely that registration as well as financing of collection and recovery are not characteristics of products (e.g. composition, ingredients, environmental impact), but additional obligations which have to be fulfilled at national level exclusively (i.e.: market surveillance and enforcement).

2.7 A revised Directive should not create any obstacles to the practice of sharing costs of WEEE management on the basis of current market shares. The way forward for Annex II is to allow interested parties to continue developing treatment standards. Currently, market-share based collective systems have proved successful in managing WEEE properly.

2.8 The Directive should fulfil its social aim to protect the environment and reduce the impact of waste on human health. Tackling the electrical and electronic waste stream in the EU in a cost-effective manner should help eradicate the shipment of this type of waste to third countries, where the environmental standards are lower and the risks for the manpower handling this waste are higher.

3. **Specific comments on the articles**

3.1 *Article 3 (j) new: Producer definition*

3.1.1 The Committee agrees with the new producer definition, but at the same time points out that this definition may lead to free-riders and distortion of competition.

3.1.2 It is intended to ensure a smooth functioning of the internal market. In this regard, the EESC appeals to the Commission to simplify the procedures, whilst blocking the way for abuse by free-riders.

3.1.3 The amended producer definition, in conjunction with the clarification of the terms 'making available on the market' under Article 3(o) new and 'placing on the market' under Article 3(p) new allows operators to voluntarily undertake specific actions without facing the risk of having to bear costs linked to the end of the life of the product.

3.1.4 By distinguishing the role of each operator, businesses can anticipate costs and thus take up a clearer part of responsibility as a result of their involvement in the supply chain of electrical and electronic equipment.

3.1.5 For the practical implementation, it must be possible for Member States to impose national obligations to the natural or legal persons who are placing products onto their national markets for the first time from third countries as well as from countries inside the Community (intra-community trade). Therefore, Member States may put in place proportionate provisions that allow them to identify these persons and have the possibility to ask these persons to provide the registration and the financing of the management of WEEE arising from their sales.

3.1.6 The Committee believes that the most positive environmental improvements and highest cost-efficiency, as a result of a clear producer definition, can be realised in the following ways:

— The producer definition should cover the same operators across all EU Member States.

— The Committee also believes that national producer registers should function in a more harmonised manner: The different administrative requirements of various national registration and reporting schemes are indeed leading to increased costs for producers operating cross boarder on the internal market.

— Producer registers differ in the information collection from producers and their operating principles. Amongst others, the definitions for types of equipment, criteria for weight, basis for the figures that are reported, as well as consideration for sales to other Member States, differ between registers. The frequency and periodicity of reporting data also vary.

— The Committee therefore deems it important that the European institutions issue recommendations and guidance in order to achieve this objective, following appropriate consultation of stakeholders.

— The Committee also believes that a European network of national registers should be created in order to exchange information. The Network would facilitate harmonised producer registration in Member States, reflecting the activities of that registrant in the entire EU. This would ease the administrative burden for registrants and at the same time lead to a more efficient enforcement of the directive. More harmonisation and less bureaucracy would make it easier to reach environmental improvements and goals.

— The Committee is of the view that in order to prevent free-riders a European clearing house should be established to monitor and make transparent flows of goods and to ensure the financial balance of European collection and recovery systems, as should mutual (administrative) law enforcement measures and effective legal assistance among the individual EU Member States.

3.2 *Article 5: Separate collection*

3.2.1 The take back schemes for WEEE are a necessary step to collect WEEE from private household equipment at a large scale.

3.2.2 The Committee insists that such waste can be returned to the distributor free of charge on a one-to-one basis as long as the equipment is of equivalent type and has fulfilled the same functions as the supplied equipment.

3.2.3 The Committee believes however that consumers should be made aware about the scope of their rights, in order to avoid confusion about the role of the market operators. Indeed, market operators should not be regarded as waste collectors at the expense of the customer, without any limits. In particular, market operators should remain free to frame their take back obligations as long as the take back did not happen at the moment of the delivery of the purchased good. The Committee thinks that this will save transport and manpower costs to businesses. These savings make sense from an environmental and a competiveness point of view.

3.3 *Article 7: Collection rate*

3.3.1 The Committee agrees with revisiting the current collection target. A collection rate of WEEE based on sales volumes, however, is inappropriate, since in almost every case, products have a much longer lifetime than one to-two years and therefore they do not come to recycling two years after sale.

3.3.2 Due to the fact that materials are more valuable now than five to ten years ago. WEEE with a net value (i.e. a high metal content) disappears from the established collection routes. The consequence is that such WEEE collected is not reported in the official WEEE channel. Such leaked WEEE goes either to bad treatment, or to no treatment/landfill, or to illegal export, or to good treatment or to legal export. Precise figures on the destination of such leaked WEEE are not available today (see Environmental Agency Report of March 2009).

3.3.3 The Committee believes that in the future, all market operators must be held responsible for management of WEEE over which they must gain more control.

3.3.4 The Committee acknowledges that the success of meeting collection targets depends on factors outside the sole control of producers, ranging from availability of collection points to the volume of WEEE generated by the end user.

3.3.5 The Committee therefore believes that producers should not be held liable alone: studies have shown that there are large flows of WEEE collected and treated outside the official WEEE systems and that there are many stakeholders, other than producers, that can influence the volumes collected and recycled.

3.3.6 The Committee underlines that the review of the WEEE Directive should aim at maximising its environmental results (collect more) and increasing the costs efficiency of WEEE treatment (treat better).

3.3.7 The Committee believes that if collection targets are measured at the moment the WEEE reaches the recycling systems, the operation of parallel flows makes it impossible for producers to collect enough WEEE to achieve the target. The Committee therefore suggests that a more effective way to reach the collection targets would be to measure when the material reaches the recycler, as this method would capture all the WEEE flows, rather than the producer flows in isolation.

All in all, the Committee underlines that parallel flows need to be subject to regulation, to ensure that all WEEE is recycled in accordance with the requirements of the Directive. In particular, that such other actors than EEE producers should be obliged to report on WEEE collected by them.

3.4 *Article 12: Financing of WEEE from private households*

3.4.1 The Committee believes that the responsibility of financing in respect of WEEE from private households should not be exclusively placed with the producers, as suggested by the Commission proposal in the new article 12.

3.4.2 The Committee deems it important that producers are given incentives to choose between individual or collective solutions based on their product portfolio and business models.

3.4.3 To date, Article 8 of the WEEE Directive obliges producers of electrical and electronic equipment to meet the costs of recycling their products at the end of their products' life. The EU established an individual producer responsibility (IPR) requirement through Article 8.2 of the WEEE Directive, whereby each producer is financially responsible for the recycling of waste from his own-brand products from private households, put on the market after 13 August 2005. The producer can choose to fulfil this obligation either individually or by joining a collective scheme.

3.4.4 At this moment, producers are investigating solutions. It could well be that in the near future producers may want to deal with this issue either in individual or collective systems.

3.4.5 The Committee shares the view that article 8.2 is the appropriate legal framework for the implementation of producer responsibility for WEEE.

3.4.6 The review of the Directive must be considered an opportunity to strengthen the freedom of choice between Individual Producer Responsibility and collective solutions.

Brussels, 11 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

# Opinion of the European Economic and Social Committee on the Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions — Towards an EU strategy on invasive species

*COM(2008) 789 final*

(2009/C 306/10)

On 3 December 2008 the European Commission decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the

'*Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions — Towards an EU strategy on invasive species*'

On 24 February 2009, the Bureau of the European Economic and Social Committee instructed the Section for Agriculture, Rural Development and the Environment to undertake the preparatory work.

In view of the urgency of the matter, the European Economic and Social Committee, at its 454th plenary session, held on 10 and 11 June 2009 (meeting of 11 June), appointed Mr SIECKER as rapporteur-general and adopted the following opinion by 109 votes in favour with 2 abstentions.

## 1. **Conclusions and recommendations**

1.1 Invasive species ('IS') are an increasing threat to biodiversity, agriculture and public health. At this moment, the estimated cost of IS is between 10 and 12 billion Euro a year, which also makes it a real threat to the economy.

1.2 The Committee acknowledges that there is a clear need for action, as also expressed at the highest political level, and takes note of the four policy options to tackle IS, as described in the Communication: 'business as usual', use of existing legal instruments together with voluntary measures, adapted existing legislation and the setting up of a comprehensive, dedicated EU legal instrument.

1.3 The Committee acknowledges that the document provides an excellent analysis, but at the same time notes that the Community should have responded already three years ago when the Biodiversity Action Plan was adopted, and therefore calls for immediate action.

1.4 The Committee is convinced that the best approach to tackle the threat of IS would be through the adoption of a comprehensive, dedicated EU legal instrument, as well as the establishment of a European Agency to monitor implementation.

1.5 The Committee emphasises the need to raise awareness among the EU public about the threat posed by IS due to rapidly growing trade and transport activities. This could be achieved through communication and education activities, highlighting the various threats and the economic cost of no/insufficient action.

1.6 The Committee deems it important that the social aspects of tackling IS are duly taken into account in the application of current EU rules or in a future comprehensive EU legal instrument, as illustrated by the significant health risks associated with the gasification of tankers upon their arrival in EU ports.

## 2. **The issues at stake**

### 2.1 *What are Invasive Species?*

2.1.1 The term 'Invasive Species' used throughout this document encompasses the terms 'Invasive Alien Species' as found in the Convention on Biological Diversity and 'Invasive non-native species'. Invasive Species are broadly defined as species whose introduction and/or spread may threaten biological diversity or have other unforeseen consequences. The European Commission states in its Communication that Invasive Species (IS) are becoming an increasing problem to the EU.

2.1.2 The DAISIE project, supported under the Sixth EU Research Framework Programme, has identified 10 882 non-native species present in Europe, 10 — 15 % of which are expected to have a negative economic or ecological impact. The main drivers directly affecting biodiversity are habitat change, climate change, over-exploitation, pollution and IS.

### 2.2 *The need for action*

2.2.1 While EU instruments exist to deal with four out of those five factors, there is, in contrast to several other OECD countries, currently no comprehensive instrument at EU level to tackle IS. This shortcoming needs to be addressed if the EU is to attain its goal 'to halt the decline of biodiversity by 2010'. In addition, IS also represent a major economic threat to the EU.

2.2.2 The need for coordinated action to tackle the IS issue has been expressed at the highest political level. The Environment Council, the European Parliament, the Committee of the Regions [1] and the European Economic and Social Committee [2] have all stressed the need for an EU strategy on IS and an effective early warning system and for effective response mechanisms at EU level. Similar commitments have been included in the Sixth Environmental Action Programme, as well as in the Communication from the Commission on Halting the Loss of Biodiversity by 2010 and Beyond and its associated Action Plan.

2.3 *The main pathways*

2.3.1 Invasive species (IS) may arrive and enter a new region through three broad mechanisms: importation as a commodity, introduction via a transport vector, and/or natural spread from a neighbouring region where the species is itself alien. These three mechanisms result in six principal pathways: release, escape, contaminant, stowaway, corridor and unaided.

2.3.2 Rapidly growing trade and transport activities expand the opportunities for IS introduction, and environmental pressures. The existence of the single market means that once an IS is introduced in the territory of one Member State, it can be dispersed rapidly throughout the EU. Therefore, addressing trade-related issues can only be done effectively at the EC's external frontier. Given the way that these species become established and spread, measures taken by one Member State can be totally negated, if neighbouring countries fail to take action or respond in an uncoordinated manner.

2.3.3 Rising $CO_2$ concentrations, warmer temperatures, greater nitrogen deposition, altered disturbance regimes and increased habitat degradation are likely to facilitate further invasions.

## 3. **The impact**

3.1 *Impact on ecology*

The environmental consequences of IS are considerable, ranging from wholesale ecosystem changes and the near extinction of native species, to more subtle ecological changes. IS are considered one of the major threats to biodiversity.

3.2 *Impact on the economy*

IS can reduce yields from agriculture, forestry and fisheries. They are also known to decrease water availability and to cause land degradation through increased soil erosion.

3.3 *Impact on public health*

A number of human health problems, e.g. allergies and skin problems, are caused by IS, the effects of which are aggravated by climate change.

3.4 *Impact on budgets*

In 2008, an initial estimate assessed annual IS-related costs in Europe at between EUR 9 600 million and EUR 12 700 million per year. This figure is undoubtedly an underestimate, as it is based on current expenditure to eradicate and control IS plus the documented cost of the economic impact.

## 4. **Approaches to tackle IS**

4.1 As regards the policy response to IS threats, an internationally agreed 'three-stage hierarchical approach' supports measures based on 1) prevention, 2) early detection and eradication, and 3) control and long-term containment.

4.1.1 *Prevention*

To reduce or prevent further introductions by trade, it would be necessary to step up controls and inspections at borders. Preventing intentional introductions could be achieved through imposing stricter rules supported by exchange of information between national, regional and international bodies working on the control of IS. Prevention in relation to hitchhiker organisms that are introduced on the hulls or in ballast water of ships would benefit from the ratification and implementation of the Ballast Water Convention.

4.1.2 *Early detection and rapid eradication*

Early detection and rapid eradication of IS depend on effective monitoring programmes, coupled with an early warning mechanism to inform other potentially affected areas as quickly as possible, and to exchange information on potential eradication strategies.

4.1.3 *Control and containment*

Where IS are both established and widespread, the emphasis must be placed on control and containment. Once again this will entail effective exchange of information and implementation of coordinated campaigns and actions to control/stop the spread of the species concerned.

## 5. **Existing tools and policy options**

5.1 *Existing legislation*

Having regard to the different elements of a strategy as described above, the Commission has assessed the current EU legislation, research programmes, action plans and

[1] OJ C 57, 10.3.2007.
[2] OJ C 97, 28.4.2007.

other initiatives. The Commission has concluded that there are major gaps between all the existing EU legal instruments, making an adequate response to the threat of IS practically impossible. At the international level, the International Maritime Organisation adopted the Ballast Water Management Convention in 2004, which should enter into force 12 months after ratification by 30 states, representing at least 35 % of world merchant shipping tonnage. As of 28 February 2009 only 18 states representing 15.36 % of world tonnage had ratified. The 18 states include just two EU Member States, i.e. Spain and France. Norway, one of the EEA States, has also ratified.

5.2 *Policy options*

The Communication describes the following four options to tackle IS appropriately:

5.2.1 Business as Usual

The 'business as usual' option provides a reference point, against which other options can be assessed.

5.2.2 Maximising the use of existing legal instruments together with voluntary measures

The formal legal requirements would remain as they are today but there would be a conscious decision to proactively address IS problems under existing legislation. Member States would voluntarily make IS issues part of their border control function. A Europe-wide Early Warning and Information System based on existing activities could also be set up.

5.2.3 Adapted existing legislation

This option is similar to option 5.2.1 in most respects, but would include amendments to the existing legislation on plant/animal health to cover a broader range of potentially invasive organisms.

5.2.4 Comprehensive, dedicated EU legal instrument

This option would involve the setting up of a comprehensive, dedicated legal framework for tackling IS with independent procedures for assessment and intervention taking into account existing legislation. If it were considered desirable and cost effective, the technical aspects of the implementation could be centralised by a dedicated agency. Member States including the European Outermost Regions would be obliged to carry out controls at borders for IS and to exchange information on IS. Mandatory monitoring and reporting procedures and efficient rapid response mechanisms might also be established. While it is possible to envisage some EU funding being dedicated to support eradication and control actions, Member States could also fund these actions directly. This option would be the most effective in terms of control of IS. It would provide the greatest legal clarity whilst respecting the principle of proportionality.

6. **Comments**

6.1 *Repetition*

The EESC acknowledges that the document is an excellent analysis. It paints a clear picture of how serious the threat of IS on biodiversity, agriculture, public health and on the economy in general is. However, the Committee notes to its surprise that the same analysis — maybe not in exact words but certainly in the same spirit — was already laid down in the 2006 Biodiversity Action Plan, which provided the same argumentation. The EESC had surely hoped that something more would have been achieved by now than just a repetition of a three year old analysis. The Communication calls for actions that should have been taken years ago.

6.2 *Need for a comprehensive approach*

6.2.1 The Commission writes in the Communication that halting the loss of biodiversity in the EU will not be possible without tackling IS in a comprehensive manner. The ecological, economic and social consequences of IS in the EU are significant and require a coordinated response. At present, the Community is unable to deal with IS efficiently and biodiversity-rich areas, e.g. EU overseas entities, do not receive appropriate attention. The existing EU legislation partially covering different aspects of IS makes coordinated implementation difficult. Policy consistency between most Member States is low or non-existent. Scientific scenarios point to a dramatic increase in biological invasions. Therefore it is likely that the situation will get worse.

6.2.2 The Committee is convinced that the best way to tackle the threat of IS would be through the adoption of a comprehensive, dedicated EU legal instrument as well as the establishment of a new European Agency to coordinate and execute the management of IS according to the three-stage hierarchical approach. That is the only way to ensure effective action, as is also stressed in the magazine *Science*. The estimated cost of such a European agency would be between EUR 4 and EUR 10 million a year, which is insignificant compared to the costs of the ecological, economic and sanitary impacts if the EU does not take action. A Commission initiative to stimulate EU-wide ratification of the Ballast Water Management Convention as quickly as possible would also be a major step forward in managing IS in an adequate way.

6.3 *Probable resistance*

6.3.1 A new European legally binding instrument, as well as a new European Agency to execute new legislation, may meet resistance in several Member States for financial reasons. In their view, this type of measures should be paid for from

the European budget, as it would be unreasonable to make the Member States with major ports and air hubs — by definition the places where most IS enter Europe — financially responsible for a policy the entire EU would profit from. Politicians in the Member States may see additional legislation and regulation to address an increasing biological invasion as a cost and therefore as an impediment to national economical growth, while taxpayers will most probably resist those extra costs, as they don't yet recognise the threats posed by IS. However this reluctance should not become an excuse for not taking action.

6.4 *Communication and education*

6.4.1 It is important to have an informed and engaged public in order to address IS issues effectively. At the moment, only 2 % of European citizens feel that biological invasions are important threats to biodiversity. Communication and education activities should build a sense of responsibility amongst European citizens, authorities and industries with regard to the potential threats of trade in and movement of potential IS. If these communication and education activities are not limited to the threat to biodiversity but also highlight the other dangers — to public health, to agriculture — people may become less reluctant towards new legislation and the establishment of a new European Agency, especially when it becomes clear that doing nothing will be much more expensive in the long term than acting now. And the sooner adequate action is taken, the lower the overall costs will be.

6.5 *Social aspects*

6.5.1 The EESC suggests that the Commission examines all existing tools and legislation to tackle IS and their harmful social side effects. The example of the gasification of containers that are shipped to Europe from other continents, to ensure that they arrive uncontaminated in European ports, illustrates these side-effects.

6.5.2 There are several ways to ensure that containers arrive uncontaminated in EU ports. However, the most common way is to gasify the containers with methyl bromide. Although that is the easiest and the cheapest way in the harbours where the containers are shipped from, it is at the same time the most complicated, as well as most expensive and most dangerous way in the harbours where the containers arrive.

6.5.3 Gasified containers need considerable time to degasify before they are safe to enter. However, as the entire economy is based on 'just-in-time' systems and containers have to be unloaded directly, there is often no time to degasify the containers properly. Due to this pressure, dock workers may enter the containers too early and without proper protection. Furthermore, gasified containers are often not labelled properly that they should be handled with care. To ship a gassed container is more expensive than to ship an un-gassed one, and in order to save costs many gassed containers are shipped without the prescribed label that they should be handled with care. In those cases, dock workers enter the containers without any protection to unload them directly after arrival. Since methyl bromide is not visible and has no smell, the poisonous gas can do its destructive work without the workers being aware of this. Consequently, an increasing number of dock workers have been contaminated with the very poisonous methyl bromide and disabled for the rest of their lives. As there are alternatives for treatment with methyl bromide, a ban on gasifying containers would fit well within a future framework of sustainable control measures for the early detection of IS.

Brussels, 11 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

# Opinion of the European Economic and Social Committee on the Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions — A European Strategy for Marine and Maritime Research — A coherent European Research Area framework in support of a sustainable use of oceans and seas

*COM(2008) 534 final*

(2009/C 306/11)

On 3 September 2008 the European Commission decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the

*'Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions — A European Strategy for Marine and Maritime Research — A coherent European Research Area framework in support of a sustainable use of oceans and seas'*

The Section for Transport, Energy, Infrastructure and the Information Society, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 20 May 2009. The rapporteur was Marian KRZAKLEWSKI.

At its 454th plenary session, held on 10-11 June 2009 (meeting of 10 June 2009), the European Economic and Social Committee adopted the following opinion unanimously.

## 1. **Conclusions and recommendations**

1.1 The European Economic and Social Committee recognises the content and proposals contained in the Commission Communication COM(2008) 534 as beneficial for the development of marine and maritime scientific research in the EU and considers that the strategy for marine and maritime research outlined in the Communication represents an opportunity for achieving the objectives set out in the Communication.

1.2 The Committee endorses the main objectives of the new Strategy for Marine and Maritime Research, especially those which, when achieved, will help integrate the individual marine and maritime research centres and programmes which exist in the different Member States.

1.2.1 The Committee believes that one effective method for overcoming the lack of integration in the research sector is the development of an appropriate research infrastructure. The Committee notes that the broad outline for developing this infrastructure, set out in the Communication, serve to achieve this aim.

1.2.2 In the Committee's view, to increase the level of integration in the research field, the Member States should tailor their strategies to the European research objectives set out in the Communication. Equally, the EU institutions should account of any feedback received from the Member States.

1.3 The Committee draws attention to the importance of informing civil society of the results of marine and maritime research. Coastal communities are particularly interested in the results of marine and maritime research as they will have an ever-increasing impact on the development of these regions.

1.4 In the Committee's view, providing the various marine and maritime research centres in Europe with access to databases used for such research in the different countries of the EU is one aspect which can have a significant impact on the effective implementation of marine and maritime research strategies. Accordingly, the Committee believes that access to databases could be increased by the Commission's proposal to launch a European marine observation and data network (EMODnet).

1.5 The Committee views as priority research on regional and global ecosystems and how they relate to the issue of climate change and its impact.

1.6 The Committee considers the following four key regions to be core areas for European marine and maritime research:

a) the Baltic Sea region

b) the Mediterranean and Black Sea region

c) the Atlantic and North Sea region

d) the Arctic Ocean region.

1.7 The Committee wishes to highlight the importance of establishing a common set of comprehensive indicators (for each of the regions identified in Point 1.6), calculated on the basis of jointly used databases. This issue should be addressed in more detail by the Commission and the Council in the follow-up work to the Communication. The Committee believes it would be particularly useful to develop further the indicators describing the state of marine ecosystems and their evolution.

1.7.1 The indicators describing the state of the marine ecosystems will provide a basis for assessing the effectiveness of any action taken to ensure the protection and sustainable management of maritime resources and will enable the observation and evaluation of any changes occurring within marine ecosystems.

1.8 It is important to ensure the continuity of marine and maritime research work, and the new strategy should ensure this to a far greater extent. There have been several recent cases of important marine and maritime research projects being terminated.

1.9 It is vital to ensure that the research requested is relevant to the economic activity of both large businesses and SMEs. Equally, in this context, it is important to provide enterprises with better access to the results of such research, so that they can make use of it. This is why the process of informing stakeholders and coastal communities about the plans, scope and results of such research has such an important role to play.

1.10 It is also necessary to resolve the issue of those fields of marine and maritime scientific research which are not covered by the European Research Strategy and which, as a result, experience difficulties in securing funding for their projects. For this reason, a reference to supporting such research through dedicated Commission funds should be included in the documents drawn up as part of the follow-up work to this Communication.

1.11 The Committee believes that the Commission's future action in the field of marine and maritime research should focus more on the threats to the natural biodiversity of the Mediterranean, Baltic, North and Black Seas caused by the progressive loss of natural habitats for marine flora and fauna.

1.12 The Committee believes that promoting the creation and supporting the development of existing partnerships for marine and maritime research represents a key aspect of the strategy. Accordingly, the EESC endorses the Commission's plan to launch a new governance model for research that will take the form of a 'Forum' bringing together a 'partnership sustainable over the long term' and urges the Commission to draw up proposals in the short term to create a network of contacts between scientific communities involved in marine and maritime research, thereby helping to harmonise the process of creating partnerships.

1.12.1 In the Committee's view, the proposed 'forum' should, in addition to scientists, also encourage the participation of representatives of the various stakeholders involved along with marine and maritime policy-makers.

1.12.2 Further to the recently established European Fisheries Control Agency, it would be desirable to involve the agency in the work of the 'forum.' The Committee considers that the agency should play an important role within the 'forum.' Its opinion should also be sought when drawing up research plans, in its areas of competence.

1.12.3 The Committee encourages the Commission to set up the planned advisory mechanism for the two-way exchange of information between the scientific community and maritime policy-makers.

1.13 The Committee calls on the Commission to support the construction of oceanographic research vessels in the Member States in order to step up marine and maritime research, improve its quality and broaden the range of research topics covered. In the Committee's view, a decision should ideally be taken to establish a pan-European marine and maritime research facility.

1.14 Taking into account the existence, importance and the development of a regional infrastructure for marine and maritime research within the EU [1], the Committee, whilst recognising and endorsing the assistance to be provided in terms of regional needs mapping, as outlined in the Communication, calls on the Commission to consider developing links between 'large' (European and national) and 'small' (regional) research networks when defining the scope of these needs.

1.15 As a final remark on the conclusions and recommendations presented in the opinion, the Committee urges the Commission in its work on the follow-up to the communication, to assess the impact of marine and maritime research not only on the sustainable maritime economy, but also on sustainable development in general.

## 2. **Context**

2.1 The European Strategy for Marine and Maritime Research presented in Commission Communication (2008) 534 constitutes an essential part of the action plan [2] accompanying the Communication on *An Integrated Maritime Policy for the European Union* [3]. The outlined strategy also represents a continuation of the Galway [4] and Aberdeen [5] declarations, two key maritime policy documents.

2.2 The strategy set out in the communication under consideration also puts into effect the EU Programme outlined in the Green Paper on The European Research Area: New Perspectives [6] and its specific recommendations contained in the Council Conclusions [7] on the launch of the 'Ljubljana Process' — 'towards the full realisation of the European Research Area.'

2.2.1 In this context, the communication under discussion represents an example of a coherent European Research Area framework in support of a sustainable use of oceans and seas.

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[1] According to the Conference of Peripheral Maritime Regions of Europe (CPMRE) — 20 % of marine and maritime research is conducted in the regions.
[2] SEC(2007) 1278.
[3] COM(2007) 575.
[4] Galway Declaration; http://www.eurocean2004.com/pdf/galway_declaration.pdf
[5] Aberdeen Declaration; http://ec.europa.eu/maritimeaffairs/pdf/Aberdeen_Declaration_final_2007.pdf
[6] COM(2007) 161.
[7] Council Conclusions on the launch of the 'Ljubljana Process' — June 2008.

2.3 A number of EESC opinions in recent years have outlined the Committee's views on a series of Commission documents dealing with the EU's maritime policy in general and the European Research Area. These opinions did not focus more widely on the issue of European marine and maritime research largely due to the fact that the EU institutions had not put forward any documents which fully addressed the issue of marine and maritime-related scientific research.

2.3.1 Among the EESC opinions mentioned above, it is worth highlighting those in which the Committee called for more marine and maritime research in the fisheries sector ([8]).

## 3. **General comments**

3.1 Given the increasing scope of marine and maritime research in the European Union and its ever-greater role, it is essential to ensure the integration and coordination of such research.

3.2 The approach set out in the Communication represents an important opportunity to develop European marine and maritime research, in particular by:

— making better use of funding for marine and maritime research;

— strengthening the international dimension of research as a common source of knowledge and skills;

— placing a greater emphasis on environmental issues and innovation;

— integrating the various fields of research.

3.3 The Communication's proposal to establish closer ties between existing European institutes specialised in the field of marine and maritime research, with the aim of eventually creating a European network of European sea and ocean research institutes, provides an important impetus for taking further joint action in the field of European marine and maritime research and may be considered to be an important step towards **building the capacity** of the EU's marine and maritime research sector.

3.4 The Communication refers to the activity of scientific research platforms, such as the ESFRI ([9]) or the principle of ensuring European support for marine and maritime research with a global dimension, which can help achieve the objectives of the EU's integrated maritime policy.

3.4.1 The Committee endorses the ESFRI initiative, which represents a significant opportunity for marine and maritime research communities across Europe. The ESFRI's activity should also be useful for a wide range of interest groups, including industry and small and medium-sized enterprises (SMEs) and regional science and research communities. Ensuring that SMEs have access to a common research infrastructure is a matter of considerable importance.

3.4.2 It is also vital to ensure close cooperation between scientists and sea/maritime resource users as well as between scientists and institutes which specialise in protecting the marine environment and NGOs.

3.5 As regards the issue of the **integration** of established marine and maritime research disciplines, as proposed in the communication, the implementation of the strategy outlined in the document should make use of the results of the cooperation between the EU Member States under initiatives such as ERA-NET and ERA-NET PLUS aimed at coordinating scientific research. These results will provide data and information on common EU research priorities and on those areas of research where the Member States are prepared to strengthen their cooperation.

3.5.1 One example of a marine and maritime research initiative involving the participation of all the countries bordering a European sea is the European Economic Interest Grouping which is preparing to implement a joint Baltic Sea research programme (BONUS) under Article 169 of the EC Treaty.

3.5.2 In the opinion of the Conference of Peripheral Maritime Regions of Europe ([10]), effective coordination should be ensured between initiatives aimed at integrating research activities, for instance through building networks of Poles of Excellence, as well as via initiatives aimed at integrating research funding programmes, for instance through Era-Nets.

3.5.3 **The integration and coordination** of marine and maritime research should provide easier access to information about the marine environment. It should also lead to savings as funding is often currently used to conduct identical or very similar research in several different research centres simultaneously.

3.6 The marine and maritime research strategy set out in the communication attaches a large degree of importance to ensuring that marine and maritime research funding under the 7th Research Framework Programme is used as leverage to promote a **synergy effect** between Member States' research efforts and, where necessary, **reach a critical mass** to address major cross-thematic marine research challenges.

3.6.1 Given the need to achieve synergies between research activities, it is vital that future scientific research focus on, among other things, the sustainable support, collection and management of data on the seas

3.6.2 It is important to ensure that action aimed at achieving synergies between research projects takes account of the various regional approaches. In the opinion of the Conference of Peripheral Maritime Regions of Europe ([11]), the regions support the objective of a better coordination of marine and maritime research programmes in Europe, an aim which is pursued, for example, by the Era-Net scheme, and, in future, by the joint programming.

([8]) EESC opinions calling for the allocation of more funding for marine and maritime research (OJ C 318, 23. 12. 2006, pp. 117-121, OJ C 224, 30. 8. 2008, pp. 77-80).

([9]) European Strategy Forum on Research Infrastructures.

([10]) Conference of Peripheral Maritime Regions of Europe 'CPMR Draft Working Document on Marine & Maritime Research' — November 2008.

([11]) See Footnote 11.

3.6.3 However, as highlighted in the CPMR documents, projects funded under Era-Net have so far rarely involved regions. It would therefore be useful to either set up new funding schemes to coordinate regional research programmes that do not have a sufficient critical mass to integrate major Era-Net projects or to establish conditions of coordination between regional authorities and stakeholders involved within Era-Nets. Such coordination should also ideally be organised on the basis of maritime basins.

3.6.4 Coordination between Structural Funds, the Framework Programme and other European funding sources is also a key objective. Such coordination can only result from a coherent use of European funding sources by beneficiaries such as researchers and SMEs and of a coherent programming of funds in which the regional level plays a crucial role.

3.7 The strategy outlined in the communication recommends the design of an effective and innovative research governance framework that engages scientists, policy-makers and the public, so as to achieve shared understanding and informed decision-making based on sound scientific knowledge.

3.7.1 This approach to governance in research should be viewed in a positive light. The Commission has made it possible for Member State governments to establish a new framework for marine and maritime research involving scientists, industry representatives and public authorities, an opportunity which should be seen as a step in the right direction.

3.7.2 Given the role which the regions play in supporting maritime transport and research, they should be considered — along with the regional economic and social councils which are also often active at local level — as partners in the proposed system of governance for marine and maritime research.

## 4. **Specific comments**

4.1 The Committee believes that the list of major research topics requiring a cross-thematic approach outlined in Box 2 should be supplemented as follows:

— by including in the above-mentioned list cultural and sociological research on the circumstances and evolution of communities living in the EU's maritime and ocean regions;

— by ensuring that the scope of the research conducted by the network of research institutes covers the creation and development of structures for the sustainable support and management of data on the seas (linked to the objectives of the Natura 2000 programme), including the creation of GIS (Geographic Information System) maps for maritime and coastal regions, which will be useful for spatial planning and the integrated management of maritime regions;

— by attaching a greater importance to marine and marine research conducted outside Europe aimed at implementing economic strategies, e.g. research into new transport options or the mining of raw materials in the Arctic region as a result of the effects of climate change as well as research on fishing in areas outside Europe which are particularly important for the EU's supply needs;

— it is important to place a greater emphasis on research covering ocean floors and trenches; in the case of these types of projects, it is important to collaborate with countries from outside the EU. For this reason, agreements should be signed with Canada, Russia, the USA or Japan regarding research in the Arctic region;

— by highlighting more the need to share research on new technologies in the field of seas and oceans relating to, for example, extraction activities in European maritime areas or investments in renewable energy in these regions;

— by making efforts to combine some of the research topics listed in the table with the marine and maritime research work carried out by the armed forces;

— it is important that the work on the research topics listed in the table is carried out in accordance with the principle of regionalism.

4.2 The Committee urges the Commission to refer directly to the list of examples of pan-European research infrastructure projects, as identified by ESFRI, and which may be developed during FP7 (2007-2013), in the documents drawn up on the basis of the Communication when discussing and assessing progress on building new observation and research infrastructure.

4.2.1 The following projects on the list are in the field of marine and maritime scientific research:

— Coastal research vessels (primarily on the Baltic Sea)

— The 'Aurora Borealis' icebreaker research vessel

— The European Multidisciplinary Seafloor Observatory (EMSO)

— EURO ARGO European infrastructure for research and protection of biological diversity (Global Ocean Observing Infrastructure).

4.3 The Committee believes there is a need to pay special attention to focusing support on building more oceanographic research vessels, which represent the principal marine and maritime research tool.

4.3.1 While the coordination and research activities conducted by research institutes are very important, oceanographic research vessels are needed if we are to investigate what is taking place further away from the shoreline. Sadly, however, Europe has only a modest fleet of research vessels. If it is to carry out comprehensive and effective marine and maritime research, the EU must above all have appropriate research vessels at its disposal.

4.4 On the issue of developing new models for higher education in the marine/maritime field, as raised in the Communication, the EESC notes one field of studies where synergies have been achieved and which merits consideration when identifying examples of educational innovation is sozology. This university discipline covers the nature-based, technical, economic and legal aspects inherent in the modern approach to sustainable development, and therefore dovetails with the contemporary approach to the maritime economy.

4.5 Considering that one of the Communication's main objectives is to achieve synergies in the field of European marine and maritime research, the EESC believes that it is possible to ensure the closer integration of research and, accordingly, increased synergies through the adoption of a comprehensive approach to the field of research in question.

4.5.1 One example of such activity is the synergy-based approach to coastal area research covering both the effects of climate change (e.g. rising sea levels) and geological events, as well as recreational opportunities etc. (necessary cooperation in the environmental, technical, economic and legal fields).

4.6 In order to achieve synergies in the area of marine and maritime research, the Committee believes that it would be appropriate to create a three-level system (organisational pyramid) to manage the finances allocated to research projects. The following core areas (regions) would represent the foundation of this structure:

a) the Baltic Sea region;

b) the Mediterranean and Black Sea region;

c) the Eastern and Central Atlantic and North Sea region;

d) the Arctic Ocean region.

4.6.1 A regional or inter-regional structural management centre should be set up to coordinate all action taken to share information and create inter-disciplinary research objectives, which integrate the research policies of the countries located in (or bordering on) the above four regions, drawing on the experience and marine/maritime scientific/research infrastructure of these four core regions.

4.6.2 The central coordination system located in the European Research Area, which would also act as an information centre on research funding, would constitute the highest level of this organisational structure.

4.7 A regional approach is necessary given the individual environmental and natural specificities of the various sea basins. While they share many characteristics common to the entire marine environment, the natural events and processes underway in these areas are different in nature and in the way they run their course. This is the case for instance, when we compare what is taking place in the Baltic Sea region with the situation in warmer seas e.g. the Mediterranean or Black Seas, or the Atlantic coast whose tides are a characteristic feature.

4.8 There is an urgent need to set-up 'associations' within these specific regions, using the existing infrastructure as a basis. Examples would be a Baltic association of research stations, research vessels, research institutes or higher education institutes.

4.8.1 The aim of these associations should be to share information on research and educational tasks being carried out and to carry out joint agreed research and educational projects.

4.9 One important field of marine and maritime research which has achieved clear synergies is research into eutrophication and its effects. While it is a worldwide phenomenon, some of its causes and effects may differ in each of the proposed regions (basins), confirming the need to adopt a regional approach. Equally, however, there is scope for clear synergies considering the causes of the phenomenon, research methods and impact analysis, particularly economic analysis, as well as the related medical/epidemiological aspects.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

# Opinion of the European Economic and Social Committee on the Green Paper — Towards a secure, sustainable and competitive European energy network

*COM(2008) 782 final/2*

(2009/C 306/12)

On 13 November 2008, the European Commission decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the

*'Green Paper — Towards a secure, sustainable and competitive European energy network'*

The Section for Transport, Energy, Infrastructure and the Information Society, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 20 May 2009. The rapporteur was Ms BATUT.

At its 454th plenary session, held on 10 and 11 June 2009 (meeting of 11 June), the European Economic and Social Committee adopted the following opinion by 124 votes to one, with four abstentions.

## 1. **Conclusions and recommendations**

In reply to the questions raised by the Commission in its Green Paper, the EESC would make the following remarks:

*On network policy:*

1.1 **Obstacles and levels for action:** Standardised procedures which can be monitored in a democratic fashion would boost transparency in international relations, the EU's choices, price setting and operators' (network regulators' and managers') profits. It is essential to listen to the views of local residents and to keep consumers informed.

1.2 **Differences of opinion:** Member States must retain freedom of choice as to the type of energy they opt for. The Commission can play a coordinating role, taking account of the population's requirements in energy supply and spatial planning. The role of the associated network managers (ENTSO-E) and the regulatory agency (ACER) [1] must be defined, as must the legal force and enforceability of their decisions.

1.3 **R&D:** the share of R&D funding should be assessed and can only be increased. Such funding contributes to the efficiency of networks, their maintenance and durability, as well as to energy efficiency which can loosen the noose of dependence and usher the EU into the new energy era.

1.4 **Main activity:** without losing sight of the interests of the end consumer, it is vital to complete the networks, as well as devising common strategic guidelines and the framework rules of the market and overcoming their shortcomings to ensure energy transportation everywhere in the Union, securing energy supply and storage and clearly defining competences and responsibilities. Promoting general interest means securing good networks, good quality service and everything which ensures universal access, security and continuity at affordable prices

1.5 **Relations with non-Member States:** the Union should speak with one voice in the international arena on matters pertaining to energy and energy transportation networks; it should also tackle these questions as an integral part of the Union's diplomacy (ENP) and propose governance standards in transit countries.

It seems a good idea to develop dialogue with Turkey. It is vital to carefully assess the investment risk in relation to expected advantages and to respect the rights of local employees and the link between energy measures and development policy. The Committee feels that energy, transport and the environment constitute three different parts of the same picture.

*On the TEN-Es:*

1.6 **Approach, support and investment:** only the Union can gain an overall view of supply and take cross-border action. EU diplomacy provides support when faced with local risks and other parties' spheres of influence. The Commission should make clear whether it is speaking about infrastructure or supply. The TEN-Es are important for infrastructures. Decisions affecting them should be taken by public authorities and there should be specific EU funding for them, at whatever level is useful. The Community aid invested in these networks should not be recouped by raising the prices charged to consumers. Operators' budgets should be transparent. Possibilities for Community guarantees for investors and loans to operators should be developed. The Union has to invent new public governance for investment.

[1] ENTSO-E: European Network of Transmission System Operators for Electricity; comprising 42 network managers from 34 European countries.
ACER: Agency for the Cooperation of Energy Regulators. Pivot role for the development of the single market in electricity and gas.

1.7 **Revision of the guidelines:** the EESC would like to see improvements in infrastructure efficiency through research, public recognition of the issues at stake and (i) the launch of genuine social and sectoral dialogue and (ii) studies on the timeliness and feasibility of a European energy SGI serving the public ([2]).

1.8 **Extension to include oil infrastructures:** This should be done to include oil infrastructures, reserving Community aid, after taking stock of the situation, for loss-making oil companies. The EESC would be against an extension to include $CO_2$. The EESC feels that extending the field of competence of the TEN-Es to $CO_2$ capture would be premature until it is established that it is worth while and safe to do so; this requires a major debate in society on clear proposals which will have to be set out in the proposal.

1.9 **New priority projects:** it is useful to stress interconnection failings; the EESC is in favour of connecting the network up to renewable energy sources, such as the Baltic and North Sea wind farms. For projects running up to 2050, connections with energy sources in the process of being developed (offshore sub-marine energy) should also be envisaged.

1.10 **Security of supply and solidarity:** evidence of this in the eyes of the public would be provided by good communication and reflected in retail price levels. The Green Paper does not spell out how solidarity should work between Member States. It supposes that everyone contributes to the movement of energy within the Union and that strategic stocks are built up which can be made available to other Member States in the event of an emergency. Together with the Union as a whole, Member States should advocate energy solidarity throughout the world and respect the principle of general public interest within the Union.

1.11 **Additional measures for a sustainable structure:** energy sustainability is supposed to be inherent in the idea of connecting renewable sources of energy up to the network, but it has not been established. For electricity networks, modernisation is necessary to remedy problems relating to line losses, frequency, voltage and the harmonisation of codes between Member States; for gas networks, the capacity and security of storage facilities have to be improved.

*Moreover:*

1.12 TEN-Es require high quality maintenance which calls for highly skilled labour. The EESC deems it vital to take account of social aspects, disregarded by the Green Paper, so as to keep to the Lisbon strategy and the sustainable development strategy. It believes that the know-how of European network professionals should be developed to safeguard expertise and jobs in Europe. It calls for a European consultative committee on energy and climate change to be set up.

1.13 The EESC advocates the creation of a European fund specifically for guaranteeing European solidarity in concrete terms for the public. An inevitable corollary of an integrated energy policy, a body of Community law on corporate responsibility towards the public, should be put together. The European Charter on the Rights of Energy Consumers should be applied.

## 2. **Introduction**

2.1 The Commission considers that the current state of Europe's energy networks is preventing it from delivering energy policy goals (sustainable, competitive and secure energy) and the '20-20-20' climate targets. TEN-Es and the network policy must therefore be updated. The Green Paper focuses on the review of the TEN guidelines and the financing tool for these networks.

2.2 The context has recently become even more strained, with a new gas crisis in the east, fresh conflict in the Middle East and a global financial crisis, all of which could affect the completion of the TEN-Es.

## 3. **Gist of the Green Paper**

3.1 The Union would develop its infrastructure policy focusing on eight regional priorities: network interconnection in the Baltic States; the south-east gas supply corridor; a Mediterranean ring; electricity connections from the centre and south-east of the Union; an action plan for liquefied natural gas (LNG); development of the wind farm in the north of the EU; creation of the TEN-E networks; and market integration.

3.2 The Union could envisage:

— devising a network policy, including import networks;

— developing supply security and solidarity between Member States, especially through infrastructure projects working towards a true European energy network;

— arranging for general studies to be carried out to benefit everyone, while supporting specific projects;

— connecting up new energy sources and ensuring the integration of carbon-zero options and new network technologies;

— encouraging private resources and moving towards a new funding instrument;

([2]) OJ C 175 of 28.7.2009, p. 43.

— making aid dependent on national strategic plans dovetailing with European priority projects;

— justifying public sector intervention when the market does not deliver; and

— helping introduce more flexibility into administrative procedures.

3.3 The Green Paper wishes to promote public understanding and solidarity to achieve the 2020 objectives.

## 4. **General comments**

4.1 The title of and introduction to the Green Paper give the impression of a global approach designed to make the energy networks more secure and sustainable. Instead of that, it concentrates on setting up international links, without proposing to draw up an inventory of maintenance, workforce training and skills, or research and development - all important aspects of security and sustainability.

4.2 Competition is of interest to consumers when it is a means and not an end in itself, allowing them to save money while providing as reliable a service as under a monopoly system. Private finance and calls for partnership to complete TEN-Es are valuable, but they nevertheless underline the real barrier to the development of integrated European gas and electricity networks, namely the lack, at EU level, of strong public commitment backed up by substantial resources.

4.3 Energy provision is a service of public interest, and private investment is hard to reconcile with this in the long term. The market will not be able to secure the change to the new energy era heralded by the energy/climate change package by building on old means of production and transportation. The Commission, which wishes to encourage private resources to come into play, can act directly at cross-border level in order to devise a new comprehensive plan and propose a new form of public governance for investment in order to secure, through the networks, the continuity of a service of general interest, namely the supply of energy.

## 5. **The state of EU energy policy**

5.1 To the EESC's mind, TEN-Es require coordination of all the stakeholders by a body which is perforce centralised; this runs counter to market logic. The Commission should state that the objective is to seek optimal cost-benefit solutions which can benefit consumers; otherwise the latter may query the purpose of the internal energy market.

The role of ENTSO-E and ACER is ambiguous in the Green Paper. They will be centres of coordination, but they must not be involved in decisions relating to the use of public funds. The EU should concern itself with ensuring continuity in research and development; this must not come under these agencies.

## 6. **Specific comments**

*The networks*

6.1 With increased resources, the networks would *trigger* energy solidarity. The Union should identify the missing links in its connections and focus its efforts on remedying shortcomings. The EESC feels that the successes of the European Neighbourhood Policy should guarantee success here too. It notes that there is no mention of the geographical limit of the connections, the way they are implemented, the organisations responsible for maintaining frequency and electric voltages, the policy to follow in the event of part of the network failing or the division of responsibilities and competences, including the Union's coordination competences.

It feels that since the infrastructures are so very cumbersome, highly structured and long-lasting, the market prospects have to be explained to investors and the public in a completely transparent fashion.

The EESC would like studies to be carried out into the timeliness and feasibility of a European energy service of general interest for the benefit of the public, with a common approach to prices, taxation, financial security rules, continuity, economic development and climate protection.

6.2 Sustainability would be obtained through the connection to the renewable energy network (northern wind farms) and $CO_2$ transportation to storage facilities; this does not in fact concern the sustainability of TEN-Es. For electricity networks, the Commission should mention their modernisation to deal with problems of line losses, frequency, voltage, code harmonisation between Member States and the development of intelligent networks.

6.3 The EESC, although aware that technology now makes it possible to capture $CO_2$, believes that it is too early to open up TEN-Es to include $CO_2$ capture networks. This question should first of all be the subject of extensive public debate ([3]).

([3]) For mankind, the ideal would be to be able to use $CO_2$ directly as a source of energy without it having to be fossilised first - could research achieve this one day?

*Security of supply*

6.4 For the EESC, oil imports could be made safer on two levels:

— **on an international level:** by reaching agreements on investment in third countries which could make a contribution; the proposal to incorporate oil pipelines into TEN-Es would alleviate the serious risks that the rising volumes of maritime oil transport pose to maritime security ([4]) and the eco-system, but this requires in-depth assessments because, from the public's point of view, it might be risky for the EU to finance the construction of installations for rich oil companies, the cost of which the market would not have covered;

— **on a national level:** by developing renewable energy sources and boosting storage capacities and the physical security of the networks.

*International relations*

6.5 The EESC believes the EU should speak with one voice in the international arena with regard to energy transportation networks. Energy should form an intrinsic part of EU diplomacy and lay the foundations for new political solidarity between Member States and with neighbouring countries. The Green Paper could have mentioned concrete measures in this respect.

6.6 These networks must not become the focus of disputes resulting in armed conflict or areas of lawlessness, particularly for workers. On the contrary, they should be a vector for development policy. Dialogue on energy issues with Turkey, a strategic area, should be developed, as should the systematic use of the euro in transactions.

*Solidarity*

6.7 **Energy solidarity works on three levels:** between Member States, between the public and the EU and between operators. The Green Paper does not spell out how solidarity will be ensured even between Member States. Commercial and contractual practices between operators do not promote solidarity (shareholder demands), while they should be defending their energy solidarity in the world. All parties should contribute to the movement of energy within the Union, without refusing or hampering interconnections. The EESC favours regulatory tools which, in emergencies and based on collective decisions, would allow unused capacities to be placed on the market (mandatory resale as part of a *'use it or lose it'* approach).

6.8 As well as pooling stored resources, the EESC believes that setting up a specific European reserve fund earmarked for emergency intervention could be another way to demonstrate European solidarity, in order to protect Member States and the public from risks linked to production sites and their geographical and geopolitical situation.

*ENTSO-E and ACER: planning*

6.9 TEN-E planning must include a clear remit for ENTSO-E and ACER and define the mediation role falling to the EU. The Green Paper is not explicit enough on this point. The EESC regrets the fact that a) the legal function of most of the European regulators is limited to establishing a competitive market, without reference to security of supply, and b) the Commission's competence is not clearly defined. Associating national regulators does not necessarily mean creating a European regulator. The EESC would query the legal nature of such a body, the extent of its powers and the monitoring thereof. It considers that one of the Commission's roles should be act to prevent differences of opinion regarding the establishment of networks, involving local authorities in TEN-E projects quite far upstream in the process.

*European dimension of general interest*

6.10 This is cited in the proposal to justify public authority intervention in the event of market failure. While it is essential, the conditions have not been clarified, and the EESC expresses its regret at this fact.

*Funding*

6.11 EU funding ([5]) serves as a catalyst for the creation of new projects. Member States have to provide most of the finance; direct subsidies may be granted for specific projects. For the 2007-2013 planning period, Community financial aid remains relatively unchanged in relation to the previous period, and therefore has shrunk in real terms. The Commission is proposing to carry out studies for the benefit of all.

6.12 **It seems that no consideration has been given to:** (i) future consumption, (ii) the condition of networks and the cost of repairing them, and (iii) the impact of new technologies (new renewable energy sources, new ways of transporting them - such as smart networks - and consuming them, and energy efficiency).

6.13 The Green Paper is proposing to combine existing ways of funding these networks with increased recourse to private sector contributions. The EESC has noted that the market is not keen on investment which takes too long to bring a return; it does however favour seeking out innovative ways of paying for strategic projects, as long as they do not place too heavy a burden on the public purse. It feels that TEN-Es must be covered by public decision-making.

([4]) See SEC(2008) 2869.

([5]) Established in EC regulations from 2236/95 to 680/2007 for the current period — 2007-2013.

*Network competitiveness*

6.14 The Commission reiterates that TENs were 'originally an internal market instrument' for which 'the assumption was that investments would be borne by the market players who pass the costs to consumers'. The EESC considers that since the Union is co-financing the TEN-Es, it should invent a new form of public governance for investment. The public money invested in these networks should not be recouped by passing the cost on to consumers.

6.15 The Green Paper does not state how the new situation will be more 'competitive', how more freely flowing energy transportation would lead to greater competition or how consumers would benefit from this. The EESC recalls the Commission's hypothesis of linking all trans-European networks.

*Research and training*

6.16 The EESC believes that the EU should focus its efforts on research in order to keep technological expertise within Europe, which is necessary to secure energy efficiency and efficient energy transportation.

*Employment*

6.17 Since know-how is not always located in the same countries as the networks and interconnections, the EESC calls for an unrestrictive application of the 'Posting of workers' directive. The EESC wishes to see the creation of a European consultative committee on energy and climate change.

*Public understanding and communication*

6.18 The EESC recommends following the Commission's proposals for promoting public 'understanding'. The major projects funded by the EU should aim to improve people's living conditions and to provide universal services, using techniques that ensure prices are as affordable as possible; this is not something which would happen automatically in a competitive market. Moreover, in order to help Member States come to the aid of the public when commitments are not met and/or networks are blocked, a European emergency intervention fund would help secure continuity of service despite network blockages (in the event of a *force majeure*, war, bankruptcy, stock exchange upset, etc). Network companies' responsibility to the public could be investigated.

6.19 The supervisory and assessment bodies should be open to greater participation and should involve all stakeholders, both social partners and civil society.

6.20 In order to obtain public support, special efforts must be made that go beyond communication. The reasons behind the almost systematic hostility of local residents to interconnection projects ([6]) should be examined and dealt with in complete transparency.

6.21 The EESC feels that security of supply, solidarity between Member States and the fight against climate change can help promote new growth.

6.22 The EESC stresses that energy, transport and environment policies should be presented together as a three-pronged approach.

Brussels, 11 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

([6]) COM(2006) 846 final/2, Priority Interconnection Plan, 23.2.2007.

# Opinion of the European Economic and Social Committee on the Proposal for a Council Directive (Euratom) setting up a Community framework for nuclear safety

*COM(2008) 790 final — 2008/0231 (CNS)*

(2009/C 306/13)

On 30 January 2003, the European Commission decided to consult the European Economic and Social Committee, under Article 31 of the Euratom Treaty on the

*'Proposal for a Council (Euratom) Directive setting out basic obligations and general principles on the safety of nuclear installations'*

*'Proposal for a Council Directive (Euratom) on the management of spent nuclear fuel and radioactive waste'*

(COM(2003) 32 final — 2003/0021 (CNS) — 2003/0022 (CNS)).

The Committee issued an opinion on these proposals on 26 March 2003.

On 4 June 2009, the European Commission decided to consult the European Economic and Social Committee on the amended version of one of these directives:

*'Proposal for a Council Directive (Euratom) setting up a Community framework for nuclear safety'*

in order to elicit its comments in an opinion complementing that of 26 March 2003.

The Section for Transport, Energy, Infrastructure and the Information Society, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 20 May 2009. The rapporteur was Mr DANTIN.

At its 454th plenary session, held on 10 and 11 June 2009 (meeting of 10 June), the European Economic and Social Committee adopted the following opinion by 100 votes, with three abstentions.

## 1. **Conclusions and recommendations**

1.1 There is now a renewed interest in nuclear energy, for economic reasons and as a result of the need to diversify energy supplies and reduce greenhouse gas emissions.

1.2 An extremely high level of safety and exemplary transparency are prerequisites for the existence and development of nuclear power.

1.3 In this context, the Committee welcomes the directive, judging that it has a considerable technical and strategic interest for the safety of the population, those working in the nuclear industry and the environment, whilst giving the Member States the freedom to choose whether or not to use this type of energy.

1.4 The EESC appreciates that nuclear energy will also be developed outside the borders of the European Union, sometimes in countries where the technological and risk management culture is less advanced than in the Member States. In view of this, the Committee would like the EU to play a proactive role and to have the capability to make proposals on nuclear safety issues beyond its borders, as it does in relation to the 'climate package'.

1.5 Nuclear safety must be '**a worldwide public good**', since a nuclear accident can have an impact on populations and the environment at a great distance from the state where it occurs. In this regard, by making compliance with the fundamental safety principles approved by all IAEA states **mandatory**, which is the objective of the directive, the EU will put itself in the position of being able to export its 'safety model' beyond its borders.

1.6 The Committee considers that the focus on obliging Member States to establish totally independent national safety authorities, making licence holders fully responsible and ensuring that information on these issues is transparent, is the best approach, and therefore wishes this aspect of the directive to be retained and for the approach to remain based on a very high level of responsibility.

1.7 The EESC is particularly interested in the question of building, maintaining and developing skills in the Member States, particularly those which have little or no experience with nuclear energy. These Member States must address this question without delay, in particular by developing the necessary training opportunities. In addition, the EESC suggests that consideration be given to European certification of competence in the field of nuclear power, and that training relates to the technical management as well as to the health aspects of nuclear accidents.

1.8 The Committee stresses that safety is also a question of industrial culture and behaviour; it is not solely a matter of drawing up regulations and restrictions.

## 2. **Introduction**

2.1 The nuclear industry developed considerably in the EU following the fuel crisis in 1973 and the need to harmonise safety practices soon became apparent.

2.2 The Council Resolution of 22 July 1975 on the technological problems of nuclear safety ([1]) gave the Commission a role as a catalyst in initiatives taken at international level in the field of nuclear safety.

2.3 A second Council Resolution was adopted in 1992 ([2]), in which the Council reaffirmed the intentions of the 1975 Resolution and invited Member States to continue and intensify their efforts towards the harmonisation of safety issues. In its ruling of 10 December 2002 in Case C-29/99, the European Court of Justice confirmed the Commission's remit to legislate in the field of nuclear safety.

2.4 On 30 January 2003, under Article 31 of the Euratom Treaty, the Commission proposed a directive on the safety of nuclear facilities ([3]), on which the Committee issued an opinion ([4]).

2.5 In the absence of a majority, the Council did not adopt this directive, but the consultation process continued with the creation of the Council Working Party on Nuclear Safety in 2004.

2.6 The Commission now intends to give fresh impetus and consideration to the implementation of a Community framework for nuclear safety.

## 3. **Objectives, approach and key elements of the new draft directive**

3.1 The general objective of the proposal is to achieve, maintain and continuously improve nuclear safety in the Community and to enhance the role of the regulatory bodies. Its scope of application is the design, siting, construction, maintenance, operation and decommissioning of nuclear installations, for which consideration of safety is required under the legislative and regulatory framework of the Member State concerned. **The right of each Member State to decide to use nuclear energy or not is recognised and fully respected**.

3.2 The approach of the directive on nuclear safety is to introduce Community regulations incorporating a set of principles already included in the IAEA's Convention on Nuclear Safety, that has been accepted by all the Member States and to supplement them with additional safety requirements for new nuclear power reactors.

3.3 The aim is therefore to **render binding** the internationally endorsed nuclear safety principles (IAEA, CSN, WENRA…), which are currently **applied on a voluntary basis**.

## 4. **General comments**

4.1 Energy from nuclear fission currently represents around 14,6 % of the primary energy consumed in the European Union and 31 % of the electricity generated. For the Member States which have recourse to it (fifteen ([5]) of the twenty-seven) it is the energy source with the least fluctuation in prices and one of the lowest production rates of $CO_2$. However, the use of nuclear power is controversial even in some countries which use it and still more so in the Member States which have not made it a part of their energy mix, for fear, in particular, of the radioactive pollution that could result from possible safety breaches and the management of nuclear waste.

4.2 In accordance with the perspectives contained in the Committee's opinion on *The issues involved in using nuclear power in electricity generation* ([6]), there is now a renewed interest in nuclear energy, both for economic reasons and due to the need to reduce greenhouse gas emissions (policies on combating climate change). Within the EU, some Member States which had decided to abandon nuclear power are now reconsidering their decisions.

4.3 If the revival of nuclear power is to be accepted by the public, the highest possible level of safety must be guaranteed.

4.4 This 'worldwide' renewal of interest raises the issue of nuclear safety in new ways, in particular in relation to organisation and monitoring. **Nuclear safety must be 'a worldwide public good'** and therefore, the **response also needs to be 'worldwide'** since the risks of nuclear power are not confined within the borders of the states using this technology.

4.5 The European Union can play a pivotal role in moving towards this objective, in view of the use of nuclear power within its territory and its industrial know-how. **The European Union can set an example, as it does in the area of climate change, starting by taking steps to unify its own regulations and safety organisations internally and by identifying and overcoming the obstacles to doing so**.

([1]) OJ C 185 of 14 August 1975, p. 1.
([2]) OJ C 172 of 8 July 1992, p. 2.
([3]) COM(2004) 526 final (revised version).
([4]) OJ C 133 of 6.6.2003, p. 70–74.
([5]) Belgium, Bulgaria, Czech Republic, Finland, France, Germany, Hungary, Lithuania, The Netherlands, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom.
([6]) OJ C 110 of 30.4.2004 pp 77-95.

4.6 **In this context, the Commission's directive comes at an opportune moment. The European Economic and Social Committee welcomes the directive and feels that it has a considerable technical and strategic interest for the safety of the population, those working in the nuclear industry and the environment, both in the Member States which have opted for nuclear power and in those which have not done so.**

4.6.1 The Committee agrees with the Commission's new in approach, which, in order to obtain a wider consensus, makes the Member States and their national regulators fully responsible. There are differences between the Member States in terms of history, organisation and practice and an approach which focuses on obliging them to respect the common rules drawn up within the IAEA, establish genuinely independent regulators and make licence holders fully responsible and allow them no possibility of delegating their responsibility, is certainly the one which all the various parties currently find the most acceptable and which is best able to guarantee the safety of nuclear installations.

4.6.2 The Committee also feels that the directive represents a step forward in terms of improving safety. There will be a need for sustained and ongoing reflection in order to understand and take account of the changes, additions or modifications that may need to be made to reflect developments in contexts, techniques and organisational approaches.

4.6.3 The Committee welcomes the fact that, both in the main provisions and in Article 5 of the draft directive, the text under consideration focuses specifically on the need for transparent and reliable information for the population, in connection with the decision-making process. To that effect, the Aarhus Convention ([7]) on access to information, public participation in decision-making and access to justice in environmental matters could be a reference for civil society players.

4.6.4 Moving beyond this and the substance of the draft directive itself, it will be necessary to take account of and internalise the fact that safety is not solely a matter of rigorous addition of technical and industrial regulations. It is also to do with **a culture**, i.e. a collection of practices which make safety a central concern and, above and beyond the requisite compliance with procedures, also incite continual exploration into ways of increasing safety and identifying both internal and external factors which might undermine it. This culture cannot be built in a day and must be shared by industrialists, operators and regulators as much as by political decision-makers, if it is to be fully effective.

4.7 Moves to improve safety may run up against limitations in relation to electronuclear technologies, stemming from a lack of experience and know-how and from a poorly adapted scientific and technological environment. A major effort will therefore have to be made in relation to training ([8]). Intra-European exchanges of theoretical and practical knowledge could be organised and support measures put in place to respond more effectively, particularly in relation to the requirements on training and human resources, set out in Articles 4, 7 and 9. European certification for training, qualifications and skills in nuclear power and nuclear safety must be developed.

4.8 The European Nuclear Energy Forum initiated by the Commission and supported by the March 2007 European Council brings together high level representatives from public authorities, Members of the European Parliament, **representatives of the Economic and Social Committee**, and representatives of electricity producers, the nuclear industry, consumers, finance, and civil society. It provides a framework for expertise and discussion on the opportunities and risks of nuclear energy. In January 2009 it issued a number of proposals and comments ([9]) on the draft directive and the Committee believes that, in view of their quality and their importance in terms of acceptance from citizens and their representatives, these should be drawn on.

## 5. **Specific comments**

### 5.1 *Scope and substance of the directive*

The Committee agrees with the reference to the IAEA's fundamental safety principles (SF-1, 2006) and the requirements of the Convention on Nuclear Safety. However, it wishes to clarify which parts of these fundamental principles correspond specifically to the aim of this directive. This should take the form of an **Appendix to the directive** as presented in point 6 of this opinion and appended to it. This will clarify the draft directive and will also allow some of its articles to be simplified.

### 5.2 *Article 1*

The Committee suggests a more explicit wording in Article 1: the directive 'aims to establish a European Framework for regulating nuclear safety, which defines the fundamental principles with which legislation and regulations on nuclear safety established at national level must comply, so as to ensure that nuclear safety is maintained and improved continuously in the Community and that the role of the regulatory bodies is strengthened.'

### 5.3 *Article 2*

5.3.1 Definition (1) '*nuclear installation*': the Committee suggests that the term '*radioactive waste*' be added after 'spent fuel storage facility' to read, '*spent fuel and radioactive waste storage facility*'.

([7]) An international convention negotiated in the framework of the United Nations Economic Commission for Europe (UNECE) and signed by 40 of the 55 UNECE countries.

([8]) OJ C 175 of 28.7.2009, p. 1–7.

([9]) See the document of the European Nuclear Energy Forum's Sub-Group on Harmonisation on the Proposal for a European Directive on Nuclear Safety.

5.3.2 Definition (8) '*regulatory body*': the Committee urges the Commission to adhere strictly to the definition set out in the IAEA Safety Glossary published in 2007: '*An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorisations, and thereby regulating nuclear, radiation, radioactive waste and transport safety*.'

5.3.3 Definition (10) '*new power reactors*': the Committee would prefer a reference to installations built following the implementation of the directive. Developments that occur at the beginning of the construction process can be taken into account by licence holders. On the other hand, post-construction changes will be more difficult to make if the installation was not designed and built to do so. The existence of certain specific cases of power stations whose construction has been halted and needs to be resumed leads the Committee to suggest the following wording: **' *"new power reactors"*, nuclear reactors whose construction is authorised (or whose construction is resumed after a break of at least 5 years) following the directive's entry into force'**.

5.4 *Article 3*

5.4.1 The Committee suggests that this article should begin by defining the framework, which is the general aspect of safety, and then the responsibility for enacting it. It also proposes that reference to the withdrawal of authorisation in the event of breaches of the safety rules be made in this article, since it is part of the general framework and strengthens the authority of the regulatory body. Consequently, there would no longer be a need for a specific article on this topic (Article 8). The Committee draws attention to the fact that the Commission has the power to check how the directive has been transposed and can if necessary launch an infringement proceeding against any Member State which has not complied with the principles of the directive.

5.4.2 Article 3 would then be worded as follows:

1. '*Member States shall establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations. This shall include national safety requirements, a system of licensing and control of nuclear installations, the prohibition of their operation without a licence and a system of regulatory inspection including the necessary enforcement, which shall include the power to suspend and withdraw licences. It is imperative that regulatory bodies have the power to withdraw licences in the case of serious or repeated breaches of the safety rules in a nuclear installation.*'

2. '*Member States must ensure that prime responsibility for the safety of a nuclear installation rests with the holder of the licence, under the control of the regulatory body, throughout the lifetime of the said installation, until such point as it is no longer subject to the safety regulation. This responsibility of the licence holder cannot be delegated. The safety management and control measures to be implemented in a nuclear installation must be proposed by the licence holder and submitted to the regulatory body for approval. They must be implemented by the licence holder under the supervision of the regulatory body*'.

5.5 *Article 4, paragraph 1*

5.5.1 The Committee attaches great importance to the independence of the regulatory body and would prefer the following wording: '*Member States shall guarantee that the regulatory body, whose sole objective is safety, is effectively independent of all bodies whose task is to promote or operate nuclear installations. It must be free from any influence that may affect its regulatory duties.*' The reference to 'bodies that justify societal benefits of nuclear power' adds nothing to the idea of promoting nuclear installations and, if this reference is maintained, bodies that campaign against the use of nuclear power would also need to be mentioned.

5.6 *Article 4, paragraph 3*

The Committee suggests that two paragraphs in the proposal, Article 4 paragraph 3 and Article 4 paragraph 4, be combined in a new wording: '*The regulatory body shall deliver licences in the light of the evidence provided by the applicant proving that the siting, design, construction, commissioning, operation, extension of the operating life, quality and number of staff, up to and including decommissioning, comply with the safety requirements, conditions and rules in force. It shall monitor the proper fulfilment of the commitments undertaken by the licence holder with respect to nuclear safety*'.

5.7 *Article 4, paragraph 4*

Deleted and incorporated in the new Article 4 paragraph 3.

5.8 *Article 4, paragraph 6*

A sixth paragraph should be added to give further clarifications on the cooperation between regulatory bodies within the EU: '*National regulatory bodies shall exchange best practice of regulation and develop a common understanding of the international requirements adopted.*'

5.9 *Article 5*

'*Transparency*': the Committee emphasises how important this article is in order to address the criticism frequently levelled at the nuclear industry with regard to secrecy and in view of the fact that **information** on the operation of nuclear installations is of concern to all Member States, whether or not they use nuclear energy within their territory, since they are responsible for protecting their citizens in view of the cross-border character of nuclear risk.

5.10 *Article 6, paragraph 1*

The Committee suggests that a more specific reference be made to the IAEA's safety fundamentals, by referring to the appendix already mentioned above. Article 6 paragraph 1 would therefore be given a new wording: '*With regard to the siting, design, construction, use and decommissioning of nuclear installations, Member States shall apply the Fundamental Safety Principles, IAEA Safety Standard Series No. SF-1 (2006), specified in the appendix.*'

5.11 *Article 6, paragraph 2*

This article, which is not precise enough in its references to WENRA and the HLG, poses a problem: how can a Member State be obliged to take account of future results not defined in terms of content and timescale at the time the directive is adopted? The Committee proposes that this paragraph be deleted, since **respect for fundamental safety principles and the development or a culture of safety evolve over time in accordance with scientific and technical progress**.

5.12 *Article 7*

This article covers the responsibility of licence holders. However, since the directive is addressed to the Member States, the Committee suggests that the aspects not directly connected with the role of the Member States be moved to an appendix. Article 7 would then read:

*Obligations of licence holders: Member States shall guarantee that licence holders are responsible for the design, construction, use and decommissioning of their nuclear installations, in accordance with the provisions set out in Article 6.*

5.13 *Article 8*

Has been integrated into Articles 3 and 4 and has therefore been deleted from this place in the text.

5.14 *Article 10*

The title, '*Priority to safety*' may lead to confusion since it suggests that Member States which do not adopt measures stricter than those set out in the directive are not giving priority to safety, or that the directive itself does not do so. The Committee proposes that the wording be changed to '**Strengthening safety**'.

5.15 *Article 11*

Article 11 concerns the submission of periodic reports on the impact of the directive to the Commission, which are both desirable and necessary. The Convention on Nuclear Safety already makes provision for reporting at specific intervals and the Committee considers that all reports should follow a common calendar, so as to simplify and coordinate procedures.

This article would then be worded as follows: '*Member States shall report to the Commission on the implementation of this directive at the same time and at the same intervals as the national reports they submit to the review meetings of contracting parties to the Convention on nuclear safety. On the basis of these reports, the Commission shall present a report to the Council on progress made with the implementation of this Directive, accompanied, where appropriate, by legislative proposals*'.

6. **Proposal for an appendix to the directive**

6.1 The objective of the Appendix to the directive is:

— to define obligations for nuclear operators that cannot be imposed by the directive since it is only binding on the Member States;

— to define, on the basis of the IAEA's ten fundamental principles, what the directive intends to make binding on the Member States.

6.2 It incorporates six principles:

6.2.1 Member States shall ensure that responsibility for the safety of a nuclear installation rests with the holder of the licence;

6.2.2 Responsibility and management for safety must be established at the highest levels of the enterprise;

6.2.3 **Safety assessments** shall be carried out from the beginning of the construction of a nuclear installation and throughout its lifetime;

6.2.4 Member States shall ensure that nuclear installations are optimised to provide the highest level of safety that can reasonably be achieved;

6.2.5 Member States, without exception, shall ensure that all practical efforts are made to **prevent and mitigate** nuclear incidents and accidents;

6.2.6 Member States, without exception, shall ensure that arrangements are made for emergency preparedness and response for nuclear accidents in accordance with Directive 96/29.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

*Appendix*

to the opinion (TEN/377) of the European Economic and Social Committee on the Proposal for a Council Directive (Euratom) setting up a Community framework for nuclear safety

COM(2008) 790 final — 2008/0231 (CNS)

**APPENDIX TO THE DIRECTIVE** [1]

**SAFETY OBJECTIVE**

**The fundamental safety objective is to protect the workers and the general public from harmful effects of ionizing radiation, which may be caused by the nuclear installations**

To ensure the protection of the workers and the general public, the nuclear installations shall be operated so as to achieve the highest standards of safety that can reasonably be achieved taking into account economical and social factors.

Besides the protection of people laid down in the Euratom Basic Standards (Directive 96/29), measures shall be taken

— to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source and

— to mitigate the consequences of such events if they were to occur.

The fundamental safety objective shall be taken into account for all nuclear installations and for all stages over the lifetime of the nuclear installation.

**SAFETY PRINCIPLES**

**1. Principle 1: Responsibility for safety**

**Each Member State shall ensure that the prime responsibility for the safety of a nuclear installation rests with the holder of the relevant licence and shall take the appropriate steps to ensure that each such licence holder meets its responsibility.**

Each Member State shall ensure that the licensee has implemented provisions for:

— Establishing and maintaining the necessary competences;

— Providing adequate training and information;

— Establishing procedures and arrangements to maintain safety under all conditions;

— Verifying appropriate design and the adequate quality of nuclear installations;

— Ensuring the safe control of all radioactive material that is used, produced or stored;

— Ensuring the safe control of all radioactive waste that is generated,

to fulfil the responsibility for the safety of a nuclear installation.

These responsibilities shall be fulfilled in accordance with applicable safety objectives and requirements as established or approved by the regulator body, and their fulfilment shall be ensured through the implementation of a management system.

**2. Principle 2: Leadership and management for safety**

**Effective leadership and management for safety must be established and sustained in all organizations concerned with nuclear safety.**

2.1 Leadership in safety matters shall be demonstrated at the highest levels in an organization. An effective management system shall be implemented and maintained, which has to integrate all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality and security, and so that safety is not compromised by other requirements or demands.

The management system also shall ensure the promotion of a safety culture, the regular assessment of safety performance and the application of lessons learned from experience.

[1] This text incorporates part of the document of the European Energy Forum's Sub-Group on Harmonisation on the proposal for a European Directive on Nuclear Safety.

2.2 A safety culture that governs the attitudes and behaviour in relation to safety of all organizations and individuals concerned shall be integrated in the management system. Safety culture includes:

— Individual and collective commitment to safety on the part of the leadership, the management and personnel at all levels;

— Accountability of organizations and of individuals at all levels for safety;

— Measures to encourage a questioning and learning attitude and to discourage complacency with regard to safety.

2.3 The management system shall recognize the entire range of interactions of individuals at all levels with technology and with organizations. To prevent safety significant human and organizational failures, human factors shall be taken into account and good performance and good practices shall be supported.

**3. Principle 3: Assessment of Safety**

**Comprehensive and systematic safety assessments shall be carried out before the construction and commissioning of a nuclear installation and throughout its lifetime. A graded approach shall be used taking in account the magnitude of the potential risks arising from the nuclear installation.**

3.1 The regulatory body shall require an assessment on nuclear safety for all nuclear installations, consistent with a graded approach. This safety assessment shall involve the systematic analysis of normal operation and its effects, of the ways in which failures might occur and of the consequences of such failures. The safety assessments shall cover the safety measures necessary to control the hazard, and the design and engineered safety features shall be assessed to demonstrate that they fulfil the safety functions required of them. Where control measures or operator actions are called on to maintain safety, an initial safety assessment shall be carried out to demonstrate that the arrangements made are robust and that they can be relied on. An authorization for a nuclear installation shall only be granted by a member state once it has been demonstrated to the satisfaction of the regulatory body that the safety measures proposed by the licensee are adequate.

3.2 The required safety assessment shall be repeated in whole or in part as necessary later in the conduct of operations in order to take into account changed circumstances (such as the application of new standards or scientific and technological developments), the feedback of operating experience, modifications and the effects of ageing. For operations that continue over long periods of time, assessments shall be reviewed and repeated as necessary. Continuation of such operations shall be subject to these reassessments demonstrating that the safety measures remain adequate.

3.3 Within the required safety assessment precursors to accidents (an initiating event that could lead to accident conditions) shall be identified and analysed, and measures shall be taken to prevent the occurrence of accidents.

3.4 To further enhance safety, processes shall be put in place for the feedback and analysis of operating experience in own and other facilities, including initiating events, accident precursors, near misses, accidents and unauthorized acts, so that lessons may be learned, shared and acted upon.

**4. Principle 4: Optimization of safety**

**Member States shall ensure that nuclear installations are optimized to provide the highest level of safety that can reasonably practicable be achieved without unduly limiting their operation.**

4.1 The optimization of safety shall require judgements to be made about the relative significance of various factors, including:

— The likelihood of the occurrence of foreseeable events and the resulting consequences;

— The magnitude and distribution of radiation doses received;

— Economic, social and environmental factors arising from the radiation risks.

— The optimization of safety also means using good practices and common sense as far as is practical in day to day activities.

**5. Principle 5: Prevention and mitigation**

**Member States shall ensure that all practical efforts are made to prevent and mitigate nuclear incidents and accidents in its nuclear installations.**

5.1 Each Member State shall ensure, that the licensees engages all practical efforts:

— to prevent the occurrence of abnormal conditions or incidents that could lead to a loss of control;

— to prevent the escalation of any such abnormal conditions or incidents that do occur; and

— to mitigate any harmful consequences of an accident,

by implementing 'defence in depth'.

5.2 The application of the defence in depth concept shall ensure that no single technical, human or organizational failure could lead to harmful effects, and that the combinations of failures that could give rise to significant harmful effects are of very low probability.

5.3 Defence in depth shall be implemented through the combination of a number of consecutive and independent levels of protection that would all have to fail before harmful effects could be caused to workers or the general public. The levels of defence in depth shall include:

a) an adequate site selection

b) an adequate design of the nuclear installation, consisting of

— High quality of design and construction

— High reliability of components and equipment

— Control, limiting and protection systems and surveillance features

— appropriate combination of engineered safety features

c) an adequate organisation with

— An effective management system with a strong management commitment to safety culture

— Comprehensive operational procedures and practices

— Comprehensive accident management procedures

— Emergency preparedness arrangements

**6. Principle 6: Emergency preparedness and response**

**Members States shall ensure that arrangements are made for emergency preparedness and response for nuclear installations accidents according to Directive 96/29.**

# Opinion of the European Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation

*COM(2008) 818 final — 2008/0238 (COD)*

(2009/C 306/14)

On 21 January 2009, the Council decided to consult the European Economic and Social Committee, under Article 242 of the Treaty establishing the European Community, on the

*'Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation'*

The Section for Employment, Social Affairs and Education, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 26 May 2009. The rapporteur was Mr RODRÍGUEZ GARCÍA-CARO.

At its 454th plenary session, held on 10 and 11 June 2009 (meeting of 10 June 2009), the European Economic and Social Committee adopted the following opinion by 114 votes, with one abstention.

## 1. **Conclusions**

1.1 The European Economic and Social Committee welcomes the proposal for a directive and wishes to express its satisfaction at the fact that at the instrument's main aim is to extend the protection of EU citizens' health, by combining safety with measures intended to improve the quality and accessibility of treatment based on organ transplantation.

1.2 The Committee firmly believes that an adequate donor recruitment policy entails the following elements: raising public awareness, creating a collective conscience, ensuring the active and disinterested involvement of the media and motivating and involving health professionals. The EESC is convinced that these elements could result in similar levels of donation in all Member States and it is on these aspects that the work of the Commission and the Member States should focus.

1.3 Organ donation in the European Union should be based on the principles of voluntary and altruistic donation, solidarity and being unpaid. Member State legislation should prevent any attempt to sell organs and must severely punish illegal trafficking in organs for the purpose of transplantation. Through joint action and coordination, the EU Member States could achieve high levels of donation, and also block attempts by organised crime to break into the field of organ transplantation.

1.4 The European Economic and Social Committee considers that legal, cultural, religious, historical, social and other factors should not be used as grounds for opposing donation, as these could result in an undesired shortage of organs. The potential shortage of organs for reasons that are not strictly scientific or related to demographics should not be counterbalanced by importing organs from other parts of the world where people are more aware of organ transplantation and demonstrate greater solidarity towards this process.

1.5 The European Economic and Social Committee has confidence in the work of the competent national authorities referred to in the proposal for a directive. The Committee considers that a strong and organised public health authority is the best guarantee of monitoring the implementation of quality and safety standards in the field of organ transplantation. It therefore takes the view that the directive should clearly specify the need for Member States to lay down periodic inspection and monitoring measures to ensure that organ procurement and transplant centres comply with these standards.

1.6 At the same time as publishing this proposal for a directive, the Commission has presented a Communication on the *Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States* [1]. Despite not having been asked to draw up an opinion on the matter, the European Economic and Social Committee considers that, because of the issue's importance to all EU citizens, it should state its position on this action plan and will thus draw up an own-initiative opinion on the matter.

1.7 The European Economic and Social Committee considers that the specific comments made on the proposal for a directive in point 4 of this opinion will make the entire text easier to understand and more coherent, and could improve the final wording of this Community instrument. This applies in particular to the comments highlighting possible inconsistencies between articles.

1.8 Amongst the specific comments, the Committee wishes to highlight two fundamental aspects that represent a clear retrograde step in relation to Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2]. In this regard, the rapporteur wishes to point out the lack of any article similar to Article 7 on inspections and control measures and to Article 10 on registers of tissue establishments. In the Committee's view, both articles should be reflected equally in the proposal for a directive, because they will improve its wording.

[1] COM(2008) 819 final.
[2] OJ L 102, 7.4.2004, p. 48-58.

## 2. **Introduction to the proposal for a directive**

2.1 Article 152(4a) of the Treaty establishing the European Community lays down that *the Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this article through adopting measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives.*

2.2 The European Parliament and the Council have already adopted Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components ([3]). The Economic and Social Committee delivered a mandatory opinion on each of these directives ([4]).

2.3 In May 2007, the Commission adopted a communication on the donation and transplant of organs, focusing on subsequent measures to be discussed in the framework of quality and safety in the donation and transplant of organs and the promotion of cooperation between Member States. The European Economic and Social Committee did not produce an opinion on this communication.

2.4 The Council conclusions of 6 December 2007 recognised the importance of having stringent safety and quality standards for organs to ensure a high level of patient protection.

2.5 The Commission has presented, at the same time, both this proposal for a directive and the communication entitled *Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States,* on which the EESC has not been asked to draw up an opinion.

2.6 Lastly, the rapporteur also wishes to highlight the European Parliament resolution of 23 April 2008, on 'Organ donation and transplantation: policy actions at EU level' ([5]). The European Economic and Social Committee wishes to state its clear support for this resolution.

2.7 The aim of the proposal for a directive is to set standards that will help ensure the quality and safety of organs of human origin intended for transplantation to the human body, applicable to the process of donation, procurement, testing, characterisation, preservation, transport and transplantation of organs of human origin.

## 3. **General comments**

3.1 The Committee welcomes the proposal for a directive on standards of quality and safety of human organs intended for transplantation, notwithstanding the general and specific comments made in this document. The rapporteur fully agrees with the Council and the European Parliament in that the ultimate aim of the directive should be to ensure the protection of human health. It is therefore crucial to attain the highest levels of quality and safety throughout the process leading to an organ transplant.

3.2 An organ cannot be transplanted without a living or deceased donor from whom the organ can be removed. The European Economic and Social Committee therefore considers that the most important aspect of the entire process is to ensure the existence of donors. This is the main aspect on which the EU's efforts should focus. Raising awareness, creating a collective conscience, ensuring the active and disinterested involvement of the media and motivating and involving healthcare professionals are key factors in achieving high levels of donation.

3.3 The Committee therefore fully supports the European Parliament in its initiative to establish an international donor day. The Commission and the Member States should establish that day as a means of promoting donation amongst Europeans and should thus be given the support and experience of civil society, through the different associations and organisations representing transplant patients.

3.4 The EESC wishes to state its agreement with the principle that donations should be voluntary, altruistic and unpaid, as set out in the proposal for a directive. All Member States should ensure that their legislation contains no legal loopholes allowing organs to be sold or allocated to patients on the basis of less than scientific criteria.

3.5 Donation is the basic and crucial starting point of the process, which ends with an organ being implanted in a patient. Raising awareness and understanding are cornerstones of the transplant process. Consent for the removal of organs from individuals who have died should thus be respected in legal terms but simplified at the operational level, to ensure that as many donations as possible are made. The existence of legal, cultural, ethical, religious, historical, social and other factors should not be used as grounds for opposing donation, as these could result in an undesired shortage of organs. The potential shortage of organs for reasons that are not strictly scientific or related to demographics should not be counterbalanced by importing organs from other States where people are more aware of organ transplantation and demonstrate greater solidarity towards this process.

3.6 The European Economic and Social Committee considers that raising awareness about organ donation and motivating health professionals in this field are equally important. Health professionals' scientific and technical knowledge is not only important to promoting the process of donation and transplantation; it is also crucial to encouraging health professionals to act as intermediaries in the task of procuring organs, improving their communication skills which will enable them to facilitate the donation process.

([3]) OJ L 33, 8.2.2003, p. 30-40.
([4]) OJ C 85, 8.4.2003, p. 44-51, Rapporteur: Mr. Bedossa and OJ C 221, 7.8.2001, p. 106-109, Rapporteur: Mr Ribeiro.
([5]) P6_TA(2008)0130.

3.7 In this regard, a sufficiently qualified and experienced figure in this field in certain Member States – Spain in particular – is the intra-hospital transplant coordinator, whose purpose is to secure as many organs for transplant as possible by monitoring potential donors and raising the awareness of the health professionals in those hospital units that are most likely to receive these potential donors. The Intra-hospital transplant coordinator supervises, promotes and coordinates the donation, removal, transport and availability of organs for transplant. The European Economic and Social Committee considers that hospitals in the EU must have health professionals carrying out this role and thus calls on the Commission and the Member States to promote the appointment of these coordinators in European hospitals, as efficiently as possible.

3.8 The Committee supports the creation of national quality programmes in all Member States as a means of ensuring compliance with the quality and safety standards set out in the directive. The EESC is also of the view that appointing national authorities to implement the requirements set by the directive is also crucial. Laying the foundations for a strong national organisation inevitably requires implementing national quality programmes, appointing national authorities that carry out their tasks effectively and lastly the close involvement of the public in an aspect of individual and collective health that is constantly increasing in scale and having an ever-greater effect on society.

3.9 It is the Member State health authorities that are primarily responsible for ensuring quality and safety in the transplant process. Adopting quality and safety standards in the donation and transplant process and common standards for the structural, material and personal requirements that organ procurement and transplant centres should have is a clear priority for ensuring a high degree of efficiency and safety in this type of surgical procedure. The competent Member State authorities should, therefore, establish detailed periodic inspection and monitoring programmes for these centres, to ensure that they comply fully with the quality and safety standards for human organs intended for transplant.

## 4. **Specific comments**

4.1 With regard to article 1:

The proposal for a directive states that its aim is to guarantee 'high' levels of quality and safety for organs and 'high' levels of health protection. The European Economic and Social Committee considers that merely seeking to ensure a 'high level' is not adequate, because in practical terms, this is too vague. In the field of transplants the aim must be excellence; a level at which errors have no place. The rapporteur therefore proposes that the word 'high' be removed from the article's wording and that the paragraph be reworded as follows: 'to ensure the necessary standards of quality and safety for organs of human origin intended for transplantation to the human body, in order to ensure the highest level of human health protection.'

4.2 With regard to Article 3(j):

This article's definition of 'procurement organisation' covers centres, units, teams and bodies. The Committee considers that the definition is vague and the term used does not tally with the definition provided in point (q) of the same article. Whilst the latter point refers to 'transplantation centres', it would more consistent to use the term 'procurement centre' and not 'procurement organisation'. Similarly, the word 'body', which features in both points, should be deleted, as both organ removal and implantation are carried out by professionals forming part of teams or units working in health centres belonging to public or private bodies. It is these centres, units and teams that receive authorisation from the competent authority to carry out these activities. Therefore, and in line with this comment, Article 5, which covers procurement centres, should be amended to reflect this.

4.3 With regard to Article 3(r):

With regard to this point, which is concerned with the definition of traceability, it is proposed that the term 'procurement organisation' be replaced by 'procurement centre', in line with the previous comment.

4.4 With regard to definitions not included in Article 3:

Article 2 of the proposal states that the directive applies to the different stages of the organ transplant process; All of the stages listed are set out in Article 3, except for testing and transport. The Committee considers that the stages described in the article should be clearly defined, particularly given that Article 8 of the directive is dedicated to organ transport.

4.5 With regard to article 6:

This article, which deals with organ procurement, makes a very brief reference to requirements for the operating theatres in which organs are procured. The requirements set out in paragraphs a) and b) are so self-evident and minor that the EESC recommends deleting them and including a reference to an appendix or subsequent document that provides an exhaustive list of the minimum structural, equipment and staffing requirements for operating theatres in which organ removals take place, from both living and deceased donors.

4.6 The Committee also wishes to express its surprise at the lack of an article on inspection and monitoring measures similar to the measure set out in Article 7 of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Article 18 of the proposal for a directive makes a brief reference to the competent authorities of the Member States ensuring that procurement organisations and transplantations centres are controlled and audited. In the EESC's view, the proposal should include a new article along the lines of the article referred to above.

4.7 With regard to Article 7 of the proposal:

4.7.1 The first sub-paragraph states that the tests required for organ characterisation shall be carried out by a qualified laboratory. The Committee wishes to point out that the word 'qualified' does not appear in the definitions provided in Article 3. In the EESC's view, the laboratory should be authorised, accredited or hold a licence to carry out activities of this nature, in line with the definition contained in Article 3(a), as referred to above. In any event, it might also be worth defining at the European Union level the conditions under which laboratories are qualified to characterise a donor, an organ or a recipient.

4.7.2 Sub-paragraph 2 of the same article confuses the matter even further, because in addition to qualified laboratories, it includes organisations and bodies in the process of characterising organs and donors. In the rapporteur's mother-tongue [Spanish], it makes sense that there should be qualified laboratories but the proposal's reference to including bodies and organisations on an equal footing with laboratories is hard to fathom. The EESC reiterates that the text must be consistent in order to prevent confusion.

4.8 With regard to article 9:

4.8.1 The words 'accreditation', 'designation', 'authorisation' and 'licence' should be deleted from sub-paragraph 2, because they are covered by the definition of authorisation set out in Article 3(a). It is also the Committee's view that when referring to a 'transplant centre', the authorisation should specify the type of transplant that the centre is authorised to carry out. This specific reference would be more discriminating than the word 'activities' used in the text.

4.8.2 Sub-paragraph 3(b) includes a word that is not defined in Article 3 or included in the scope of Article 2. This is the word 'storage'. The EESC considers that unless there is good reason for the contrary, this is a mistake, because the word used in the proposal's scope and definitions is 'preservation'. We urge that the text be corrected to reflect this.

4.8.3 Lastly, the Committee believes it to be important that national requirements for the authorisation of transplant centres are available on request by any State but considers that it would be more flexible and efficient for this information to be available without first having to submit a request. The Commission could hold this information, provided by the different competent authorities and make this available to any other competent Member State authority.

4.9 With regard to article 11:

With regard to the adverse reactions likely to apply to one or more stages of the donation and transplant process and as stated in comment 4.4, the EESC considers that the text includes a stage that does not feature in the directive's scope – testing – and omits two stages that are described and which could have adverse effects – characterisation and preservation. In the Committee's view, the text should be corrected to reflect this.

4.10 With regard to article 15:

As regards the protection of living donors, the article sets out Member States' obligations to ensure that these individuals are fully aware of all the circumstances surrounding their disinterested action and the steps to be taken to protect their health. For the sake of consistency with the article's heading, the Committee proposes deleting part of the last line of the second sub-paragraph, which refers to third persons, leaving it as follows: 'may provide for the exclusion of persons whose donation could present a serious risk to themselves'.

4.11 With regard to Article 19(2):

This sub-paragraph grants the Commission and the Member States access to the registers of organ procurement and transplant centres in other Member States that request them. The European Economic and Social Committee considers this article to be a retrograde step in relation to the wording of Article 10 of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. In the Committee's view, the wording of the directive referred to above should be used in this matter, especially as regards setting up national public national registers of procurement and transplant centres and as regards establishing an EU-level network encompassing all national registers.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

# Opinion of the European Economic and Social Committee on the Amended proposal for a Directive of the European Parliament and of the Council on the protection of workers from the risks related to exposure to asbestos at work

*COM(2009) 71 final/2 — 2006/0222 (COD)*

(2009/C 306/15)

On 11 March 2009, the Council decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the

*'Amended proposal for a Directive of the European Parliament and of the Council on the protection of workers from the risks related to exposure to asbestos at work'*

The Section for Employment, Social Affairs and Citizenship, which was responsible for preparing the Committee's work on the subject, adopted its opinion 26 May 2009. The rapporteur working alone was Mr VERBOVEN.

At its 454th plenary session, held on 10 and 11 June 2009 (meeting of 10 June), the European Economic and Social Committee unanimously adopted the following opinion.

## 1. **Conclusions and recommendations**

1.1 The Committee essentially supports the proposal, but calls on the Commission to take account of the three reservations raised and to amend the text of the recitals accordingly. It hopes to see the swift approval of the proposal by the European Parliament and the Council.

## 2. **Explanatory statement**

### 2.1 *Summary of the Commission proposal*

2.1.1 The purpose of this proposal is to undertake a codification of Council Directive 83/477/EEC of 19 September 1983 on the protection of workers from the risks related to exposure to asbestos at work (second individual Directive within the meaning of Article 8 of Directive 80/1107/EEC). The new Directive will supersede the various acts incorporated in it [1]; according to the Commission, this proposal fully preserves the content of the acts being codified and hence does no more than bring them together with *only such formal amendments* as are required by the codification exercise itself.

### 2.2 *General comments*

2.2.1 Exposure to asbestos remains a major risk factor for various occupational categories, particularly in the construction sector. It is generally considered that many tens of millions of tons of asbestos were used in Europe during the 20th century. Despite the EU's asbestos ban in 1999, exposure to asbestos will continue for decades, mainly due to the number of buildings containing the substance. Moreover, waste management and the scrapping of a wide range of equipment containing asbestos can also pose risks of exposure. Similarly, the existence of a second-hand market for a wide range of articles containing asbestos is a cause for concern.

2.2.2 The Committee has, on several occasions, examined the issues raised by the protection of workers exposed to asbestos. One example worth citing is the own-initiative opinion adopted on 24 March 1999 [2].

2.2.3 The first directive designed to protect workers from the risks of asbestos exposure dates back to 1983. It was amended on a number of occasions in order to extend its scope, strengthen prevention measures and reduce the limit values for exposure.

2.2.4 These different amendments could cause problems for those affected by the legislation. The present codification proposal makes it possible to bring together in a single piece of legislation the various provisions currently in force without affecting the content. The proposal does no more than incorporate such formal amendments as are required by the codification exercise itself.

2.2.5 The Committee nevertheless feels that there are some shortcomings in respect of the codification of the recitals. Several of the recitals appearing in previous directives are not included in the codification. In some cases, these omissions represent more than purely editorial changes. They affect fundamental aspects which the EU legislator has judged important to draw to attention to.

2.2.6 This is the case with recital (2) of Directive 2003/18/EC where the EU legislator points out, inter alia, the importance of a preventive approach with regard to substitute fibres for asbestos. This is particularly important so as to ensure that the alternatives used do not pose any health problems.

[1] Council Directive 83/477/EEC, Council Directive 91/382/EEC, Council Directive 98/24/EC (Article 13 only) and Directive 2003/18/EC of the European Parliament and of the Council.

[2] See the EESC opinion on *Asbestos* of 24.3.1999, rapporteur: Mr Etty (OJ C 138, 18.05.99).

2.2.7 This also applies to the omission of recital (4) of the same directive, which draws attention to the importance of the Community decision banning the use of chrysotile asbestos with effect from 1 January 2005. This omission is even less justified given the fact that recital (4) of Directive 91/382/EEC has also been omitted. The said recital refers to the importance of the principle of substitution for the prevention of risks associated with dangerous substances. The omission of these two recitals does not seem justified in the light of the European Union's commitment to work for a worldwide ban on asbestos.

2.2.8 This is also the case with recital (15) of Directive 2003/18/EC, which calls for Member States to bring the content of the exposure register and medical records for workers exposed to asbestos into line with that of the records for workers exposed to other carcinogens.

2.2.9 The omission of these recitals seems to go beyond the normal limits for a codification. The EESC feels that recitals of equivalent scope should be included in the proposal so as to clarify the legal scope of the proposed act with regard to these specific points.

2.2.10 A codification must not make any substantial change to the content. Having examined the proposal, the Committee believes that the text in question upholds this principle, subject to the reservations set out above concerning the omission of some recitals. It combines the various provisions in force in a logical manner and makes them clearer, and thus does not pose any major problem.

2.2.11 The Committee believes that the present proposal should be submitted for consultation to the Advisory Committee on Safety and Health at Work in accordance with Council Decision 2003/C 218/01 of 22 July 2003. This consultation should be mentioned in the recitals of the directive in accordance with the practice applied hitherto.

2.2.12 The Committee essentially supports the proposal, but calls on the Commission to take account of the three reservations raised and to amend the text of the recitals accordingly. It hopes to see the swift approval of the proposal by the European Parliament and the Council.

## 3. **Specific comments**

The Committee recalls its opinion of 4 March 1999 and, in particular, reiterates its wish that the Member States ratify ILO Convention 162 on Safety in the use of asbestos. To date, only ten of the 27 Member States have ratified it. Ratification by all EU Member States would contribute to the reputation of the ILO Convention as a major instrument for worldwide protection of workers' safety and health.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

# Opinion of the European Economic and Social Committee on the Results of the Employment Summit

(2009/C 306/16)

On 13 March 2009 the president of the European Commission asked the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, to draw up an opinion on the

*'Results of the Employment Summit'*.

The Section for Employment, Social Affairs and Citizenship, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 26 May 2009. The rapporteur working alone was Mr GREIF.

At its 454th plenary session, held on 10 and 11 June 2009 (meeting of 11 June 2009), the European Economic and Social Committee adopted the following opinion by 140 votes to 27, with 24 abstentions.

## 1. **Recommendations**

1.1 The EU Member States have been hard hit by the current financial and economic crisis. Unemployment is growing at a worrying rate; top priority must therefore be given throughout the EU to preventing mass lay-offs and further rises in unemployment. The EESC realises that this will require particular efforts by all stakeholders at national and European level. 'Business as usual' is not an adequate response to this exceptional situation, and it is not an option for current employment policy.

1.2 This opinion sets out the following EESC recommendations to overcome the current labour market crisis. They are intended as groundwork for the relevant decisions by the European Council on 18/19 June 2009:

— restoring consumer and investor confidence by ensuring and encouraging private and public-sector demand;

— using publicly subsidised active employment policy instruments to enable employees to stay at work while training;

— avoiding income cuts as far as possible and promoting equality of opportunity, paying attention to inequalities and ensuring greater security on labour markets;

— ensuring public investment through a provisional, flexible approach to the Stability Pact and expanding the tax revenue base in Member States;

— increasing the supply of European funding, facilitating access to European Structural Funds, acting swiftly to improve the Globalisation Fund.

— progressing with socially acceptable structural reforms, upgrading skills, matching labour market needs more effectively, improving mobility and promoting entrepreneurship.

1.3 Social partners and other representatives of organised civil society have a key role to play in tackling the crisis. Decision-makers from business, social and political spheres are responsible for ensuring that a similar crisis does not happen again.

## 2. **Introduction: given the huge rise in EU employment, 'business as usual' is not an option for employment policy**

2.1 The EU Member States have been hard hit by the current financial and economic crisis. The number of companies affected by the economic slowdown has risen drastically since September 2008. Unemployment is growing at a worrying rate:

— recent forecasts suggest that unemployment in the euro area will increase from 7,5 % in 2008 to 10 % in 2009; in 2010 it could even reach 12 % ([1]);

— compared to previous downturns, unemployment is growing at a much faster rate – whereas in the early 1990s unemployment rose about 1 % every 4-5 quarters, it will grow by 3 % in the euro area in 2009 alone ([2]);

([1]) OECD Interim Forecast, March 2009. Compared to these forecasts for the EU-16 Group, in 1999 unemployment in the EU-15 was 9,9 % and 10,9 % in the EU-11 (URL: https://www.oecd.org/dataoecd/7/20/2666439.pdf)

([2]) ibid.

— in many sectors – both services (especially banking) and manufacturing (especially the automotive industry and its suppliers, chemicals and the construction sector) – numerous workers have been laid off;).

— we need to prepare for further painful rises: according to current European Commission and OECD forecasts, another 8 million will become jobless.

2.2 In view of these worrying labour market trends, top priority must be given throughout the EU to preventing mass lay-offs and further rises in unemployment. The EESC realises that this will require particular efforts by all stakeholders at national and European level. 'Business as usual' is not an adequate response to this exceptional situation, and it is not an option for current employment policy. In view of this, the EESC welcomes the holding of an employment summit as a good opportunity for launching a debate on the necessary steps to ensure that a crisis with such dramatic implications for employment does not happen again. This is why the Committee has responded to the call for active collaboration with the social partners and civil society interests.

2.3 In its Programme for Europe ([3]) and previous opinions (e.g. on the European economic recovery plan) the EESC has already highlighted some key steps which are of particular importance as short-term crisis management measures.

2.4 To complement these, this EESC opinion sets out some other recommendations for curbing further growth in unemployment, as a contribution to preparations for the relevant decisions by the European Council on 18/19 June 2009:

## 3. EESC recommendations to overcome the current labour market crisis

### 3.1 *Restoring consumer and investor confidence by ensuring and encouraging private and public-sector demand.*

3.1.1 Employment policy per se does not create jobs. It can support the job creation process; however, it cannot take the place of the dynamism which is needed to generate new jobs. A stable economy is the basis of an efficient labour market policy. Without economic regeneration no positive employment development will occur. Thus, especially in the difficult conditions prevailing on labour markets, employment policy measures can only succeed if macroeconomic conditions are more favourable. In view of this, when the European recovery plan was adopted in December 2008 it received EESC backing. The Committee feels that the plan is the right response to the challenges faced by the European economy, but urges the Commission and all national stakeholders to implement the programme without further delay ([4]).

3.1.2 However, if mass lay-offs are to be avoided and mass unemployment contained, much more intensive efforts are now needed at national and European levels. The EESC therefore reiterates its previous concern that the recovery plans launched so far are too limited in scope. ([5]) Should it become clear by the autumn that the measures so far taken lack the power to prevent mass lay-offs, the EESC advocates the adoption of a second European economic recovery plan, which would have a wide-ranging impact on labour markets, with funding in the order of 2 % of GDP. Alongside additional national investments to boost the employment impact, which should be implemented in a more coordinated fashion than has hitherto been the case, major European investment projects must also be identified.

3.1.3 Labour market policy measures to accompany economic revival are key. The planned expenditure, therefore, of 1 % of GDP should be allocated to specific employment policy measures, varying according to the situation on a given national labour market (e.g. strengthening unemployment benefits, promoting flexicurity arrangements, supporting short-term employment while providing appropriate income support, investing in education and training, further introduction of employment incentives, preventative and business-friendly measures, creating jobs in the third sector, etc.), and an additional 1 % of GDP to investment projects with a significant employment impact. Such investments can yield a double dividend in terms both of solving environmental and social problems and of promoting innovation, provided that they do not merely provide a short-term economic stimulus but also boost competitiveness and future growth potential, in line with the Lisbon strategy.

### 3.2 *Using publicly subsidised active employment policy instruments to enable employees to stay at work while training*

3.2.1 The EESC is pleased that more and more EU countries have – in view of the dramatic employment situation and the difficulties faced by many companies – implemented publicly subsidised active employment policy instruments, enabling employees to be kept on and engage in further training instead of being laid off (short-term employment is the watchword here). The EESC feels that arrangements enabling

([3]) See 'A programme for Europe: proposals of civil society' – www.eesc.europa.eu.

([4]) EESC opinion of 24 March 2009 on the 'European Economic Recovery Plan', rapporteur: Mr Delapina (OJ C 228, 22.9.2009).

([5]) ibid.

companies to keep employees on during the crisis, combined with solid income support for employees whose hours are cut, are a much smarter way of getting to grips with the crisis than simply laying off skilled employees as soon as orders fall off, as it ensures that sufficiently skilled workers are available once the economy recovers. The EESC feels that such arrangements should also be extended to EU countries where they are currently lacking and to employees on non-standard employment contracts.

3.2.2 Although such measures could temporarily take off the pressure on companies and sectors which are in a particularly difficult situation, we need to consider what can be done if the economy continues to slow down and such company-specific measures are not enough to prevent lay-offs. In this case, additional instruments to provide comprehensive employment protection and retraining must be developed with the involvement of the social partners and the requisite funding put in place in order to mitigate the full force of the crisis on labour markets (e.g. sector-specific safety nets, demand-orientated qualifications in sectors important for the future such as the environment, energy and health, for example).

3.2.3 In addition, adequate, effective and sustainable social security networks are needed, taking particular account of employment assistance for the most vulnerable, i.e. socially disadvantaged groups. Generally, it is those in the weakest position, those with insecure employment conditions, such as temporary and contract workers, as well as disadvantaged groups on labour markets, who experience unemployment first. Young people are also disproportionately affected. Bringing young people into the labour market should therefore be given top priority during the recession. The social economy also has a key role to play in overcoming the crisis, particularly in terms of creating worthwhile jobs which are of social value. Care must, however, thereby be taken, that this does not lead to any distortion of competition.

3.3 *Avoiding income cuts as far as possible and promoting equality of opportunity, paying attention to inequalities and ensuring greater security on labour markets*

3.3.1 The sharp rise in unemployment and the use of short-term work arrangements shows that in most countries there is sufficient flexibility on labour markets to enable companies to respond quickly when orders dry up. In view of this, we can hardly claim that European labour markets are rigid. In the current crisis, calls for the watering down of existing labour protection rules are completely unfounded. Given that more and more employees are facing increasing risks due to the deteriorating employment situation, what we actually need is more effective security on labour markets. The EESC feels that one way of doing this is to facilitate access to social benefits to the jobless in particular, and to make them more generous to prevent even greater inequalities. With this in mind, the EESC urges the Commission to re-table its proposal to extend the eligibility period for unemployment benefit [6].

3.3.2 Care should be taken to ensure that the measures taken in response to the crisis do not counteract the objective of stimulating demand and employment and of cushioning social impacts. They must be designed to be socially acceptable and conducive to growth and employment. In view of this, appropriate fiscal and income policies should be developed in co-operation with the social partners to stimulate private consumption.

3.3.3 The EESC has already pointed out that wages policies appropriate to the double economic role played by wages have a key role to play in dealing with the crisis. As companies will only invest and create jobs if they expect strong demand, a medium-term strategy of keeping wage rises in step with productivity growth in the national economy as a whole will, from a macro-economic viewpoint, make sure a proper balance is struck between sufficient growth in demand and price competitiveness. The social partners must therefore work to avoid wage restraints along the lines of a beggar-thy-neighbour policy [7]. In view of this, the EESC emphasises – especially against the backdrop of a severe economic slowdown – the need to gear wage policy towards productivity trends throughout the entire economy.

3.4 *Ensuring public investment through a provisional, flexible approach to the Stability Pact and expanding the tax revenue base in Member States*

3.4.1 Measures to revive the economy and stabilise labour markets will be expensive. Most EU countries will exceed the 3 % budget deficit threshold. The EESC has already pointed that in the framework of the more flexible, reformed Stability and Growth Pact this can under certain circumstances be considered sensible, necessary, and therefore as something to be tolerated without penalty. The conditions of the Pact should certainly not be an obstacle to forward-looking public-sector investment in research, development and education in order to develop potential for future growth [8], because this growth will provide the basis for putting public finances back onto a sustainable course rapidly once the crisis has been overcome. We need to start thinking now about how we can return to a long-term sustainable path after the crisis.

[6] Commission Communication on 'Driving European Recovery', 4 March 2009 – COM(2009) 114 final.
[7] See footnote 4.
[8] ibid.

3.4.2 Government money cannot be used for everything – bailing out banks, making benefits more generous, investing in innovation and supporting business. It will be essential for government to tap new sources of revenue. The EESC believes that Member States' tax base will have to be broadened, not least by closing tax havens, ending tax competition and taking measures to tackle tax evasion. In addition, a general re-think of tax systems is needed, with due regard for questions of contributions from different kinds of income and assets ([9]).

3.4.3 Strengthening the European dimension also requires that consideration be given to joint European projects, for instance in energy supply infrastructure. Greater flexibility between the various EU budget headings would make it possible for such projects to be part-funded from unused resources. Thought should also be given to the idea of a European bond from a European sovereign wealth fund.

3.5 *Increasing the supply of European funding, facilitating access to European Structural Funds, swift action to improve the Globalisation Fund*

3.5.1 When allocating resources from various European funds there should, in addition to efficiency, be emphasis on a flexible, pragmatic approach with a view to accelerating the impact of spending. In view of this, there is a need to simplify the administrative aspects of using funding, and also to provide for additional funding through transfers of unused funds from other Community policy areas.

3.5.2 With regard to the European Globalisation Fund, the EESC recently issued a separate opinion on this subject ([10]), which wholeheartedly endorsed the Commission's proposal to temporarily extend the scope of the fund to employees who have lost their jobs as a result of the current economic crisis.

3.5.3 The EESC also recommended increasing the fund to EUR 1 billion, doubling the contribution period to 24 months, halving the minimum eligible number of redundancies from 1 000 to 500, and raising the co-financing rate. The EESC also urges that social partners at all levels be involved in processing applications. If the economic crisis continues, consideration should be given to further beefing up of funding, and to reducing the minimum eligible number of redundancies for an application from 500.

([9]) ibid.

([10]) EESC opinion of 24 March 2009 on the 'European Globalisation Adjustment Fund', rapporteur: Mr Pariza Castaños (OJ C 228, 22.9.2009).

3.6 *Upgrading skills, matching labour market needs and promoting mobility*

3.6.1 Upgrading skills is critically important for Europe's future growth and productivity, for its capacity to adapt to change, and for equity and social cohesion. It is the best way to exploit new opportunities for sustainable job creation.

3.6.2 When the economy starts to recover all labour resources will be needed, not least because of demographic change, with a shrinking labour force of working age.

3.6.3 Worker mobility is a key instrument for an efficiently functioning Single Market and is essential for enabling more people to find better employment, a key objective of the Lisbon strategy. Workers need to be more mobile both between jobs and between regions and Member States, provided that such mobility is consistent with the applicable wage agreements and national labour law. Mobility also boosts economic growth and EU competitiveness in global economic competition.

## 4. **Comments on the priorities identified at the employment summit**

4.1 Based on the above key points, the EESC supports the priorities identified at the employment summit, which could help to stabilise the situation on labour markets.

4.1.1 *Staying in work*: In this context, the EESC feels that it is particularly important to focus on the issue of the quality of work ('more and better jobs') and to making transition from one job to another pay. The concept of flexicurity must ensure 'security in change', with equal priority in practice for labour market security, stable employment and maintaining employability, social security and labour market flexibility. In leaving behind the crisis and finding our way back to growth, we therefore need to give employees greater security, with less flexibility and less precarious employment conditions.

4.1.2 *Promoting mobility*: Changing economic conditions require a high degree of innovative adaptability, not least on labour markets. We need to be able to respond intelligently to rapidly changing structural conditions. In line with the flexicurity approach, we need to ensure that employees are equipped for the new challenges in the world of work, so as to enable mobility between high-quality jobs. In the context of

the current crisis, special attention must be paid to maintaining employability. It is important to create and safeguard jobs instead of just supporting unemployment. We also need to do everything we can to ensure that employment policy measures do actually ensure mobility from lost jobs to newly created ones rather than mobility from work to unemployment or the trap of low-quality jobs.

4.1.3 *Providing training in line with labour market needs*: The EESC feels that access to training, funding for such training and the use of working time for lifelong learning are of key importance. However, all this needs to go hand-in-hand with the creation of productive, highly skilled and well-paid jobs so that employees are not forced to accept low-skilled jobs, as happens all too often. Highly skilled employees and the availability of productive employment are essential in order to bring young people onto the labour market and promote competitiveness and prosperity.

4.1.4 *Improving labour market access*: This is an especially important priority in view of the current crisis, which has deepened inequalities and created existential problems for more and more people. It is especially important to create jobs particularly for those who are excluded from the labour market and to take effective steps to remove discrimination as far as access to and remaining in the labour market are concerned. The EESC has already adopted a separate opinion on promoting labour market access for priority groups, in which it pointed out that (re)entry into employment must always go hand-in-hand with efforts to ensure that employees from such groups have a good chance of remaining and progressing on the labour market ([11]). In view of this, the EU must – with the involvement of the social partners, whose autonomy must be respected – ensure that appropriate rules on non-standard employment are in place, while making it clear that permanent employment contracts should remain the norm in future.

4.1.5 Encouraging entrepreneurship and job creation: The EESC recognises that short-term measures have to be accompanied by long-term measures and forward-looking strategy. Business need to be helped to overcome the credit crunch and revitalise their day-to-day mission to produce, to provide services and to create jobs. An entrepreneurial mindset has to be promoted. The unemployed, particularly young people, who are willing to start their own businesses must be encouraged through economic instruments, support for productive investments and specific training.

4.1.6 Progress on structural reforms, as provided for in the EU Strategy for Growth and Jobs, must continue. These reforms must be carried out in a socially responsible manner without counteracting the objective of stimulating demand and employment and of cushioning social impacts.

4.2 Social partners and other representatives of organised civil society have a key role to play in tackling the crisis. A strengthened social dialogue – and in particular strengthened wage agreements – is needed, to draw up and implement a policy to put an end to the crisis as soon as possible, while mitigating as far as possible the economic and social fallout of the crisis on ordinary citizens. Decision-makers from business, social and political spheres are responsible for ensuring that a similar crisis does not happen again.

Brussels, 11 June 2009

The President
of the European Economic and Social Committee
Mario SEPI

([11]) EESC opinion of 12 July 2007 on the 'Employment of priority categories (Lisbon Strategy)', rapporteur: Mr Greif (OJ C 256, 27.10.2007).

*Appendix*

**to the Opinion of the European Economic and Social Committee**

The following amendments, which received at least a quarter of the votes cast, were rejected in the course of the debate (Rule 54(3) of the Rules of Procedure):

**Point 3.3**

Amend as follows:

*'Avoiding income cuts as far as possible and promoting equality of opportunity~~, paying attention to inequalities and ensuring greater security on labour market~~; flexicurity is the right approach, to modernise and foster adaptability of labour markets.'*

**Voting**

For: 84 Against: 90 Abstentions: 11

**Point 3.3.1**

Amend text as follows.

*'The sharp rise in unemployment and the use of short-term work arrangements shows that in most countries ~~there is sufficient~~ flexibility on labour markets contributes considerably to companies' ability to respond quickly when orders dry up. ~~to enable companies to respond quickly when orders dry up. In view of this, we can hardly claim that European labour markets are rigid. In the current crisis, calls for the watering down of existing labour protection rules are completely unfounded~~. Given that more and more employees are facing increasing risks due to the deteriorating economic and employment situation, what we actually need is an adequate balance between security and flexibility. In order to promote equal opportunities for all and to avoid an increase of inequality, relevant measures should be introduced, especially for the most disadvantaged. The EESC believes that such measures should include a reduction in wage-related costs and appropriate income support while at the same time maintaining re-employment incentives. ~~more security on labour markets. The EESC feels that one way of doing this is to facilitate access to social benefits to the jobless in particular, and to make them more generous to prevent even greater inequalities. With this in mind, the EESC urges the Commission to re-table its proposal to extend the eligibility period for unemployment benefit.~~'*

**Voting**

For: 78 Against: 96 Abstentions: 9

# Opinion of the European Economic and Social Committee on the Proposal for a Council Directive amending Directive 2006/112/EC on the common system of value added tax as regards the rules on invoicing

*COM(2009) 21 final — 2009/0009 (CNS)*

(2009/C 306/17)

On 27 February 2009 the Council decided to consult the European Economic and Social Committee, under Article 93 of the Treaty establishing the European Community, on the

*'Proposal for a Council Directive amending Directive 2006/112/EC on the common system of value added tax as regards the rules on invoicing'*

The Section for Economic and Monetary Union and Economic and Social Cohesion, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 28 May 2009. The rapporteur was Mr BURANI.

At its 454th plenary session, held on 10-11 June 2009 (meeting of 10 June), the European Economic and Social Committee adopted the following opinion by 114 votes, nem. con. with one abstention.

## 1. **Conclusions and recommendations**

1.1 The Commission document is presented as a response to the requirement for the Commission to report to the Council by 31 December 2008 on **technological developments in e-invoicing** and to present proposals if appropriate. The relevant provisions of the VAT Directive (2006/112/EC) did not fully meet their stated objectives; moreover, their revision led to further reflection, and **other shortcomings** were identified. The proposal is intended to contribute to the policy of simplification, reducing burdens for operators, particularly SMEs, and — indirectly but effectively — tackling fraud.

1.2 The proposals on invoicing are detailed and extremely technical, all contributing to the achievement of the above objectives; special mention should be made of the explicit recognition of the principle of **equal treatment of electronic and paper invoices**. The EESC **endorses the proposed measures**, which are streamlined and in line with the principles of good administration, but it has serious reservations regarding the **excessive freedom given to Member States** to decide whether or not to adopt a number of provisions. The EESC is aware of the difficulties encountered by the Commission in drafting binding rules which are to be valid throughout the EU, but Member States' reluctance to adopt these rules could be due to differences in levels of sophistication of administrative procedures or legislative inflexibility. In any case, the result of this situation is **flexibility in implementing the legislation, slowing down progress towards harmonisation** as well as increased red tape for business.

1.3 The EESC has serious reservations on just one point: the proposal to **give other Member States' authorities access to the invoices stored electronically by operators**. This goes well beyond the principles of administrative cooperation and is not legally tenable, especially given that the provision stating that data may only be used 'for control purposes' is being deleted at the same time.

## 2. **Background**

2.1 The VAT invoicing rules, which, in a nutshell, are the legal and regulatory basis for collecting VAT and, indirectly, for combating tax evasion, are laid down in Directive 2001/115/EC and now incorporated into the VAT Directive (2006/112/EC). Article 237 of the latter requires the Commission to present a report and, if appropriate, a proposal amending the conditions applicable to **e-invoicing** in order to take account of technological developments in that field. In the proposal being discussed here, the Commission notes that the original provisions have not fully met their stated objectives: it is therefore taking the opportunity to widen the scope of the proposals in order to remedy the shortcomings identified in this area.

2.2 The set of new rules has four key aspects: simplifying rules to reduce administrative burdens on businesses; promoting SMEs; increasing the use of e-invoicing and, lastly, helping to tackle fraud: this is by no a means simple matter but the Commission is taking excellent steps to address it. The results will, however, depend on the goodwill and efficiency of national administrations in implementing the Directive's provisions.

2.3 The Commission committed to **cutting red tape** when it adopted the 2007 Action Programme. With the current proposal, by including **e-invoicing** in a package of 'better regulation' measures to lighten the bureaucratic load on businesses, the Commission aims to kill two birds with one stone: ensuring

acceptance by tax authorities of electronic invoices as having the same probative value as paper invoices, and creating a set of harmonised rules reducing the options currently open to Member States, particularly when it comes to self-certification.

2.4 As regards SMEs, two measures are particularly welcome: extension of the scope for using **simplified invoices** and the opportunity to **account for VAT on a cash basis**. This should cut costs, simplify procedures and, indirectly, encourage SMEs to extend and/or resume their activities abroad.

2.5 The proposal is in line with the Lisbon Strategy for growth and jobs, and is of great political importance in that it enables the single market to be further consolidated. In this context, promoting **increased use and storage of electronic invoices** will help make commercial transactions smoother, enabling businesses to take new opportunities and benefit from new technologies in terms of cutting costs and greater productivity, particularly by redeploying the resources used to receive, record and store data.

2.6 As a contribution to **tackling fraud**, the Commission proposal, while attempting to remove legal barriers to e-invoicing, particularly cross-border invoicing, seeks to tighten up the rules on the role of the invoice in VAT deduction and bring about speedier exchange of information on intra-Community supplies.

2.7 The EESC believes that the set of rules is in keeping with the principles underpinning the proposal and, in general, endorses them, although it would like to make some comments and proposals, which, if accepted, would lead to more effective practical implementation of the rules.

## 3. **Principal measures proposed and comments**

3.1 As regards **statements of account or subsequent payments** (Article 64(2)), the new rules state that **continuous supplies of goods** over a period of more than one calendar month, which are supplied or transferred **VAT-exempt**, are to be regarded as being completed on expiry of each calendar month; **supplies of services for which VAT is payable** over a continuous period of more than one year are to be regarded as being completed on expiry of each calendar year. Member States have the option of applying the conventional timeframe of a year to supplies of goods and services 'in certain cases' other than these two categories.

3.1.1 The simplification introduced with these rules is to be welcomed, not least because it allows better control of continuous trade. However, the EESC has some reservations regarding the option given to Member States of applying the conventional timeframe of a year in cases other than those laid down in the Directive: harmonisation is watered down and the unduly vague wording could lead to confusion, not to say disputes.

3.2 Article 167a states that where the deductible tax becomes chargeable upon receipt of payment (cash accounting), Member States *may* provide that the right of deduction is to arise when the goods or services are supplied or at the time the invoice is issued. These options are possible only if the taxable person operates a cash accounting system and if their annual turnover does not exceed EUR 2 million.

3.2.1 These provisions make things much simpler for SMEs operating a cash accounting system and for those businesses which carry out reverse charge transactions but do not hold an invoice. However, Member States are **given the right, rather than required, to adopt them**: again, this waters down harmonisation and, to some extent, distorts the level playing field. In the explanatory memorandum the Commission proposes to extend the optional measures to all Member States, but the text of the article ('may') is ambiguous as regards the stated intention.

3.3 Article 1(9) of the proposal makes a number of changes to points a), c) and f) of Article 178 of Directive 2006/112/EC. Basically, for deductions to be applied invoices have to be drafted in accordance with the requirements of Title XI, chapter 3 of the VAT Directive; essentially, where the supplier operates a cash accounting system Member States *may* authorise the recipient to claim an immediate right of deduction. The provision introduces a principle that will make transactions smoother but, once again, allowing Member States to decide whether or not to apply it does nothing to further the desired harmonisation.

3.4 A number of measures (deletion of Articles 181 and 182, new Articles 218a and 219a) should solve the problems of **Business to Business supplies**, where businesses have at present — in principle, although difficulties of interpretation often arise — to comply with the **invoicing rules** in force in the customer's Member State. A set of harmonised proposals are introduced for both electronic and paper invoices making them valid throughout the EU; this is also the case for **Business** to **Consumer supplies**, although they continue to be subject to the rules in force in the place of taxation.

3.4.1 There are new rules concerning **simplified invoices**, which *may be permitted* in certain cases, mainly where the taxable amount is less than EUR 200 and where the supply is exempt without deductibility; this right becomes an obligation which Member States '*may impose*' in respect of the supply of goods or services '*within their territory*'.

3.4.2 The distinction between a 'full' invoice and a simplified invoice is their different potential uses: the former helps to exercise the right of deduction while the latter does not have this function in principle, except in the permitted cases and then only within the Member State in question. The changes introduced are in line with the Commission's aim of streamlining procedures and reducing burdens on businesses, but the different options available to Member States once again conflict with the harmonisation principle: this is a clear sign of ongoing resistance from Member States to adopting uniform administrative procedures and systems. With regard to the provisions concerning simplified invoices, a binding provision would be preferable to the current optional version provided for in the proposed directive to avoid additional administrative costs for businesses operational in several Member States, who would have to apply a variety of different rules.

3.5 Member States may impose time limits on taxable persons for the issue of invoices when supplying goods or services in their territory. In this proposed directive, the time limit provided for in Article 222 of Directive 2006/112/EC is to be reduced, the invoice having to be issued no later than the 15th day of the month following that in which the chargeable event occurs. The Committee is of the view that many sectors, for example, the construction industry, may find this period too short, and suggests either deleting this amendment, thereby leaving the original Article 222 unchanged, or extending the period for issuing an invoice to at least two months

3.6 A number of new provisions relate to the **procedures for recording and storage** (including by electronic means) of taxable and non-taxable transactions and related **accounting**. The EESC has no particular comments to make in this regard, except when it comes to Member States' option of requiring **particular invoices to be translated into their official languages**: this requirement already exists in some countries but it nevertheless constitutes a not inconsiderable burden on businesses.

3.7 A major change is introduced by the new Article 249 on **controls**: the original provision granted access to invoices stored electronically only to the authorities of the country in which the operator is established, while the new text proposes that **access be extended to the authorities of another Member State** in which VAT is due. The present restriction, to the effect that *national* authorities have the right to access invoices 'in so far as those authorities require for control purposes', is removed at the same time.

3.7.1 The EESC believes that extending the right of access to the authorities of another Member State, without restrictions, is **granting a right which goes beyond the rules on administrative cooperation**. To date, there is no provision allowing a foreign administration, with or without authorisation from the judicial authority of the relevant country, to question a citizen or search their property; the new provision introduces a **concept equivalent to an electronic search**. Moreover, it is difficult to imagine how it might be possible to access electronic invoices stored and only notice the data being searched for, remaining unaware of data which are not relevant to the search.

3.8 To sum up, the EESC congratulates the Commission on giving fresh impetus to its endeavours to simplify procedures, reduce administrative and accounting burdens and tighten up rules on fraud; it is concerned at the poor progress made towards harmonisation of rules, although it acknowledges the difficulties caused by Member States' resistance; and it has strong reservations about both the legality and the principle of the new rules on access to invoices stored by electronic means.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

# Opinion of the European Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council on the conservation of wild birds (codified version)

*COM(2009) 129 final — 2009/0043 (COD)*

(2009/C 306/18)

On 3 April 2009 the Council decided to consult the European Economic and Social Committee, under Article 175 (1) of the Treaty establishing the European Community, on the

*'Proposal for a Directive of the European Parliament and of the Council on the conservation of wild birds (Codified Version)'*

Since the Committee unreservedly endorses the contents of the proposal and has already set out its views on the subject in its earlier opinion, adopted on 25 May 1977 (*), the opinion adopted on 14 September 1994 (**) and the opinion adopted on 22 April 2008 (***) it decided, at its 454th plenary session, held on 10 and 11 June 2009 (meeting of 10 June 2009), by 110 votes in favour and 5 abstentions to issue an opinion endorsing the proposal and to refer to the position it had taken in the above-mentioned documents.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mr Mario SEPI

(*) Opinion of the Economic and Social Committee on the *Proposal for a Council Directive on bird conservation* — OJ C 152 on 29.6.1977, p. 3.

(**) Opinion of the European Economic and Social Committee on the *Proposal for a Council Directive amending Directive 79/409/EEC on the conservation of wild birds (94/C 393/19)* — OJ C 393 on 31.12.1994, p. 93.

(***) Opinion of the European Economic and Social Committee on *Adaptation to the regulatory procedure with scrutiny/ Proposal for a directive of the European Parliament and of the Council amending, as regards the implementing powers conferred on the Commission, Council Directive 79/409/EEC on the conservation of wild birds* — OJ C 211 on 19.08.2008, p. 46.

# Opinion of the European Economic and Social Committee on the Proposal for a Regulation of the European Parliament and of the Council laying down general rules for the granting of Community financial aid in the field of trans-European networks (codified version)

*COM(2009) 113 final — 2009/0037 (COD)*

(2009/C 306/19)

On 26 May 2009, the Council decided to consult the European Economic and Social Committee, under Article 156 of the Treaty establishing the European Community, on the

*'Proposal for a regulation of the European Parliament and of the Council laying down general rules for the granting of Community financial aid in the field of trans-European networks' (codified version)*

Since the Committee unreservedly endorses the content of the proposal and feels that it requires no comment on its part, it decided, at its 454th plenary session of 10 and 11 June 2009 (meeting of 10 June), by 112 votes with 2 abstentions, to issue an opinion endorsing the proposed text.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

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