Committee on Legal Affairs
The Chair

18.5.2010

Mr Jo Leinen
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on the legal basis concerning the placing on the market and use of biocidal products (COM(2009)0267 – C7-0036/2009 – 2009/0076(COD))

Dear Mr Leinen,

By letter of 21 April 2010 you asked the Committee on Legal Affairs pursuant to Rule 37(2) of the Rules of Procedure, to give its opinion on a proposed change to the legal basis of the proposal from a single basis of Article 114 TFEU to a triple basis of Articles 114, 192 and 168 TFEU.

The committee considered the above question at its meeting of 17 May 2010.

I. Background

Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market was adopted on 16 February 1998. It establishes a harmonised regulatory framework for the authorisation and the placing on the market of biocidal products, the mutual recognition of these authorisations within the EU and the establishment at EU level of a positive list of active substances that may be used in biocidal products.

The regulatory framework for biocidal products also consists of a number of implementing

Commission Regulations, in particular Commission Regulation (EC) No 1451/2007[1] on the second phase of the 10-year work programme referred to in Article 16(2) of the Directive.

The report submitted by the Commission on the implementation of the Directive (COM(2008)620, hereinafter "the review") forms the basis for the proposal. The review found that modifications of the Directive including procedural simplification of product authorisation, simplification and adaptation of the scope of the Directive, a tiered approach to data requirements and simplified data protection rules, improvement of the simplified procedures, and measures to encourage innovation could be beneficial in reducing the costs and administrative burden for companies and public authorities for introducing biocidal products onto the market.

The aims of the proposal, as stated in the Explanatory Memorandum, are to "tackle the identified weaknesses of the regulatory framework during the first eight years of its implementation, to improve and update certain elements of the system and to avoid problems anticipated in the future". As far as an overarching aim is concerned, the proposal states in its Preamble, paragraph 3: "The purpose of this Regulation is to increase the free movement of biocidal products within the Community ... to remove as far as possible obstacles to trade in biocidal products stemming from different levels of protection in the Member States".

II. The Proposed Legal Bases

The legal bases put forward for the proposed regulation are:

Article 114 TFEU

1. Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. If, after the adoption of a harmonisation measure by the European Parliament and

[1] OJ L 325, 11.12.2007, p. 3.

the Council, by the Council or by the Commission, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.

When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 258 and 259, the Commission and any Member State may bring the matter directly before the Court of Justice of the European Union if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Union control procedure.

Article 192 TFEU

1. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall decide what action is to be taken by the Union in order to achieve the objectives referred to in Article 191[1].

2. By way of derogation from the decision-making procedure provided for in paragraph 1 and without prejudice to Article 114, the Council acting unanimously in accordance with a special legislative procedure and after consulting the European Parliament, the Economic and Social Committee and the Committee of the Regions, shall adopt:

(a) provisions primarily of a fiscal nature;

(b) measures affecting:

— town and country planning,

— quantitative management of water resources or affecting, directly or indirectly, the availability of those resources,

— land use, with the exception of waste management;

(c) measures significantly affecting a Member State's choice between different energy sources and the general structure of its energy supply.

The Council, acting unanimously on a proposal from the Commission and after consulting the European Parliament, the Economic and Social Committee and the Committee of the Regions, may make the ordinary legislative procedure applicable to the matters referred to in the first subparagraph.

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[1] *Article 191*

1. Union policy on the environment shall contribute to pursuit of the following objectives:
— preserving, protecting and improving the quality of the environment,
— protecting human health,
— prudent and rational utilisation of natural resources,
— promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change.
2. Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.
In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a procedure of inspection by the Union.EN C 83/132 Official Journal of the European Union 30.3.2010
3. In preparing its policy on the environment, the Union shall take account of:
— available scientific and technical data,
— environmental conditions in the various regions of the Union,
— the potential benefits and costs of action or lack of action,
— the economic and social development of the Union as a whole and the balanced development of its regions.
4. Within their respective spheres of competence, the Union and the Member States shall cooperate with third countries and with the competent international organisations. The arrangements for Union cooperation may be the subject of agreements between the Union and the third parties concerned.
The previous subparagraph shall be without prejudice to Member States' competence to negotiate in international bodies and to conclude international agreements.

3. General action programmes setting out priority objectives to be attained shall be adopted by the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions.

The measures necessary for the implementation of these programmes shall be adopted under the terms of paragraph 1 or 2, as the case may be.

4. Without prejudice to certain measures adopted by the Union, the Member States shall finance and implement the environment policy.

5. Without prejudice to the principle that the polluter should pay, if a measure based on the provisions of paragraph 1 involves costs deemed disproportionate for the public authorities of a Member State, such measure shall lay down appropriate provisions in the form of:

— temporary derogations, and/or

— financial support from the Cohesion Fund set up pursuant to Article 177.

Article 168 TFEU

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The

European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure 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 in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

III. Applicable law

It is settled case-law that the choice of legal basis for a Community measure must rest on objective factors amenable to judicial review, which include in particular the aim and content of the measure[1].

[1] Case C-440/*05 Commission* v. *Council* [2007] ECR I-9097.

In principle, a measure is to be founded on only one legal basis. If examination of the aim and the content of a Community measure reveals that it pursues a twofold purpose or that it has a twofold component, falling within the scope of different legal bases, and if one is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, the measure must be based on a single legal basis, namely that required by the main or predominant purpose or component[1].

Only if, exceptionally, it is established that the measure simultaneously pursues a number of objectives or has several components that are indissociably linked, without one being secondary and indirect in relation to the other, will that measure have to be founded on the various corresponding legal bases, insofar as their procedures are compatible[2].

Recourse to a dual legal basis is not possible where the procedures laid down for each legal basis are incompatible with each other[3].

IV. Analysis of Directive 98/8/EC and the proposal

The Directive provides for a regulatory system of authorisation, mutual recognition and a finite list of authorised active substances, which aims to overcome possible barriers to the internal market in biocidal products while taking as a condition "a high level of protection for humans, animals and the environment"[4].

The proposal is essentially a harmonisation measure, designed to simplify the Directive's system of authorisation of biocidal products across the Union in order to facilitate the free movement of goods and to maintain the internal market. It is aimed at the weaknesses of the Directive's regulatory framework and at updating the authorisation procedures. It also extends the scope of the Directive to include materials that might come into contact with food, and articles or materials that have been treated with biocidal products. By turning the Directive into a regulation, the proposal aims to achieve a more harmonised implementation of the regulatory framework as there will be no need for a transposition period or for national transposition measures in Member States.

V. Analysis of the legal bases proposed

Article 114 TFEU mandates via the ordinary legislative procedure Community measures "which have as their object the establishment and functioning of the internal market".This article should be read in the context of Article 26 TFEU, establishing free movement of goods as a fundamental principle in the establishment of the internal market. In addition Article 114(3) should be noted as establishing a "high level of protection" in measures dealing with health, safety, environmental and consumer protection. Paragraphs (4) to (9) permit Member States to take national measures to introduce justified prohibitions or restrictions on imports, exports or goods in transit, pursuant to Article 36 TFEU, after a harmonisation measure has been adopted. Paragraphs (4) to (9) therefore represent a significant qualification of the

[1] Case C-91/05 *Commission* v. *Council* [2008] ECR I-3651.
[2] Case C-338/01 *Commission* v. *Council* [2004] ECR I-4829.
[3] Case C-178/03 *Commission* v. *Parliament and Council* [2006] ECR I-107.
[4] Recital (4), Directive 98/8/EC

overall aim of the article in fostering the establishment and functioning of the internal market.

Article 168 TFEU comes under Title XIV on Public Health. It concentrates on maintaining a "high level of human health protection" in terms of health services and the prevention of cross border threats to human health. Article 168(4)(b) however provides by way of derogation a mandate for "measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health", using the ordinary legislative procedure. Whilst it could be argued that the aim of the proposal, in facilitating the internal market in biocides which can protect and preserve animal and plant life, corresponds with this provision, the proposal does not have as its "direct objective" the protection of public health. The direct objective of the proposal, as indicated in recital (3) in the preamble, is to increase the free movement of biocidal products within the Community. As will be posited in more detail below, the protection of public health should be regarded as one, but not the main or dominant, purpose of the proposal.

Article 192(1) TFEU permits measures to be taken under the ordinary legislative procedure to enact Union policy under Article 191 on, *inter alia*, preserving, protecting and improving the quality of the environment, and protecting human health. Article 192(2) permits measures to be taken under a special legislative procedure which concern, *inter alia*, measures affecting the quantitative management of water resources, and land use. It is submitted that the more relevant provision in terms of the proposal is Article 192(1): in particular the proposal falls within the scope of preserving and protecting the quality of the environment and protecting human health specifically set out in that provision.

As we have seen, the case law makes it clear that where there is more than one possible legal basis for a Community measure, the general rule is that the basis which corresponds to the main or dominant purpose of the measure should be used, *unless* exceptionally the purposes of the measure are indissociably linked without one being secondary to the other, and the corresponding legal bases are procedurally compatible.

It is clear that the legal bases put forward in the Committee on the Environment, Public Health and Food Safety are procedurally compatible: those parts of the suggested articles which provide for special legislative procedure do not correspond to the scope and aim of the proposal, while the key parts of each proposed legal basis which do correspond to the scope and aim of the proposal all apply the ordinary legislative procedure. It must therefore be considered whether the aims of the proposal can be regarded as indissociably linked without one being secondary to the other: if so, a multiple legal basis may be possible.

It is posited above that the aim of maintaining the internal market by facilitating inter-Member State trade in biocidal products is the dominant or main purpose of the proposal, while the protection of the environment and human and animal life is a secondary purpose. It is instructive to compare the proposal with similar recent legislation in this area such as the REACH regulation on chemicals, Regulation (EC) No 1907/2006, which according to the Explanatory Memorandum of the proposal, was taken into consideration in the creation of the proposal. REACH, also based on Article 114 TFEU, clearly states in Article 1 that its purpose is to ensure a high level of protection of human health and the environment, *as well as* the free circulation of substances on the internal market. By contrast; the proposal acknowledges that biocidal products "can pose risks" to humans, animals and the environment, while retaining as

its explicit stated purpose improving the free movement of biocidal products on the internal market. Concerning specific references to the level of protection within the proposal, REACH has embedded within Article 3 the precautionary principle which determines that where there are reasonable grounds for concern that a measure poses potentially dangerous effects to the environment, human, animal or plant health inconsistent with the high level of protection adhered to by the EU, certain action may be taken to remedy the situation as long as there is a risk which is too high to impose on society. While according to recital (10) in the preamble, the most hazardous substances are not permitted for authorisation "with a view to achieving a high level of environmental and human health protection", there is no reference to the precautionary principle itself in the preamble or the enacting terms of the proposal.

The extension of the scope of the Directive to include in the regulation devices which produce biocides and materials containing biocides which may come into contact with food, and articles treated with biocides such as furniture, as well as the phasing out of products which contain hazardous carcinogenic substances, indicates that the proposal is also aimed at reaching an optimum balance between the benefits and risks attached to trade in biocidal products within the European Union. Recital (1) in the preamble to the proposal states as follows:

> *"Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured products. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic property and associated use patterns".*

This demonstrates an awareness of the tension between the benefits of facilitating trade in biocidal products and the risks of making such products more widely available and therefore increasing the chance of contact with humans, animals and the environment. It is submitted however that the proposal's statements throughout the preamble that its aim is to facilitate the free movement of goods and the internal market suggest that the risks of making biocidal products more widely available are weighed as an integral part of the measures used to achieve the aim of the proposal. Protection is therefore a key aim of the proposal, but cannot be said to be its dominant or main purpose.

Further substantive elements of the proposal support this argument. There is an apparent refusal to authorise "active substances with the worst hazard profiles" in recital (10) in the preamble, which suggests a strong commitment to the protection of human, animal and plant life. However, this is undermined by relatively imprecise exemptions such as:

i. the approval of such substances in "situations when the exposure of humans to the substance is negligible or the substance is necessary for public health reasons" (recital (11).

ii. Article 5, concerning exclusion criteria, permits active substances which do not comply with the conditions in Article 16(1) of the proposal (including not having an "unacceptable effect" on human, animal and plant life) to be authorised if it is shown that *not* including them would cause "disproportionate negative impacts

when compared with the risk to human health or the environment arising from the use of the substance" (Article 5(1)(c)).

iii. the requirement of a full in-depth evaluation of an application to renew the authorisation of an active substance only exists where the competent authority that was responsible for the initial evaluation decides to carry out such an evaluation itself. This leaves renewals at a much lower level of protection than initial authorisation.

By contrast, the key elements of the proposal are targeted at facilitating the free movement of biocidal products within the Community. The proposal focuses on the following measures:

- removing the simplified procedures for the evaluation of active substances, in particular low-risk substances;

- simplifying the authorisation procedures for biocidal products, including setting up a centralised system for authorisation, for which the European Chemicals Agency will be competent in carrying out the technical and scientific tasks, and harmonising procedures for mutual recognition of authorisations;

- providing for specific parallel trade rules to minimise the administrative burden on cross-border trade in biocidal products.

All the above measures are aimed at simplifying and harmonising administrative procedures in the authorisation process, which will facilitate cross-border trade in biocidal products.

Further, in paragraph 3.3 of the Explanatory Memorandum, dealing with subsidiarity, the justification given for the EU taking action in this area is the harmonisation of potential "obstacles to trade in biocidal products" resulting from different levels of protection in different Member States. The characterisation of levels of protection as potential "obstacles to trade", even where the level of protection in another Member State could be higher than is currently provided in the Directive, indicates that the facilitation of trade is clearly the dominant aim of this proposal.

Having established that there is one dominant purpose in the proposal and therefore that following the case law it is appropriate to have a single legal basis rather than multiple bases, it is therefore necessary to determine which of the three proposed legal bases is appropriate. A further comparison with the REACH regulation reveals that that measure is based on Article 114 TFEU, but clearly holds the protection of human, animal and plant life in higher regard than the proposal. Neither Article 192 nor Article 168, both of which overwhelmingly concern the protection of human, animal and plant life, is used as a legal basis in REACH. It would therefore be logical that a proposal with a much weaker emphasis on protection, but with a greater emphasis on the free movement of goods within the Union should rely on Article 114 as its legal basis.

Any basis in Article 168 would be weak as the proposal does not satisfy the criteria in Article 168(4)(b) of having as its "direct objective" the protection of public health.

Article 192 is perhaps more applicable; however, the incompatibility of Article 192 and the proposal is clear from the inconsistency between the proposal's dominant aim in facilitating the internal market, and the overriding purpose of Article 192 in terms of protection. Further, Article 191 TFEU requires Union policy in this area to be based on the precautionary principle; but this principle does not appear in the proposal. Article 114 however provides sufficient protection to the same level as the proposal - a "high level of protection" in Article 114(3) corresponds with the "high level of protection" in recital 10 in the preamble and in the Explanatory Memorandum: "The proposal is seeking to improve the existing regulatory framework, without reducing the high level of protection for the environment and human and animal health". Article 114 is therefore the more appropriate legal basis from a protection perspective.

Taking into account the fact that the internal market is the dominant aim of the proposal and the protection aspect of the proposal an incidental or secondary aim, rather than the two aims being "indissociable" and equal in status, it would not be appropriate to condone the use of a dual legal basis at all in the context of the case law in this area.[1] It would indeed be appropriate to conclude that the legal basis which best corresponds to the dominant aim of the proposal, Article 114, should be retained as the sole legal basis of the proposal. [2]

V. Conclusion and recommendation

At its meeting of 17 May 2010 the Committee on Legal Affairs accordingly decided, unanimously[3], to recommend to you that Article 114 of the Treaty on the functioning of the European Union should be the sole legal basis for the proposal for a regulation in question.

Yours sincerely,

Klaus-Heiner Lehne

[1] Case C-338/01 Commission v Council (2004)
[2] Case C-91/05 Commission v Council (2008)
[3] [3] The following were present for the final vote: Luigi Berlinguer (acting Chair), Raffaele Baldassarre (Vice-Chair), Evelyn Regner (Vice-Chair), Sebastian Valentin Bodu (Vice-Chair), Kurt Lechner (rapporteur), Françoise Castex, Christian Engström, Marielle Gallo, Eva Lichtenberger, Antonio Masip Hidalgo, Bernhard Rapkay, Francesco Enrico Speroni, Cecilia Wikström, Tadeusz Zwiefka.