

THE ROLE OF DG SANTE IN THE ADOPTION OF VETERINARY LEGISLATION AND FOOD SAFETY

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ABSTRACT

The law-making process in the EU is a complex and sometimes very long process. Depending on the nature, scope of application and the type of the draft act, this process is a multistep one. It is implemented by the three institutions in the European Union (EU)- the Council, the European Commission (EC) and the European Parliament (EP), working in coordination. In operational line the law-making procedures carried out by DG SANTE within the margin of the internal consultation procedure (intra-SANCO consultation) and the inter-service consultation level (inter-service consultation) are discussed.

The work of the Standing Committee on Plants, Animals, Food and Feed (SCPAFF) is described in details. In addition, a mechanism of operation and interaction between the Council, the European Parliament and the Commission and three types of procedures for the adoption of primary legislation: the consultation procedure (consultation) cooperation (cooperation) and a co-decision or the ordinary legislative procedure (co-decision) has been analyzed.

Key words: European Union, primary and secondary legislation, food safety, legislative procedure.

Introduction

The EU law making process is a complex and sometimes very long process. It depends on the nature, scope of application and the type of draft acts and this process is a multistep one. The process is implemented by the three institutions of the European Union (EU) - the Council, the European Commission (EC) and the European Parliament (EP), working in coordination with each other. The EU institutions have competence in the field of law. It is not universal, but limited within the defined and permitted by the Member - States (MS) legislative competence.

Concerning the legislative competencies in the veterinary field (including animal health and welfare and food safety and quality) the EC is being supported by DG SANTE. In some cases, the views of stakeholders' organizations are taken also into account when the proposals for amendment of veterinary legislation are being prepared by experts. Examples how the social and public choices reflect the policy making in the veterinary field are given by Matt (2014), McInerney (2004), Garner (1993) [7, 8, 5].

Material and methods

For the purpose of the study we made a content analysis [9] of official documents from the EU legislation, concerning the procedures for the exercise of implementing powers conferred on the Commission and procedures in matters of food safety.

Results and discussion

European Union law consists of primary legislation - Treaties and secondary legislation - regulations, directives and decisions adopted by the Union institutions on the basis of the Treaties.

In the association with the Lisbon Treaty [6] only the Commission has the right to submit legislative proposals – draft acts (right of initiative), except where the treaties provide otherwise. It may also change or modify any its own proposal (Article 293, paragraph 2) [12].

The primary legislation is constantly relevant and covers treaties establishing the European Community and the European Union, the accession treaties of the new Member States and other treaties and protocols, bringing changes or complementary norms of Treaties. By its nature primary law is comparable to the constitutional law at national level. It regulates the fundamental principles and essential characteristics of the European Communities and, later on, of the European Union, the legislative procedures, the Union institutions and their competence. The adoption of the treaties themselves is a subject of the direct negotiations between the governments of the Member States, after which they are ratified in accordance with national procedures used in relation to international contracts (usually by national parliaments or by referendum).

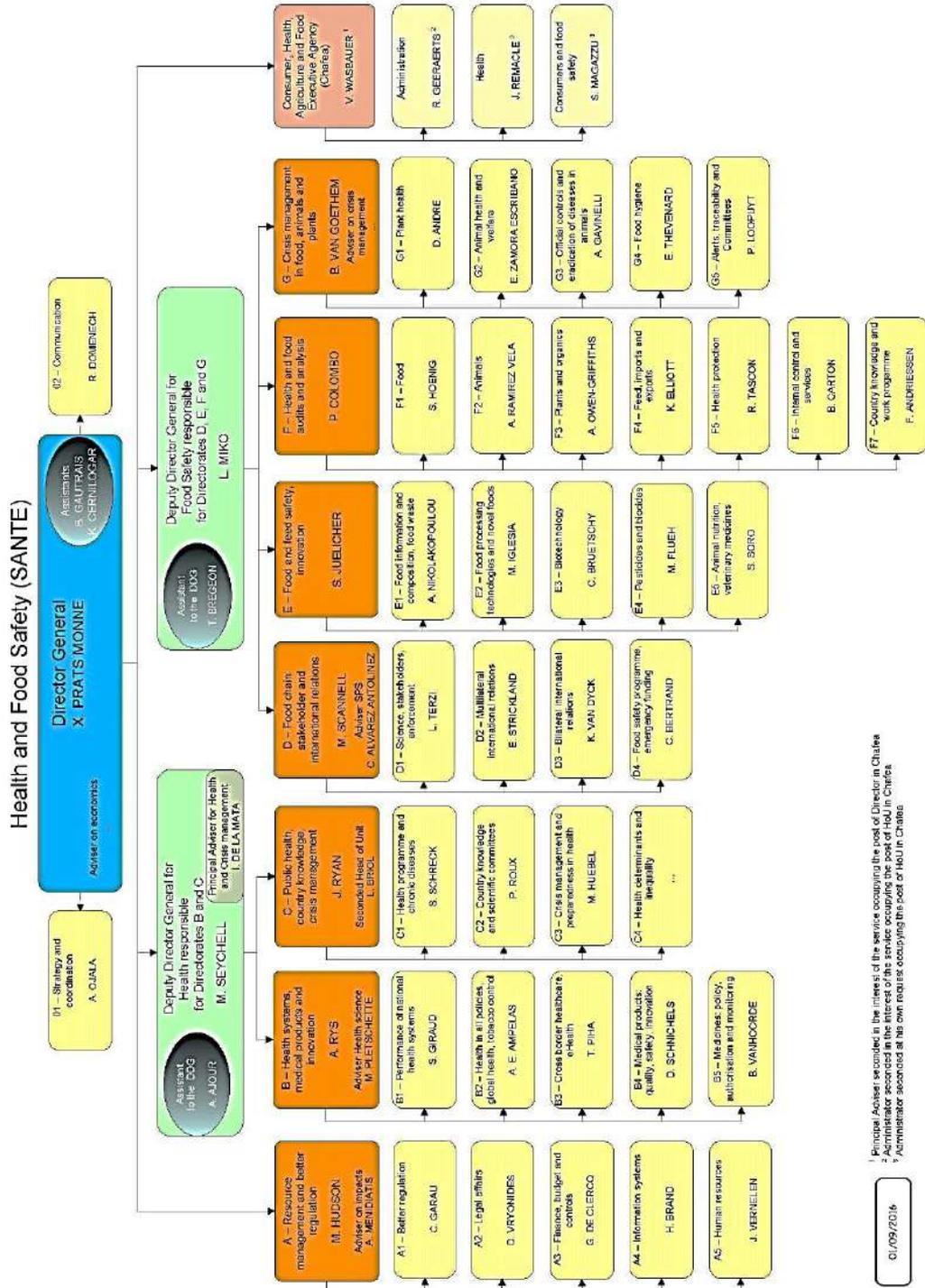
The secondary legislation is the second major source of Union law. It involves unilateral acts and agreements. Unilateral acts can be divided into two categories:

- mentioned in Art. 288 of TFEU [12]: regulation, directives, opinions and recommendations;
- not mentioned in Art. 288, so called non typical secondary legislation that includes the communications, white and greens books et cet.

The secondary legislation introduces the primary legislation where necessary and is therefore known as the implementing legislation. Most legislation adopted by Council and Parliament provide a legislative basis for the introduction of further legislation (secondary or supplementary legislation), which is prepared and adopted by the Commission. With its adoption, it certifies that the measures taken correspond to the particular circumstances or refer to the technical details and that their updating can be done as quickly as possible. The vast majority of EU legislation or secondary implementing legislation is made by the Commission.

The main mission of DG SANTE is to make Europe a healthier, safer place, where citizens can be confident that their interests are protected. A zero-risk society may not be possible but it is doing as much as it can to reduce and manage risks for the EU citizens.

DG SANTE is organized into seven directorates (Fig. 1) and has approximately 850 employees, 600 of whom are based in Brussels, 75 in Luxembourg and the other 175 in Ireland (Grange, County Meath).



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Figure 1: Structure and organization of DG SANTE.
 (Source: http://ec.europa.eu/dgs/health_food-safety/chart.pdf)

Directorate D „Veterinary Affairs and International Relations” consists of seven units that are relevant to veterinary legislation and food safety:

Unit 1 – Animal feed;

Unit 2 – Animal Health;

Unit 3 – Animal welfare;

Unit 4 – Food systems for rapid communication and training;

Unit 5 – Food Chain and spending in the veterinary field;

Unit 6 – Multilateral international relations;

Unit 7 – Bilateral international relations.

The main tasks of the directorate include:

- ensuring a high level of health protection and animal welfare, including the drafting of the legislation on animal by-products, and zootechnical standards;
- ensuring the free movement of feed / food and feed / food materials, rules on labeling requirements for hygiene, as well as registration and control of producers and traders of feed and food for animals;
- to oversee the application of the requirements for animal health and food safety in bilateral international agreements with third countries to which the EU is a party;
- to contribute to the rights and obligations of EU health and food safety included in multi-lateral international agreements, especially WTO and international standard-setting bodies - the OIE and Codex Alimentarius;
- Management of the Standing Committee on plants, animals, food and feed (PAFF Committee).

The proposals to amend the veterinary legislation in DG SANTE are prepared by the experts in the relevant departments of the Directorate “D”. If necessary, underservice groups of officials from other DGs, which are relevant to a given problem (DG Trade, DG Agriculture, etc.) are created. In some cases the views of stakeholders’ organizations (producers, NGOs) and the international organizations of the relevant committees and “ad hoc” panels, which include selected veterinary experts from some MS. With the creation of the European Medicines Agency (EMA) [4], the European Food Safety Authority (EFSA) [3] and the European Centre for Disease Prevention and Disease Control (ECDC) [2], recommendations of a scientific or technical nature given are also requested from these organizations. All proposals for legislation initially follow so called „road map“ and must be accompanied by an impact assessment and a detailed financial statement.

The next step in the legislative process is intra-SANTE consultation procedure, where the draft document is sent to all other departments of the Directorate for comments and observations. After gathering of the all reflections, the document is sent for inter-service consultation the other relevant Directorates General (mostly these are DG Agriculture, DG Trade) and the Commission's Legal Service.

The Commission is often empowered to implement EU legislation with the assistance of committees. It is done through the comitology process. The term „comitology“ refers to the way in which the Commission exercises its implementing powers conferred on it by the EU legislation by the support of the working groups called committees. The latest are composed of representatives from the EU Member States and chaired by the Commission staff.

Broadly speaking, before being able to perform a legal act of the EU, the Commission must consult the detailed implementing measures (known as “implementing acts“) offered by the committee. The Committee provides opinion on the Commission's proposed measures. This opinion may

be mandatory or optional for the Commission depending on the procedure referred to in the legal instrument applicable. A detailed description of the functioning of comitology is defined in the Regulation (EC) № 182/2011 [11] that lays down the rules and general principles concerning mechanisms for control by Member States on the exercise of implementing powers of the Commission. It defines two types of procedures. The choice of procedure for each committee is indicated by the EU legislator in the basic instrument depending on the type of implementing powers.

According to Article 3 of Regulation (EC) № 182/2011 [11], PAFF Committee is a regulatory committee which assists the European Commission in developing measures for food safety and veterinary issues. The Committee shall consist of representatives of the 28 Member States and observers from member countries of the EEA (Iceland, Liechtenstein and Norway) and Switzerland. The Committee is chaired by a representative of the European Commission (level department heads in the „D“). Its power covers the entire food chain including animal health and plant, animal welfare, animal feed and animal feed, food safety and animal products. Thereto the following sections are created:

- General food law;
- Biological safety of the food chain;
- Toxicological safety of the food chain;
- Controls and requirements on imports;
- Animal nutrition;
- Genetically modified food and feed and environmental risk;
- Health and welfare, plant protection products, plant health;
- Seedlings and ornamental plants seeds in agriculture;
- Horticulture and forestry, for variety testing;
- Wine.

Three sections of the committee - animal health and welfare, biological safety of the food chain and controls and requirements on imports cover a wide range of food safety and other veterinary issues so that decisions of the Commission are relevant for the implementation of veterinary measures. The Commission provides for the opinion of the committee all proposals of the secondary legislation. The Committee works in the following way:

The Chairman brings the draft of the implementing act, which is to be adopted by the Commission (it is included in the invitation and agenda for each meeting of the Section Committee). Except in duly justified cases, the Chairman shall convene a meeting not earlier than 14 days after the date of submission of the draft implementing act and the draft agenda of the committee. Within this period, the members of the committee have the opportunity to consider the proposed agenda and draft acts to express their views or to make a proposal for changes. Usually, the procedure is performed electronically. Until the committee delivers an opinion, any committee member may suggest amendments and the chair may present to all modified versions of the draft implementing act. In duly justified cases, the Chairman may obtain the committee's opinion by written procedure. Usually this is done in exceptional cases of implementing acts immediately applicable. The Chairman sends to the committee's members the draft implementing act and set a deadline for an opinion according to the urgency of the matter. For each committee member who does not oppose the draft implementing act or not explicitly abstain from voting before this deadline shall be deemed to have given his tacit agreement to the draft implementing act.

PAFF Committee adopts implementing legislation for two procedures: the examination and consultation procedure

The examination procedure applies in particular to adopt implementing acts of a general nature and other implementing acts, mainly related to programs with a significant impact on food safety, the common agricultural policy and the common fisheries, environment, security and safety or protection of health or safety of humans, animals or plants and common commercial policy. When the procedure applies, the committee shall deliver its opinion by the majority provided for in Article 16, paragraphs 4 and 5 of the Treaty on functioning of the European Union ⁽¹²⁾ and, where applicable, Article 238 paragraph 3 of the TFEU ⁽¹²⁾, for acts should be adopted on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in those articles.

The current system for reporting the votes in the SCFCAH is given in Table 1.

Table 1: Member States Votes in the SCFCAH.

Member States	Votes
France, Germany, Italy, United Kingdom	29
Poland, Spain	27
Romania	14
The Netherlands	13
Belgium, Czech Republic, Greece, Hungary, Portugal,	12
Austria, Sweden, Bulgaria	10
Denmark, Finland, Ireland, Lithuania, Slovak Republic, Croatia	7
Cyprus, Estonia, Latvia, Luxembourg, Slovenia	4
Malta	3

Qualified majority: 352 votes expressing the votes of 28 Member States

When the committee gives a favorable opinion (in favor), the Commission shall adopt implementing act. If the committee gives an unfavorable opinion (not in favor), the Commission does not adopt the draft implementing act. Where an implementing act is deemed necessary, the Chairman may either submit to the same committee an amended version of the draft within two months after giving an adverse opinion or within one month of such delivery to submit a draft implementing act in appeal committee for further discussion.

When there is no opinion (failure to deliver an opinion), the Commission may adopt the draft implementing act. If it does not accept the project implementation, the President may submit an amended version thereof. However, when it relates to the protection of health or safety of humans, animals or plants, the basic act provides that the draft implementing act cannot be adopted if it is not delivered, or a simple majority of committee members opposed the draft, then the Commission shall not adopt the implementing act.

The consultation procedure applies as a rule for the adoption of implementing acts not falling within the scope of the examination procedure. However, in duly justified cases, it can also be applied for the adoption of implementing acts in other procedures. Through it, the committee shall, where necessary, deliver its opinion by voting. If the committee votes, the opinion shall be adopted through the simple majority of its members. The Commission shall decide on the draft, which is to be adopted, taking into account the full extension of the conclusions of the discussions within the committee and of the opinion.

The PAFF Committee may adopt implementing acts in exceptional cases and implementing acts immediately applicable. Furthermore, the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC ⁽¹⁾ on comitology still apply in relation to all the main legal

instruments in which reference is made to this procedure. If the Commission is prevented from applying its proposed implementing measure (especially when the committee voted against it under the examination procedure), it may refer the case to the Appeal committee.

The Appeal Committee is composed of representatives of the Member States, chaired by the Commission's representative and has the same voting rules as other committees. It is not a permanent body, but rather a procedural tool that allows the Member States to hold a second discussion with representatives of the higher level. If the Appeal Committee votes against the Commission's proposed measure, the Commission must comply with this decision. When the Appeal Committee gives a favorable opinion, the Commission shall adopt the draft implementing act.

In the event that no opinion is delivered by the Appeals Committee, the Commission may adopt the draft implementing act.

Within the work of the PAFF Committee a Member State may delegate another right to represent it at meetings of the Committee, but a country may represent only one other Member State.

More information on the Standing Committee on animal health and the food chain, including the most recent reports and opinions can be found at:

http://ec.europa.eu/food/committees/regulatory/index_en.htm

Once the final text is finalized and the text is translated into the official languages of the EU, the draft act is published in the Official Journal of the European Union.

As for veterinary legislation to be approved within the context of Article 152 (public health) and Article 251 (procedures) of TFEU (¹²), the legislative procedure used is a co-decision procedure (co-decision). By applying its many legislative acts are entitled as "Regulation or Directive of the European Parliament and the Council", rather than just regulations and directives. It should be emphasized also that a large amount of primary legislation on food safety is adopted by this procedure, such as Regulation (EC) 178/2002/EC (¹⁰).

Summary of key legislation on food safety is available at the following link: http://europa.eu/legislation_summaries/food_safety/index_bg.htm.

In conclusion it can be said that the work in the EU law making structures is well organized with a view to achieving maximum effect process and making consensus decisions.

Conclusion

In conclusion it can be said that the work in the EU law making structures is well organized with a view to achieving maximum effective process and making consensus decisions. Finally, the most important point remains the implementation of legislation. Although there is a technically and legally appropriate legislative basis, which is correctly drafted and designed for long term, its effective and satisfactory implementation depends on several important factors. Among them we could point out the competencies and capacities of national Food Safety Agencies for execution of their enforcement duties, and the involvement of all stakeholders in the whole process of decision-making in order to be interested in the implementation of the adopted measures.

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