

Legal and political hybridity of the European Union – genetically modified organisms' case

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Abstract

The European Union can be described as a particular hybrid integration structure that combines features of a state and intergovernmental organisation. Its institutional framework, legal system and division of competences are examples of a supranational organisation or a transnational decision-making system. The decision-making process is an outcome of network interactions between multiple actors, whose relations are non-hierarchically ordered. Genetically modified organisms (GMO) as an example of modern biotechnology application is a highly polarising subject in the EU, as well as globally. Thus, the policy towards GMO is an exemplification of legal and political hybridity of the EU. The analysis of the EU's legal and political hybridity will be narrowed down to the GM plants case and methodologically organised around the concept of decision-making analysis that is composed of five categories: decision-making situation, actors, decision-making process, decision, implementation of the decision.

Keywords: European Union, legal and political hybridity, decision-making analysis, decision-making process, genetically modified organisms (GMO)

Prawna i polityczna hybrydowość Unii Europejskiej na przykładzie prawa dotyczącego organizmów genetycznie zmodyfikowanych

Streszczenie

Unię Europejską można opisać jako szczególną hybrydową strukturę integracyjną, która łączy w sobie cechy państwa i organizacji międzyrządowej. Jej ramy instytucjonalne, system prawny i podział kompetencji są przykładami organizacji ponadnarodowej lub ponadnarodowego systemu decyzyjnego. Proces decyzyjny jest wynikiem interakcji sieciowych pomiędzy wieloma podmiotami, których relacje są niehierarchicznie uporządkowane. Organizmy zmodyfikowane genetycznie (GMO) jako przykład zastosowania nowoczesnej biotechnologii są tematem wysoce polaryzującym w UE, jak i na świecie. Tym samym polityka wobec GMO jest przykładem prawnej i politycznej hybrydowości UE. Analiza prawnej i politycznej hybrydowości UE zostanie zawężona do przypadku roślin zmodyfikowanych genetycznie i metodologicznie zorganizowana wokół koncepcji analizy decyzyjnej, która składa się z pięciu kategorii: sytuacja decyzyjna, podmioty, proces decyzyjny, decyzja, wdrożenie decyzji.

Słowa kluczowe: Unia Europejska, hybrydowość prawna i polityczna, analiza decyzyjna, proces decyzyjny w UE, organizmy genetycznie zmodyfikowane (GMO).

The aim of this article is to analyse the phenomenon of the political and legal hybridity of the EU as exemplified by the Community regime in the area of agrobiotechnology. The focus is on the multi-level management system of GMO usage for the purpose of food or feed, or their production, and release of GMO into the natural environment. Narrowing the analysis down to GMO is not accidental. This example makes it possible to show how a complicated management model we are dealing with and how it is changing under the influence of factors coming from inside and outside the system.

Approaching the EU as a transnational decision-making system, the analysis will be ordered according to the categories of the decision analysis. Using the categories of the political decision theory according to Z. J. Pietraś (2000), the analysis will concern a decision-making situation, decision-making centre, decision-making process, political decision, and decision implementation. A decision-making situation – understood in the objective sense as a political reality, and in the subjective meaning as a problem (challenge) faced by a decision-making centre and demanding a solution (Pietraś 2000: p. 46) – has been presented below. Another step is a discussion about the EU hybridity phenomenon on the basis of the other four criteria of the decision analysis.

Decision-making situation

The European Union (EU) is an example of an international organisation that combines features of a supranational and intergovernmental institution, as well as a transnational decision-making system, whose integral component is hybridity manifested in many aspects of the EU functioning and consisting in simultaneous occurrence of features of a state and an intergovernmental organisation (Pietraś 2000). In each international organisation, the advancement level of the integration processes depends on intentions of its Member States, which decide, what part of their autonomy they wish to transfer to the organisation's level. The division of competences between the EU and its Member States has been specified in the EU founding treaties and amendments. Beginning from the Maastricht Treaty (1992), a hybrid constitutional regime has been developing in the EU. It comprises the supranational regime in the area of the EU internal market management and the intergovernmental regime pertaining to the common foreign and security policy and to the policies connected with internal security. This constitutional dualism was maintained by the Lisbon Treaty (Fabbrini 2016: p. 11). The sector policies of the supranational character are those pursued on the basis of the uniform legal norms developed during the supranational decision-making process, and their execution is entrusted to the supranational institutions, which monitor how the EU legal regulations are implemented in the EU Member States. These policies comprise the ones belonging to the exclusive competence of the EU (Article 3 (1, 2) of the Treaty on the Functioning of the European Union – TFEU), but also the policies referring to the competence shared

between the EU and the Member States (Article 4 (1) of the TFEU) (Blanke, Böttner 2016: p. 244). A separate category comprises the policies classified under the intergovernmental regulatory regime, characterised by the dominant role of the Member States in their governance process and the activity of the supranational institutions to support, coordinate or supplement the states' actions (Article 6 of the TFEU) (Wouters et al. 2014: p. 197). Moreover, it is worth mentioning that hybridity can also be a feature occurring within a specific sector policy as a consequence of mixing the tools of "hard" and "soft" law.

The EU hybridity is manifested in mixing of contradictory trends, e.g. aimed at deeper European integration and, thus, expansion of the regulatory capacity of supranational institutions and the simultaneous intent of the Member States to keep control over the actions of supranational institutions, to maintain the national independence and autonomy. The law of the European Union is a separate and specific legal order, functioning in parallel with the law of the Member States, different from the public and private international law. As observed by P. Tosiek, the EU law is a bonding institution, connecting on the supranational level various entities participating in the decision-making process within the EU, which makes this legal system stronger than international law and demanding compliance from the Member States (Tosiek 2016: p. 130). Delegating some of their competences to the EU level, the states participate in a process defined by C. Scott as a creation of post-regulatory state, which transfers its legislative powers to the newly established and growing transnational regimes or transnational regulatory regimes, being a hybrid of administrative and legislative structures, and agrees also to restrictions on its veto right (Chowdhury, Wessel 2012: p. 337). Not only Member States but also their citizens are subject of the EU legal regulations. The EU law is based on the primacy rule and direct effect principle. However, after D. Braun, we can point to the hybrid character of the EU legal system also here, as well as to the coexistence of the intergovernmental logic (*representation without bargaining*), that is enactment of legal acts, which require transposition to the domestic law, and supranational logic (*representation within bargaining*), that is activity of the EU institutions issuing legal acts or judicial decisions (in the case of the Court of Justice of the European Union) having a direct effect in the Member States (Ruszkowski 2010: p. 220). As it has already been mentioned, the EU law is the law of the Member States and the effort connected with implementation of the EU regulations to national legal systems is expended by the state administration. Simultaneously, apart from the legal regulations classified as the "hard law," there are also various acts of the "soft law" character issued in the EU, such as recommendations, opinions, guidelines etc. (Ruszkowski 2010: p. 223).

The hybrid character of the EU is also manifested in the institutional system and the decision-making process, which comprises several governance levels. In the political and legal dimensions, the European Union is the arena, where the two ideas are clashing. The first one is based on the principle of the Member States' sovereignty, and the second one consists in the advancing process of extending the influence and centralisation of supranational administration. Nevertheless, the latter trend does not indicate that the EU intends to become a super-state, but it rather confirms the fusion-based character of the organisation, which is called a *non-state-like polity* by E. Heidbreder (2013: p. 136).

The EU institutional system consists of the supranational institutions (the European Commission, the European Parliament, the Court of Justice of the European Union, the European Court of Auditors, the European Central Bank) and the intergovernmental institutions (the Council and the European Council). In accordance with the general principle, the supranational institutions represent the Community's interests, whereas the intergovernmental institutions consist of the Member States' representatives who advance the national interests. Apart from the above-mentioned entities, many other stakeholders, active on various governance levels, participate in the process of enactment and implementation of the EU law. The European Union is frequently presented as a multi-level governance system, a polycentric governance system, a multi-level regulation system, or – as defined by N. Chowdhury and R. A. Wessel (2012) – “new architecture of experimental governance.”

As a multi-level governance system, the European Union is an organisation with at least two governance levels (usually more) in the vertical dimension; the relations between the stakeholders of the decision-making process have a non-hierarchical character; competence is distributed and delegated (primary and secondary delegation); as a result of the spillover effect the communitisation of one area enforces the same process in other overlapping areas, which reduces the national autonomy sphere; mixing of the supranational and intergovernmental entities, as well as the supranational and intergovernmental decision-making ways etc., leads to the formation of fuzzy sets, which constitute a new value and a category between the supranational and the intergovernmental. In particular policies it is possible to indicate the simultaneous use of various governance methods by a decision-making centre, e.g. the community method or the open method of coordination, various manners of taking decisions (majority vote in most cases, unanimity, consensus), “agencification”, which means the increasingly popular delegation of the decision powers to Community agencies and their active participation in the decision-making process (Tosiek 2016: p. 151–160).

Despite the expanding scope of the supranational regime, the states still exercise effective supervision of the EU governance processes, for instance by exerting control over the entities whose members are international officers (the European Commission) in the comitology procedure by committees consisting of the Member States' representatives (Tosiek 2016: p. 161).

The technological development, exemplified by the advancement in modern biotechnology, is an interesting case how a new political and regulatory area is formed. Biotechnological innovations, such as genetically modified organisms (GMO), are widely used in various sectors of economy. However, the greatest controversy among the general public in the EU is aroused by the use of GMO as food or in the production of food and feed, as well as the release of GMO into the natural environment. Therefore, the article focuses solely on GMO as a product of modern agrobiotechnology, especially on transgenic plants.

The acreage of genetically modified crops in the EU states is limited and accounted for over 131 000 ha in 2017. Since 2000, the European Commission approved for cultiva-

tion only two varieties of transgenic plants: MON 810 corn and Amflora potato. Currently, the above-mentioned acreage comprises only MON 810 corn cultivation in Spain and Portugal. Along with the limited area and the restricted variety of plants, the number of states with transgenic plant cultivation is decreasing year by year (James 2012).¹ Czech and Slovak farmers stopped GMO farming in 2017, as they encountered serious problems with selling their crops. Currently, the register of transgenic plants approved as food and feed or for their production contains more than 60 varieties, mostly corn, cotton, oilseed rape, sugar beet and soy. It should be mentioned that these plants are not intended to be grown within the EU territory (ISAAA 2017). The negative attitude to GMO in the EU results from a number of factors, both exogenous and endogenous. Since the mid-1980s the European Communities have aimed at development of coherent norms regulating the technological progress and innovation, which has been motivated by the intention to create favourable conditions for the European companies competing with their counterparts from Japan or USA. One of the internal factors was the awareness of the European institutions that only the supranational regulation makes it possible to avoid atomisation of legal norms and creation of separate national regulatory systems, which would jeopardise the operation of the single market. In the 1990s, in some Member States the centre-left wing coalition governments were formed, presenting a sceptical attitude towards the development of agrobiotechnology, particularly GMO. As a result, four states announced moratoria on the release of new GMO varieties into the environment. Another internal factor is a crisis of public trust in the EU regulatory institutions, scientific circles and governments of Member States, as well as undermined effectiveness of legal regulations pertaining to risk management in food chain and food safety, which is a consequence of serious crises, including BSE epidemics in Great Britain, Germany and Belgium (Burns 2012: p. 349–352).

The legitimisation crisis, as well as significant politicisation of issues related to the development of modern agrobiotechnology, GMO popularisation and the operation of the green biotechnology product market in the EU, became the immanent feature of the Community legal regime in agrobiotechnology, developed since the beginning of the 1990s. A considerable challenge, both for the states and the supranational institutions, was to create a management model, which would be coherent in the vertical and horizontal aspects, due to the multi-sector character of agrobiotechnology, overlapping and frequent inseparability of issues, which were present in parallel in various sector policies (e.g. agriculture, environmental protection, research and development, industry, public health, consumer protection, trade, intellectual protection or competition policy), as well as a need for horizontal coordination of the policy, in which many different stakeholders were involved: public and private, from the subnational, national, transnational, supranational and supra-supranational levels. On the one hand, it was obvious that such complicated issues required unification of standards and harmonisation of laws, which could occur only in the supranational decision-making process. On the other hand, the

¹ For comparison, in 2012 GM plants were grown in Spain, Portugal, Czech Republic, Romania and Slovakia (see: James 2012).

interest of the general public, who questioned the legitimacy of GMO popularisation and doubted its safety, caused exceptional activity and involvement of Member States' governments whose representatives, in fear of electorate loss, abandoned the logic of Community interest to the benefit of particular national interests, or rather fulfilment of voters' expectations (Kritikos 2017: p. 2–4).

It was necessary to satisfy – certainly right – demands for establishment of an effective risk management system, which would cover the whole internal market of the EU and form a multi-level network of communicating vessels, defined by the European Commission as the “from farm to fork” system, but at the same time to introduce such regulations, which would not lead to hampering of the scientific and technological progress and loss of competitiveness of the European agrobiotechnology sector on the global market (Dederer 2016: p. 146).

Decision-making centre (decision makers)

The EU decision-making system can be defined as a transnational decision-making centre based on the principle of transferring a specified and equal part of sovereignty on an international organisation by each state participating in the integration process. Moreover, the EU can be described as a hybrid decision-making centre as it combines the features of an international and national centre, being neither a typical super-state, nor a standard intergovernmental organisation. In accordance with the system approach, the EU – as a transnational decision-making system – consists of subsystems, which perform a more or less active role in the decision-making process, depending on the integration area. This is also the case of the agrobiotechnological regime, in which (apart from the entities participating in the decision-making process and in the implementation phase of a political decision) defined in treaties and particularly in secondary legislation, it is possible to enumerate many other stakeholders having a direct or indirect impact on the operation of a decision-making centre, political decision and its implementation or lack of it. The agrobiotechnological regime is predominantly an area of competence shared between the EU and the Member States, hence it could be claimed that we are dealing here with a polycentric management model (McGinnis 2006) involving supranational, national and regional actors, which is especially pronounced as a consequence of the amendments to the EU law in the recent years. In this particular case we should not disregard the societies of particular Member States, which participate in the decision-making process indirectly by means of public consultations, but their opinions are taken into consideration by the Council.

Appropriate definition of a decision-making centre of the EU agrobiotechnological regime is a difficult task due to the number and diversity of entities participating in the decision-making circles. Moreover, this is a challenge in connection with the occurrence of such phenomena as: primary and secondary delegation of competence, functional and non-hierarchical dispersion of competence, lack of hierarchy in the relations between particular entities (one institution can fulfil the role of the principal, agent or super-

visor, based on the notions introduced by the PAT: principal-agent theory, or its variation – PSA: principal-supervisor-agent theory) (Delreux, Adriaensen 2017: p. 1–34), functional dispersion of executive powers, activity of entities lacking legislative powers within the regulatory space, emergence of new management forms and new actors along with them, e.g. management by experts, dispersion of governance processes onto public and private entities, which leads to the formation of so-called fuzzy sets and actors operating between management levels (e.g. supranational, national and subnational).

The division into the decision-making circles suggested by Z. J. Pietraś, in a version modified and adjusted to the specific features of the EU functioning, can be used to identify the subject-related scope of a decision-making centre. In accordance with the hierarchical stratification, we should distinguish the *supranational circle* comprising such treaty-based institutions as the European Commission, the European Parliament, the Court of Justice of the European Union, the European Court of Auditors and decentralised agencies, e.g. the European Food Safety Authority (EFSA), as well as executive agencies of the European Commission e.g. the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA). On the other hand, the *national circle* consists of 28 Member States with the government administration representing them. The *subnational circle* comprises regional and local authorities and any other cooperation forms, e.g. non-governmental organisations, lobbyists, regional and local business associations, which also advance the interests of their regions or local communities. The hierarchical stratification is complemented with dispersal stratification, which consists of two circles. The first one is the *intergovernmental circle*. In the discussed case it is represented primarily by the Council and comitology committees. The other is the *transnational circle* comprising non-state entities, including international enterprises, interest groups, professional social movements and trade organisations (Ruszkowski 2013: p. 19–60).

As emphasised by Z. J. Pietraś (2000), a decision-making centre is subject to the processes of professionalisation on the one hand and politicisation on the other hand. The former type of influence is characterised by the increased role of experts, lower involvement of civil society – described as the permissive consensus – and technocratisation of the decision-making process. The dominance of the latter process entails intensified activeness and role of politicians and the decreased role of experts. The EU policy in the area of agrobiotechnology, or specifically the use of GMO, is a hybrid of both types of influence. Similarly as in many other areas, where transaction costs are high, which is connected e.g. with a need to acquire specialist scientific and technical knowledge, it is possible to notice a tendency towards delegation of governance powers and their centralisation in the hands of a specially prepared institution. At the same time, the EU policy towards GMO use is strongly politicised, as a result of much higher interest of the general public contesting the legitimacy of GMO promotion in the EU. In these policy areas, where a conflict of values occurs, the space for technocratic management, based on expert knowledge, is shrinking to the benefit of political and civic deliberations, and the activity of the Member States and intergovernmental institutions representing them is growing (Blanke, Böttner 2016: p. 250).

The supranational circle of the decision-making centre of the political and legal GMO management system in the EU comprises primarily the European Commission as an institution with the legislative initiative rights and broad executive powers e.g. in the procedure of new GMO varieties registration (comitology procedure). Moreover, the European Commission supervises the progress of the EU law implementation and execution by the Member States and is entitled to lodge complaints with the Court of Justice of the European Union. The EU policy towards GMO is managed by the Directorate General for Health and Food Safety. Furthermore, the Commission is supported by the CHAFEA whose tasks include: implementation of coordination mechanisms for effective spending of EU funds, support for coherent implementation of the EU law in all the Member States, and supervision of the European training programmes aimed at promotion of knowledge about food quality standards. The Agency cooperates with General Directorates of the European Commission, as well as with many other entities from various EU management levels (Consumers, Health, Agriculture and Food Executive Agency 2020).

The other agency strictly associated with and being a part of the Community bureaucracy of the supranational range is the European Food Safety Authority (EFSA). This is a decentralised agency, established pursuant to the Regulation (EC) No 178/2002 of the European Parliament and the Council, the so-called *General Food Law*. In accordance with the PAT concept, Community agencies should contribute to the "functional decentralisation of tasks", owing to which it is possible to relieve such institutions as the Commission of a considerable part of duties and to provide impartial and evidence-based knowledge necessary in the law enactment process (Egeberg, Trondal 2017: p. 677–678). Some agencies originate from transnational networks of national agencies, other from supranational structures, such as advisory committees (Boeger, Corkin 2017: p. 976). The EFSA was established as the EU reaction to food crises (the outbreak of a scandal over BSE infections and dioxins), with a view to restoring trust in representatives of science and political decision-makers. The Agency's structure includes the GMO Panel. First and foremost, the EFSA cooperates closely with the European Commission, providing it with substantive knowledge necessary in the registration procedure of new GMO varieties, assessment and management of risk connected with GMO release into the environment, or giving advice to the Commission at the stage of drafting legal acts. In a situation, when draft legal acts largely concern technical issues, we can even talk about the role reversal and the Commission fulfilling the function of an authority rubber-stamping the draft prepared by the EFSA (Egeberg, Trondal 2017: p. 682). In addition, an element distinguishing EFSA among other agencies and testifying to its supranational character is the composition of the Agency's management board. As a rule, the Council, as an intergovernmental institution, tries to influence agencies' operations through representatives of the Member States sitting in the agencies' management boards. The exception is EFSA whose structure is primarily supposed to reflect the highest possible level of expert knowledge, and membership of the management board (14 places) has a rotational character (Saurer 2011). Both the growing number of Community agencies and their increasing significance in the decision-making process testifies to the supranationalisation of executive powers,

which (still belonging formally to the Commission) are exercised in practice by decentralised or executive agencies.

Detailed regulations concerning GMO release into the environment or its use as food or feed, stipulate that the European Commission, on its own initiative or at the motion of the European Parliament, the Council or a Member State, consults the European Group on Ethics in Science and New Technologies, which is appointed by the European Commission and its members are independent in their opinions (see: European Commission 2016a). While working on draft legal acts and exercising its executive powers, the European Commission is supported by expert groups formed on the initiative of the European Commission or its internal entities. Members of these groups are experts in a given area, representing both public and private sectors (see: European Commission 2016b), e.g. the Advisory Group on the Food Chain and Animal and Plant Health. Apart from the EFSA, the Commission consults the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) about the issues not connected with food.

Another institution belonging to the supranational circle is the European Parliament whose function in the legal and political system in the area of GMO management in the EU is performed through an ordinary legislative procedure and fulfilment of the co-legislator's role together with the Council. As one of the legislative institutions, the Parliament co-enacts law through issuing directives and regulations.

It is also worth mentioning the European Court of Auditors, which does not have any specific powers related to the discussed area, but those based on the general rules, defined in primary law regulations, similarly as in the case of other sector policies (TFEU: art. 285–287).

Furthermore, the circle of the supranational decision-making centre includes the Court of Justice of the European Union, which in the analysed case resolves complaints lodged by the European Commission against the Member States, which infringe EU laws, as well as entrepreneurs' complaints, answers prejudicial questions posed by national courts and settles disputes (Poli 2013: p.147–149).

The circle of the national decision-making centre consists of government administration representatives from 28 Member States and relevant public administration authorities whose competence includes specific actions connected with GMO management in a given state. Another circle comprises regional and local actors. Similarly as states, regions also become increasingly significant, which is associated with the process of renationalisation of competence with respect to enactment of law pertaining to GMO in the EU, introduced by the provisions of Directive (EU) 2015/412. The new regulation extended the list of reasons, on the basis of which a Member State or a region can apply for establishment of a GMO-free zone in its territory. Moreover, the new regulation has accelerated the development of such initiatives as the European GMO-Free Regions Network, which gathers 64 regions from various Member States (see: Tosun, Shikano 2016; European GMO-Free Regions Network W/W). This circle includes also other entities operating at the local or regional levels and supporting interests of these micro-communities. Non-governmental organisations and individual entrepreneurs also have

an influence on the shape of the decision-making process at the supranational level, because the directives and regulations concerning GMO provide for social consultations as a stage in the decision-making process. What is equally significant, both in the case of the procedure of obtaining a permit for trading, using or processing transgenic food or feed, and applying for a permit to release GMO into the environment, the applicant is a natural or legal person. Therefore, these entities should also be included in the circle of a subject-related decision-making centre.

The intergovernmental circle comprises the representatives of the Member States sitting in the Council and the Committee of Permanent Representatives COREPER, because the Council, along with the European Parliament, has law-making competence that is exercised through an ordinary legislative procedure. Moreover, this circle comprises also comitology committees, specifically the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) – the Section on Genetically Modified Food and Feed and Environmental Risk, and the Regulatory Committee (Directive 2001/18/EC).

The entities belonging to the transnational circle include: representatives of the biotechnological industry associated in the European technological platforms and cooperating with the European Commission through this formula, the European innovative partnerships, common technological initiatives, European business organisations, e.g. the European Association for Bioindustries (EuropaBio), or international non-governmental organisations, e.g. Greenpeace European Unit, Friends of the Earth Europe.

Decision-making process

The next category of the decision analysis is the decision-making process. The EU policy in the area of using genetically modified organisms or transgenic food and feed belongs to a group of shared competence, exercised by the EU institutions and Member States together. Basic legal acts are passed through an ordinary legislative procedure (TFEU: art. 289, 294).

In accordance with the Treaty provisions, the European Commission prepares a draft legal act or suggests amendments to the already binding provisions of the EU secondary law. At this stage, work goes on at the level of relevant internal structures of the European Commission, but the European Commission also consults and seeks opinions of experts and representatives of interest groups from the public and private sectors and the Member States themselves. The European Commission presents a draft legal act to the European Parliament and the Council, which jointly decide on accepting or rejecting the proposed regulation. Details and stages of an ordinary legislative procedure are specified in Article 294 of the TFEU. Provisions of directives and regulations are executed by the European Commission and the Member States. As a result of the decision of the European Parliament and the Council on granting the European Commission powers to issue executive acts, the committee procedure is applicable (TFEU: art. 291 sec. 3), based on the principle of the Member States' supervision of the European Commission's operation, through the Member States' representatives sitting in the comitology committees. Due

to the specific character and the purpose of applying comitology as a procedure used for enforcement of the existing EU laws, it will be discussed in more detail in the section devoted to implementation of political decisions. However, a reference will be made here to the Regulation (EU) No. 182/2011, which contains the legal basis of the committee procedure, and specifically to the amendments reforming the procedure, suggested by the Commission. This is an example of a decision-making process, in which the Commission initiates an amendment to an existing legal regulation, but we can also talk here about confrontation between the supranational and intergovernmental logic, where it is suggested that the latter ought to be reinforced. It should also be emphasised that one of the most important arguments, which prompted the Commission to take an action is the application of comitology in GMO-related areas.

In 2016 the European Commission initiated a debate on changes to comitology, as a result of negative experiences in using the committee procedure e.g. in such policies as GMO management, which is a consequence of controversy around this issue at the Member States' level. The reasons can also be sought in the specific character of the decision-making process at the supranational level, which lacks uniform coordination procedures, especially in these areas, where the objects of the regulation are multi-sector issues, which most frequently become the field of confrontation among sector priorities and interest of various entities (Kritikos 2018: p. 11).

The European Commission suggests four modifications to the procedure. Firstly, the voting rules in the final stage of the procedure ought to be changed (appeal committee), so that only "for" or "against" votes should be taken into account. Owing to this, it will be possible to limit the usage of abstention from voting, which – in the current version of the regulations – results in lack of a committee's opinion, and in consequence forces the European Commission to act (to issue executive regulations) without an explicit mandate from the Member States. Secondly, the European Commission proposes introduction of the second appeal to the appeal committee, which is supposed to consist of the Member States' representatives at the ministerial level, in a situation, when national experts are unable to issue an opinion during the first appeal phase. Thirdly, results of voting in the appeal committee should be made public, which would be a form of supervision of the national public over their representatives in the committee. In the fourth place, the European Commission calls for an increase in the intergovernmental component through a possibility to request an opinion from the Council, if the appeal committee is unable to issue it. Such solutions will enhance transparency of the decision-making process with the use of comitology and, most of all, will make the negotiation positions of particular states more visible to the public opinion and increase responsibility for the decisions taken (European Commission 2017a).

On the basis of an analysis of opinions expressed by stakeholders during the process of social consultations, which took place in February–April 2017 it can be concluded that the direction of changes was received with reserve or negatively. It may be affected by the fact that most opinions were given by the entities representing the agrobiotechnological business (10 opinions), and two by non-governmental organisations. Most of them are

critical opinions, which focus on the fact that the suggested changes can undermine the principle of certainty of the EU law, weaken the rule of scientific evidence as the basis for risk assessment of registered/non-registered GMO and undercut the principle of harmonisation of rules pertaining to the EU law execution. This is one of the most unconventional opinions: "In our opinion the proposal is – like the "Brexit" – a further step in the direction to abandon the ideas of a European Union. We strongly demand objective and science-based decisions on critical issues, we are not Trump-country. Therefore, as European citizens and scientists, we object", authored by a German NGO *Gesellschaft f. Pflanzenbiotechnologie* (see: European Commission 2017b).

Political decision

An effect of a decision-making process is the issue of a political decision, which is another category of the decision analysis. In the discussed case, we should mention, first of all: Directive 2001/18/EC, Regulation (EC) No. 1829/2003, Regulation (EC) No. 1830/2003, Directive (EU) 2015/412 and Regulation (EC) No. 178/2002. All the aforementioned documents are legally binding acts, with which the European legislator has created a multi-level GMO management system characterised by the co-existence of the intergovernmental and supranational logic components.

Decision implementation

The last phase, that is decision implementation, includes cooperation between Member States and the European Commission. As indicated above, the Commission fulfils obligations specified in relevant legal acts, by issuing executive regulations in the committee procedure. The Commission's participation in the phase of the EU law implementation is supposed to guarantee harmonisation of the ways, in which the EU legal norms are executed. Moreover, the Commission supports the Member States, fulfilling the coordinating and controlling role, e.g. through supervision of information exchange in the risk management system. Another active institution is the European Food Safety Authority, which evaluates risks associated with transgenic products in cooperation with its counterparts on the national level, whereas research is carried out by reference laboratories in the Member States. The applicants themselves (natural or legal persons) play an important role, as well, because they have a number of duties connected with execution of provisions contained in directives and regulations. An entity reporting a new GMO is obliged e.g. to evaluate product risk and enclose the results with the application. The analysis of Directive 2001/18/EC and Regulation (EC) No. 1829/2003 points to a multi-level system of the EU law implementation.

The amendments to the EU law with respect to the analysed issue, introduced since 2010, are another example of the hybrid character of this organisation, and specifically they constitute one of the few examples of de-Europeanisation or renationalisation of competence. As it has already been mentioned, the European legislator's intent was to

harmonize law and to formulate the uniform rules and procedures pertaining to GMO risk analysis and management, GMO farming or launch of GMO or transgenic food and feed onto the single market. With a view to achieving this goal, it was decided to introduce the supranational system of granting applications for new GMO admission, as well as evaluation and monitoring of GMO-associated risk. As an institution safeguarding the Community interests, the European Commission plays an active role, both as the author of draft legal acts of the general character, and as an entity issuing executive regulations in the committee procedure. The two legal acts (Directive 2001/18/EC and Regulation (EC) No. 1829/2003) provide the legal basis, which specifies the form of the GMO and transgenic food and feed management system in the EU and defines the roles of particular entities in the decision-making process and in the decision implementation phase.

Nevertheless, this decision-making model, optimal in theory and ensuring continuity and – most of all – harmonisation of new technology management systems, which is especially important for the proper functioning of the single European market, did not operate the way it was planned by its authors. It can be compared to a device operating on the basis of computer software, which in an exceptional situation, e.g. an error or a system fault, switches to the safe mode. The EU law in the area of GMO, transgenic food and feed management was implemented in the "safe mode" every time.

Both in Directive 2001/18/EC and in Regulation (EC) No. 1829/2003 the process of execution of the legal provisions contained therein is based on the committee procedure. In essence, the procedure itself is the exemplification of the EU hybrid character. Comitology is applied in these situations, when the European Commission is entrusted with executive powers, which is connected with the need to create "the uniform conditions for implementation of legally binding EU acts." The Commission is not completely autonomous in its actions due to the procedure of Member States' supervision how the Commission exercises its executive powers. Hence, it is an example of balancing and combining of the supranational and intergovernmental logic. The Member States use their supervisory powers through comitology committees consisting of their representatives. In the case of the committee procedure based on Directive 2001/18/EC this is the Regulatory Committee (Article 30), while in the Regulation (EC) No. 1829/2003 this is the Standing Committee on the Food Chain and Animal Health – its current name is the Standing Committee on Plants, Animals, Food and Feed (Article 35) and the appeal committee. In both legal acts, comitology is the basic decision-making procedure. However, analysing the process of the EU law implementation *sensu largo*, that is the process of political deliberation with the participation of numerous entities, and not considering it narrowly, only from the legal perspective, as an act of accepting a legal norm by a designated authority, we should remember that both Directive 2001/18/EC and Regulation (EC) No. 1829/2003 provide for the operation of other bodies and entities apart from the Commission. First of all, we should mention people and business entities applying for a permit to launch GMO or transgenic food or feed onto the market, relevant national authorities participating in the chain of verification of applications, risk analysis and control, cooperating in this area with the European Commission and the European Food Safety Authority, reference laboratories etc.

In both these regulatory packages, the committee procedure stipulates that, before enactment of an executive act, the European Commission seeks an opinion from a relevant committee, which takes a decision following a majority vote. The committee can back up the Commission's motion, reject it or not to give any opinion. As follows from the analysis of the voting results since the time the Regulation 1829/2003 came into effect, the PAFF Committee was able neither to back up the Commission's motion nor to reject it. In 2015 and 2016 the European Commission issued – without the Member States' mandate – 17 executive acts permitting the launch of e.g. GMO and other products and substances, equally controversial to the public opinion in the Member States, onto the EU market. Since 2004, that is from the time the ban on GMO farming was lifted in some EU regions or states, every voting within the committee procedure had a similar result. The only exceptions, which were admitted to the European market as a result of correctly performed comitology are: Amflora potato by BASF Crop Science for industrial use and MON 810 corn variety by Monsanto. As far as other 67 decisions are concerned, neither the Council (in the previous committee procedure formula), nor the appeal committee (in the currently binding procedure) achieved the qualified majority of votes required. It is also worth mentioning that the case of GMO and difficulties in reaching an agreement between the European Commission and representatives of states should be treated as a rare departure from a general rule that decisions are taken at the level of a reporting committee and are not transferred to an appeal committee. Due to the permanent lack of decision by states' representatives in committees, the decision-making process has been completely deprived of the intergovernmental component and has been taken over by the Commission's officials and the Community agencies (first of all EFSA) (Kritikos 2018: p. 180–183). As a result, the Commission's situation became uncomfortable, as – on the one hand – an institution, which (as it may seem) operates without political legitimisation of states, against views of some of them and ignoring the public opinion, and – on the other hand – as an organ, to which the states assigned the responsibility for taking politically unpopular decisions, that in fact is the states' duty. Therefore, we can talk here about a political non-decision. In a further stage of the procedure – when the European Commission requested the appeal committee to give an opinion – the scenario was similar every time, which led to a situation, when the Commission passed an executive act itself (see: European Commission 2015a).

It should be emphasised that an emerging tendency consisting in lack of decision at all levels of the comitology procedure is a significant deviation and is not a norm in other areas of Community policies.² This unusual situation led to legislative changes in the form of Directive (EU) 2015/412, which extends the scope of reasons for using the opt-out clause by the Member States and for introducing restrictions on GMO cultivation, or total/partial ban on GMO in their territories. Until that time it was possible to establish the

² According to the data of the European Commission, in 2015 out of a total number of 1726 opinions of comitology committees, 2 were negative and 36 voting sessions ended in failure to issue an opinion (2% of all cases). See: Commission Proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No. 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing power.

GMO-free areas only pursuant to an application based on scientific evidence confirming the risk connected with GMO cultivation/release to the environment.

The Member States, including: Austria, Hungary, Greece, Poland, France, Germany or Italy, unable to refer to the principle of change of circumstances and provide new scientific evidence to the Commission, confirming the risk associated with a given variety of GMO, argue that the basis for using the protective clause from Article 23 of Directive 2001/18/EC or emergency measures from Article 34 of the Regulation (EU) No. 1829/2003 is scientific uncertainty, which accompanies assessment of risk connected with new technological solutions. According to the governments of these states, this was a suitable basis for a lawful temporary restriction or a ban on using and/or selling a given GMO as a product or a product ingredient in their territories. Such an interpretation of the Directive provisions led to numerous cases of its execution with infringement of law. The justifications submitted by the states to the Commission were verified each time and evaluated by EFSA as not corroborated by the contemporary scientific knowledge. As a result of the actions taken by some states, including Poland, the Commission lodged complaints with the Court of Justice of the EU. On the basis of the arguments of the ethical and religious character, Poland introduced the legislation prohibiting free trade in sowing material of transgenic varieties and entry of GMOs into the national register of plant varieties. In the case of the Commission versus Poland, lodged with the Court of Justice in April 2008, the Commission claimed that Poland failed to comply with the obligations stemming from Directive 2001/18/EC. The decision of the Court in Case C-165/08 was unfavourable to Poland (see: Judgment of the Court 2009).

The provisions of Directive (EU) 2015/412 introduce a more flexible formula and a wider list of reasons that can be cited by the state or regional authorities wishing to prohibit transgenic plant cultivation. Restrictions or a ban on GMO cultivation on a part or the whole territory have to be compliant with the EU law, justified, proportional and non-discriminatory. This can refer to a GMO or GMO groups already approved on the basis of the provisions of Directive 2001/18/EC or Regulation (EC) No. 1829/2003 and those, for which a permit issue procedure is pending. The reasons for lodging an application include: goals of the environmental protection policy, landscape planning policy in urban and rural areas, land use, social and economic effects of cultivation, avoidance of GMO in other products, agricultural policy goals or reasons connected with the public policy (Article 26b).

According to the Commission's representatives, renationalisation of executive competence, introduced by this Directive, is aimed at enabling the Member States to decide, taking into account their domestic circumstances, not only social and political, but also geographical and biological determinants. At the same time, the rules of the procedure for issuing permits for cultivation of new GMO varieties have not been changed, similarly as the Community procedure of GMO risk analysis and control. In both cases, the decisive factor is scientific knowledge and verifiable results of research, on the basis of which the EFSA issues opinions.

Another stage of the legislative changes suggested by the European Commission is the introduction of a similar flexibility clause to the provisions of the Regulation (EC) No. 1829/2003. The Commission suggests that states should be able to decide about a re-

striction or a ban on using GMO and transgenic food/feed on a part or the whole of their territories. The restrictive measures can be adopted with respect to the food and feed already approved, hence the EU procedure of approving new products remains unchanged. It is equally important that suggested solution does not refer to transgenic products, which do not need to be labelled pursuant to the provisions of the Regulation (EC) No. 1829/2003; that is such products, in which a share of genetically modified material does not exceed 0.9% of a food or feed ingredient or if its presence is accidental or technically unavoidable (see: European Commission 2015b). A draft act amending the Regulation is currently debated in the European Parliament, where it is in the first reading phase.

The legal solutions proposed by the European Commission and reflected in Directive (EU) 2015/412 or the suggested amendments to the comitology procedure, still pending, are contrary to an opinion that the European Commission belongs to the category of institutions referred to as competence maximizer. Supporting the process of competence decentralisation and renationalisation in such a controversial area as the GMO launch on the single European market, the Commission rather applied a strategy of avoiding responsibility for socially unpopular decisions. The new regulations grant the Member States again the right to decide on GMO trade within their territories, but, what is more important, transfer responsibility for these decisions from supranational institutions onto state governments. A question arises about the scope and range of exercising the rights granted by Directive (EU) 2015/412 to the Member States, which will be largely dependent on profit and loss account (with respect to political, economic and social issues) carried out by the states.³ It should also be remembered that the states are free to choose how to transpose the Directive's regulations into the national laws. As a consequence, decisions about a restriction or a ban on GMO cultivation can be taken solely on the central level in some states, whereas in other countries the right to decide is granted also to the regional authorities. The states and their regions have an opportunity to decide *ex ante*, which consists in reporting an intention to restrict or prohibit cultivation of a specific GMO variety with respect to which the European application procedure has not begun yet. Another variant is to take such a decision *ex post*, which pertains to these GMO varieties, which have already undergone the application and registration process (Tosun, Hartung 2018: p. 804–807).

The situation can change with the introduction of the opt-out clause in the Regulation (EC) No. 1829/2003. Central or regional governments are hardly likely to decide on restricting or prohibiting trade in genetically modified feed, because this would have serious consequences for the animal breeding sector. Thus, the Member States will face a dilemma and will have to decide whether the economic interest or social interest is more important.

Conclusions

The aim of the article was to present the hybrid character of the European Union in the legal and political dimensions, as exemplified by the still evolving system of the

³ According to data of the European Commission, 19 states filed an application for restriction/ban on GMO cultivation in a part or the whole of their territories (see: European Commission 2018).

regulations pertaining to genetically modified organisms, especially transgenic plants. The analysis was carried out on the basis of the decision analysis category and divided into five parts: decision-making situation, decision-making centre, decision-making process, political decision, and decision implementation.

As a result of the analysis carried out, it has been confirmed that the European Union is an example of a hybrid international organisation, in which intergovernmental logic coexists with the supranational logic. This is visible in the specific features of the EU law, the institutional system and the division of powers between the EU and Member States. The EU is a special category of an international organisation in whose functioning and structure it is possible to find the elements typical for the traditional intergovernmental organisation, but also those, which can suggest an intention to transform it into a super-state (e.g. euro area management) or at least the dominance of the supranational governance component.

Nowadays, states and international organisations have to face a challenge of quickly advancing technological changes and of the legislative process always lagging behind. Thus, the selection of a regulatory regime concerning GMO as a case for analysis was not accidental. As it is known, each decision-making centre undertakes regulatory activity in response to a technological change, which constitutes an element of the process of adaptation to the changing reality. There are challenges connected with a need to confront the qualitatively new regulatory areas, the presence of an uncertainty factor, which accompanies innovation, as well as the attitude of public opinion – usually not having expert scientific knowledge – to advanced technological products. The European public opinion displays an ambiguous attitude to modern technology, from definite support for medical biotechnology to scepticism or hostility towards agricultural biotechnology, especially use of transgenic plants as food/for food production or as feed. This contributes to significant politicisation of the process of establishment of a legal regulation system in this area.

The decision-making centre is polycentric and comprises the entities representing intergovernmental logic (governments of the Member States, the Council, comitology committees), as well as supranational logic (Commission, European Parliament, the Court of Justice of the European Union, Community agencies). The image of a governance model in the discussed area is complemented by transnational level actors, e.g. enterprises, sector organisations and other interest groups. The hybridity of the decision-making process is connected with the treaty-based classification of sector policies in accordance with the competence division criterion. In this particular case this is the shared competence area, where the legislative powers are executed on a supranational level, in an ordinary law-making procedure, by the Council (intergovernmental component) with the European Parliament (supranational component, representation of citizens) at the request of the Commission (supranational component). Law implementation is another field, where the supranational logic (European Commission, Court of Justice of the EU) is combined with the intergovernmental logic (Member States with competent public administration bodies, comitology committees).

It should be emphasised that the EU hybridity – as exemplified by the GMO governance model – does not consist in balance between intergovernmental and supranational

components at all five levels of the decision-making system categories. On the contrary, the system undergoes continuous change under the influence of internal and external factors. Homeostasis of the system consists in balancing the intergovernmental and supranational logic competing with each other. On the one hand, the decision-making centre and process display features of professionalisation (management by experts, the Community procedure of GMO risk analysis and management based on scientific knowledge, technocratisation of the decision-making process), but on the other hand it is possible to observe their politicisation, as well (higher involvement of states in supervision of the decision-making process at the supranational level, comitology operating in the "safe mode", renationalisation of executive competence). The higher the dissent connected with the regulated issue, the more probable the dominance of intergovernmental logic and such phenomena as renationalisation or de-Europeanisation of competence. A question arises about the border, which sets out a critical moment of loss of homeostasis between the intergovernmental and supranational components. In this particular case, an indicator should be the calculation of transaction costs (including political accountability) for renationalisation of executive powers, which has already taken place on the basis of Directive (EU) 2015/412 and can be continued by amendment to the Regulation (EC) No. 1829/2003.

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