



*Committee on Legal Affairs
The Chair*

6.12.2018

Ms Adina-Ioana Vălean
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on the legal basis of the proposal for a Regulation on transparency and sustainability of the EU risk assessment in the food chain (COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))

Dear Madam Chair,

By letter of 19 November 2018 you asked the Committee on Legal Affairs pursuant to Rule 39(2) to consider whether the legal basis of the above Commission proposal was valid and appropriate.

The committee considered the above question at its meeting of 6 December 2018.

I - Background

The proposal aims at amending the General Food Law Regulation¹ (the “GFL Regulation”), and eight related legislative acts² when it comes to risk assessment in the food chain.

The Commission proposal was based on Article 43 of the Treaty on the Functioning of the European Union (TFEU), on agriculture, Article 114 TFEU on harmonisation in the internal market, and Article 168(4)(b) TFEU on public health.

An amendment tabled in ENVI seeks to add Article 192(1) TFEU, on the environment, to the legal basis.

¹ Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food (OJ L 31, 1.2.2002, p. 1).

² See footnote 8 in the Opinion of the Legal Service for a list of the full titles of and references to these acts.

II - Relevant Treaty Articles

The following Articles of the TFEU were presented as the legal basis in the Commission's proposal (emphasis added):

Article 43 TFEU, on agriculture and fisheries, has the following wording:

Article 43 (ex Article 37 TEC)

1. The Commission shall submit proposals for working out and implementing the common agricultural policy, including the replacement of the national organisations by one of the forms of common organisation provided for in Article 40(1), and for implementing the measures specified in this Title.

These proposals shall take account of the interdependence of the agricultural matters mentioned in this Title.

2. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, shall establish the common organisation of agricultural markets provided for in Article 40(1) and the other provisions necessary for the pursuit of the objectives of the common agricultural policy and the common fisheries policy.

3. Council, on a proposal from the Commission, shall adopt measures on fixing prices, levies, aid and quantitative limitations and on the fixing and allocation of fishing opportunities.

[...]

Article 114 TFEU, on harmonisation in the internal market, has the following wording:

Article 114 (ex Article 95 TEC)

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.

[...]

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 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.*

Article 168(4)(b) TFEU, on public health, has the following wording:

Article 168
(ex Article 152 TEC)

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

[...]

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.

[...]

Article 192(1) TFEU, on the environment, which is proposed to be added to the legal basis, has the following wording:

Article 192
(ex Article 175 TEC)

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.

[...]

Article 191 TFEU has the following wording:

Article 191
(ex Article 174 TEC)

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.*

[...]

Article 193 TFEU has the following wording:

Article 193
(ex Article 176 TEC)

The protective measures adopted pursuant to Article 192 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with the Treaties. They shall be notified to the Commission.

Article 207 TFEU on the common commercial policy, which formed part of the legal basis of the original GFL Regulation, has the following wording:

Article 207
(ex Article 133 TEC)

1. The common commercial policy shall be based on uniform principles, particularly with regard to changes in tariff rates, the conclusion of tariff and trade agreements relating to trade in goods and services, and the commercial aspects of intellectual property, foreign direct investment, the achievement of uniformity in measures of liberalisation, export policy and measures to protect trade such as those to be taken in the event of dumping or subsidies. The common commercial policy shall be conducted in the context of the principles and objectives of the Union's external action.

2. The European Parliament and the Council, acting by means of regulations in accordance with the ordinary legislative procedure, shall adopt the measures defining the framework for implementing the common commercial policy.

[...]

III - Case-law on legal basis

It is settled case law of the Court of Justice 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. The choice of an incorrect legal basis may therefore justify the annulment of the act in question.

Whilst the choice of the legal basis should in principle not depend on the choice made for earlier legislative acts, according to settled case-law the legal basis for a measure must be determined having regard to its own aim and content and not to the legal basis used for the adoption of other EU measures that might, in certain cases, display similar characteristics. However, where a legislative act is designed merely as a supplement or a correction of another legislative act, without altering its original goal, the EU legislature is fully entitled to base the latter act on the legal basis of the first act.²

When it comes to multiple bases it has to be established whether the proposal either:

1. pursues multifold purposes or has multifold components, and one of those is identifiable as the main or predominant purpose or component, whereas the others are merely incidental; or
2. 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.

According to the case law of the Court of Justice, in the first case the act must be based on a single legal basis, namely that required by the main or predominant purpose or component, and in the second case the act will have to be founded on the various corresponding legal bases.³

IV - Aim and content of the proposed regulation

The main aim of the proposal is to make studies used in risk assessment in the food chain more transparent and address the demands of society for a more transparent and independent risk assessment process and more effective risk communication. By strengthening the European Food Safety Authority's (EFSA) governance and making risk assessment more sustainable, it aims at ensuring that EFSA will continue to play a fundamental role in the Union food safety system and to contribute to the health and wellbeing of Union citizens and to an innovative and competitive Union agri-food industry.

The proposal more specifically aims at increasing the guarantees of reliability, objectivity and independence of studies which the EFSA uses in its risk assessment, in particular in the context of authorisation applications. To those ends, the proposal seeks to improve the governance of and strengthen the scientific cooperation of Member States with and their involvement in EFSA, to strengthen the ability of EFSA to maintain a high level of scientific expertise in the different areas of its work, especially its capacity to attract excellent scientists to be members of its Scientific Panels, and to develop a comprehensive and effective risk

¹ Case C-45/86, *Commission v. Council* (Generalised Tariff Preferences) [1987] ECR 1439, para. 5; Case C-440/05 *Commission v. Council* [2007] ECR I-9097; Case C-411/06 *Commission v. Parliament and Council* [2009] ECR I-7585.

² See judgment of 21 June 2018, *Poland v Parliament and Council*, C-5/16, EU:C:2018:483, p. 49, p. 69 and case-law cited.

³ See the Case C-411/06, cited above, paras 46-47.

communication strategy, involving the Commission, Member States and EFSA throughout the risk analysis process.

The proposal consists of 40 recitals and 11 articles. Article 1 includes amendments to the GLF Regulation by introducing 18 new articles on risk communication, EFSA governance questions, register of studies, consultation of third parties, controls, verification studies, confidentiality, data protection and the conferral of the power to adopt delegated acts establishing a general plan for risk communication on matters relating to the agri-food chain. Articles 2-9 includes minor amendments to the other eight legislative acts, primarily on transparency and confidentiality. Finally, Articles 10 and 11 deal with transitional measures and entry into force.

The final report on the dossier adopted in ENVI consists of 131 amendment, but with the exception of the amendment which seeks to alter the legal basis, they do not seem to substantially alter the aim and content of the Commission proposal.

V - Determination of the appropriate legal basis

It should first be noted that the GFL Regulation which is now being amended was based on the three legal bases put forward by the Commission in the proposal, plus Article 133 EC on the common commercial policy (now Article 207 TFEU). The Commission has however not included Article 207 TFEU in the proposal, which seems to be correct since the proposal does not have anything to do with the common commercial policy.¹

The Legal Service has provided this useful overview of the legal bases of all nine of the legislative acts covered by the proposal²:

GFL Regulation	Articles 37, 95, 133 and 152(4)(b) EC
Directive 2001/18	Article 95 EC
Regulation 1829/2003	Articles 37, 95, 152(4)(b) EC
Regulation 1831/2003	Articles 37 and 152(4)(b) EC
Regulation 2065/2003	Article 95 EC
Regulation 1935/2004	Article 95 EC
Regulation 1331/2008	Article 95 EC
Regulation 1107/2009	Articles 37(2), 95 and 152(4)(b) EC
Regulation 2015/2283	Article 114 TFEU

It could first be concluded that all of the acts which are proposed to be amended were based on one or a combination of the three legal bases in the Commission's proposal. Regulation 1107/2009 is however specifically based in part on paragraph 2 of Article 43 TFEU (ex Article 37 EC), which is the operative paragraph which makes reference to the ordinary legislative procedure.

¹ The ENVI report does however introduce a new Recital 4a which does indirectly touch upon the common commercial policy: "On signing trade agreements, the Union needs to ensure that the food legislation of third-country partners is at least as protective of food safety as Union law, so as to guarantee consumer safety and prevent unfair competition with European products."

² See the Opinion of the Legal Service, SJ-0333/18, point 15.

Given that, according to the case law cited above, where a legislative act is designed merely as a supplement or a correction of another legislative act, without altering its original goal, the EU legislature is fully entitled to base the latter act on the legal basis of the first act, it would seem that the Commission correctly included the three relevant articles in the legal basis, not least considering that the aim of the proposal is not to alter the original goals of the amended acts but simply to strengthen certain limited aspects thereof.

According to Article 1 of the GLF Regulation, on its aim and scope, it provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, whilst ensuring the effective functioning of the internal market, and it establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

The current proposal does not in any way alter these goals of the GLF Regulation but rather aims at strengthening certain aspects thereof, in particular relating to transparency of risk assessment and certain governance aspects of EFSA, a body which also was established by the GLF Regulation. The other eight legislative acts are primarily amended only as to transparency and confidentiality aspects whereas their original goals are unaffected by these changes. The Commission's proposal could for these reasons therefore correctly be based on the legal basis of the original acts, i.e. the three articles put forward by the Commission, as illustrated in the table above.

The question then becomes whether all of these three articles must be included in the legal basis or whether only one or two of them would suffice.

As the Legal Service points out, Article 114 TFEU (ex Article 95 EC) is already a legal basis for all but one of the amended acts and given that the proposal aims at strengthening the procedural framework and the transparency of authorisation processes, it could be said that its main purpose is to ensure the proper functioning of the internal market and therefore, in principle, recourse to Article 114 TFEU as a legal basis could be sufficient.¹

It must therefore be determined, in accordance with the case-law cited above, whether these internal market aspects constitute the main or predominant purpose or component, whereas agriculture and fisheries in Article 43 TFEU and public health in Article 168(4) TFEU are merely incidental, or whether all three of these objectives or components are pursued simultaneously and indissociably linked, without one being secondary and indirect in relation to the other.

Given that the GLF Regulation lays down the general principles and requirements of food law and also establishes EFSA as the responsible Union risk assessment body in matters relating to food and feed safety, the establishment of the common organisation of agricultural markets and the common agricultural and fisheries policies (Article 43(2) TFEU) and measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health (Article 168(4)(b) TFEU) could hardly be said to be secondary or indirect to the general internal market objective but must be considered to be pursued simultaneously and

¹ Idem, point 18.

indissociably linked therewith.

Articles 43(2) and 168(4) TFEU must therefore be joined together with Article 114 TFEU to form the legal basis for the proposal.

Finally, we are left with the question of whether Article 192(1) TFEU should be added to the legal basis.

The amendment which was adopted in ENVI and which aims at adding this article on the environment to the legal basis was justified thusly: *“The authorisation to cultivate or to put into circulation genetically modified organisms, plants or animals as well as the authorisation of active substances of pesticides has considerable impacts on the natural environment and on human health; the protection of human health forms part of the EU environmental policy”*.

While it is clear from the Treaty that the Union policy on the environment shall contribute to pursuit of the objective of protecting human health, environmental protection is simply not the primary aim and content of the proposal. As outlined above, the aim and content of the proposal must rather be considered to be agriculture/fisheries and public health aspects of authorisation processes in the single market.

Furthermore, Article 114(3) TFEU already requires the Parliament, the Council and the Commission, within their respective powers, to take as a base a high level of protection in matters concerning environmental protection in any measures for the approximation of the provisions which have as their object the establishment and functioning of the internal market, including taking account in particular of any new development based on scientific facts.

Finally, as the Legal Service also points out, there are in any event different legal regimes applicable under Articles 114 and 192 TFEU concerning the possibility for the Member States to adopt more stringent national measures.¹ Whereas Article 193 TFEU makes clear that the protective measures adopted pursuant to Article 192 TFEU do not prevent any Member State from maintaining or introducing more stringent protective measures, Article 114 TFEU includes an intricate verification system for diverging national measures which grants the Commission a prominent role in ensuring that such national measures are not a means of arbitrary discrimination or a disguised restriction on trade between Member States, and the Commission must determine whether or not they constitute an obstacle to the functioning of the internal market. Those two legal regimes are clearly incompatible with each other.

Article 192(1) TFEU may therefore not be added to the legal basis for the proposal.

VI - Conclusion and recommendation

In the light of the foregoing analysis Articles 43(2), 114 and 168(4)(b) TFEU constitute the proper legal basis for the proposal.

At its meeting of 6 December 2018 the Committee on Legal Affairs accordingly decided, by

¹ See the Opinion of the Legal Service, SJ-0333/18, point 24.

10 votes to 0, with 7 abstentions¹, to recommend that the Committee on the Environment, Public Health and Food Safety should therefore not take on board Article 192(1) TFEU as an additional legal basis in the ensuing procedure on this dossier.

Yours sincerely,

Pavel Svoboda

¹ The following were present for the final vote: Pavel Svoboda (Chair), Jean-Marie Cavada, Mady Delvaux (Vice-Chairs), Axel Voss (rapporteur for opinion), Max Andersson, Joëlle Bergeron, Geoffroy Didier, Angel Dzhambazki, Rosa Estaràs Ferragut, Mary Honeyball, Ana Miranda, Julia Reda, Evelyn Regner, Jens Rohde, Virginie Rozière, Tiemo Wölken, Georges Bach, Philippe Loiseau, (for Marie-Christine Boutonnet pursuant to Rule 200(2)).