Strategic Transformation in Agriculture and Rural Space (STARS RAS)

Background Document

Food safety and Sanitary and Phytosanitary Policy in Croatia

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Introduction

1. Food safety (FS) and sanitary and phytosanitary (SPS) approaches in Croatia are harmonized with the EU policy framework and organized in compliance with the existing European and global standards. The main two bodies authorized for programs and activities in FS and SPS are the Ministry of Agriculture and the Ministry of Health. The legal background for establishment of the FS system is based on the so-called Hygienic Package consisting of:
   - Food law (Official Gazette: 81/13, 14/14),
   - Veterinary law (Official Gazette: 82/13, 148/13, 115/18),
   - Law on food hygiene and microbiological criteria (Official Gazette: 81/13),
   - Law on animal protection (Official Gazette 135/06, 37/13, 125/13),
   - Law on implementation on EU directive on animal protection (Official Gazette 125/13, 14/14, 92/14)
   - Law on official controls implemented in the area of food, feed, animal health and welfare (Official Gazette 81/13, 14/14, 56/15)
   - Law on veterinary medical products (Official Gazette 84/08, 56/13, 94/13, 15/15)

Main actors in the food safety system in Croatia

Food and Phytosanitary Policy Directorate (Ministry of Agriculture)
2. **Functions:** Plans, prepares and harmonizes regulations related to phytosanitary policy and phytosanitary controls, prepares and harmonizes legislation on food information to consumers; plans and harmonizes regulations on quality standards of certain food categories regulated at the EU level, methods of sampling and analysis for certain food categories; plans policies to reduce and prevent food waste.

**Veterinary and Food Safety Directorate (Ministry of Agriculture)**

3. **Functions:** Carries out tasks related to the animal health strategy, implements measures for early detection and prevention of occurrence, control, surveillance, monitoring, investigation of the emergence of animal diseases, including zoonoses, carries out tasks related to food safety and registration of the food business operators, organizes and conducts veterinary controls, including border control and managing of TRACES (Trade Control and Expert System) for controlling the import and export of live animals and animal products.

**Sanitary Inspection Directorate (Ministry of health)**

4. **Functions:** Performs inspection, statistical, administrative and other tasks related to supervision over the implementation of laws, other regulations and general acts in the field of sanitary supervision.

**Croatian Agency for Agriculture and Food**

5. **Functions:** The Agency is the national contact point of the European Food Safety Authority (EFSA) and ensures the exchange of information between the EFSA and national stakeholders. It is authorized to establish and coordinate the national network of institutions in the field of food and feed safety (Official Gazette 43/2010), develop and apply methodologies for risk assessment in the field of food and feed safety, cooperate with the institutes, academic community, laboratories and other legal entities in Croatia involved in the food safety system.

**Public Health Institute**

6. **Functions:** Perform activities on epidemiology of infectious diseases and chronic non-transmissible diseases, public health, health education with health promotion and disease prevention, microbiology, school medicine, mental health and prevention of addiction.

**Croatian Veterinary Institute**

7. **Functions:** The institute is responsible for monitoring and studying the epizootiology condition of infectious and other animal diseases and improving methods for their prevention, detection, monitoring and study of the occurrence and spread of infectious and other diseases,

**Food Control Center (FCC)**

8. **Functions:** FCC is an accredited laboratory for testing food and animal feed. It performs food and raw material testing when used in food production (chemical, microbiological, sensory testing), food quality checks in relation to legislation.

**Croatian Institute for Toxicology and Antidoping (CITA)**

9. **Functions:** The CITA is a public entity in charge of prevention of poisoning and other harmful effects of chemicals, including reducing the consequences of accidents involving hazardous chemicals.
EU context

Single Market Program of the EU

10. The protection of human, animal and plant health at every stage of the food production process is a key public health and economic priority of the European Union. For the new programming period, in June 2018 the EC adopted a legislative proposal for a new Single Market Program based on the proposed Multiannual Financial Framework for the period 2021-2027. The aim of the new program is to strengthen and rationalize the management of the EU's internal market. It will support business competitiveness and promote the health of humans, animals and plants, and secure agricultural and food supply chains, as well as finance European statistics to provide reliable data relevant to the single market. The proposal combines and simplifies a wide range of activities, including food safety, which were previously funded separately and linked to one program.

11. Under the new Single Market Program, funding will support safe food production, prevention and eradication of animal diseases and plant pests, and improve animal welfare in the EU. It will also promote access to the market for food producers from the EU, contribute to exports to non-EU countries and significantly support the agri-food industry as the leading EU economy sector. The Commission proposed a total budget for the food supply chain measures for the period 2021-2027 in the amount of EUR 1.68 billion. In addition, in line with more flexible and agile financial framework, food chain measures will be integrated into other budget priorities such as Horizon Europe, Digital Europe, Research, Innovation and Digital Policy. These instruments, like the European Social Fund Plus (ESF+), will also include health-related activities, such as antimicrobial resistance measures in the context of the One Health approach.

12. The new Single Market Program will focus and support in greater extent than before: i) Competitiveness of businesses, in particular SMEs: support given to small business to scale up and expand across borders; ii) Consumer protection; iii) A high level of human, animal and plant health; iv) Effective enforcement of standards; v) Fair competition in the digital age: IT tools and expertise that it uses to effectively enforce competition rules in the digital economy; vi) High quality European statistics

From cross compliance to conditionality

13. Based on the previous system of cross compliance\(^1\) to be applied by 2020, the new conditionality\(^2\) system connects the entire support for farmers with the requirement that users meet basic environmental, climate, public health, animal and plant health and animal welfare standards. The basic standards include, in a simplified form, the Statutory Management Requirements (SMR) and the standards of Good Agricultural and Environmental Conditions (GAEC)\(^3\) of land. In the new programming period 2021-2027, 12 SMRs will be applied (and

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\(^1\) In order to receive direct payments and some other forms of support, farmers are required to respect certain rules. This requirement is known as cross-compliance. These rules concern food safety, animal health, plant health, the climate, the environment, the protection of water resources, animal welfare and the condition in which farmland is maintained. There are two components of these rules: Statutory Management Requirements (SMR) and Good Agricultural and Environment Conditions (GAEC). If a farmer is found not to respect these rules, their direct payments may be reduced. For more information on the parameters of cross compliance: https://marswiki.jrc.ec.europa.eu/wikicap/index.php/Cross_Compliance

\(^2\) Direct payments (coupled and decoupled) will be conditional on the use of environment- and climate-friendly farming practices.

\(^3\) For more information on GAEC: https://marswiki.jrc.ec.europa.eu/wikicap/index.php/Good_Agricultural_and_Environmental_Conditions_(GAEC)
controlled by the Paying Agency), with two new ones to be introduced: in animal health and sustainable use of pesticides. The goal of the conditionality system is to raise the level of awareness of the users about the need to comply with these core standards and, thus, contribute to the development of sustainable agriculture. Member States should ensure that farmers who do not meet these conditions apply proportionate, effective and dissuasive penalties.

**Veterinary policy**

14. For the programming period EU 2021-2027 several important regulations will govern the veterinary sector, with implementation expected in the upcoming years:


15. In the programming period 2021-2027, it is expected that Croatia will be able to carry out a series of activities, that will be financed by the EC, including: i) emergency veterinary and phytosanitary measures in the event of outbreaks (animals and plants) or food crises (African swine fever, etc.); ii) improving animal welfare; iii) funding of reference laboratories in the field of food safety and animal health, in order to ensure high-quality diagnostic and uniform testing in all EU Member States; iv) implementation of coordinated control programs for the control and eradication of animal and plant diseases and pests; v) the prevention and reduction of food waste and the fight against food-related frauds, including raising of public awareness; vi) education of competent authorities of the CC responsible for the implementation of official controls and other stakeholders responsible for the prevention of animal or plant diseases.

**Phytosanitary policy**

16. The key elements of the phytosanitary policy include plant quarantine, damage prevention from organisms harmful to plants in general, safe use of plant protection products and harmonized approval of plant protection products. Two regulations govern the policy:

i) Directive 2000/29/EC, which regulated the plant health system was substituted by new Regulation 2016/2031 which will enter into force in December 2019. The Regulation aims at improving, strengthening and further harmonizing the plant health system and responding adequately to contemporary challenges.

ii) The area of plant protection products is regulated by Regulation 1107/2009, which will continue to be in effect throughout the programming period 2021-2027. The use of plant protection products is regulated by Directive 2009/128 EC, which is also presumed to remain in force through the programming period 2021-2027.
Croatian context

Food safety

17. Within the Ministry of Agriculture and the Ministry of Health, databases and registers of approved and registered food and feed business operators, as well as various records and registers in the field of live animals and phytosanitary areas, have been established.

18. The Ministry of Agriculture is part of the Rapid Alert System for Food and Feed (RASFF)\(^4\), developed at EU level as a key tool to ensure the flow of information enabling swift reaction when risks to public health are detected in the food supply chain. The National Contact Point (NKT) for RASFF in Croatia is the Veterinary and Food Safety Directorate of the Ministry of Agriculture. It manages and coordinates the RASFF in Croatia, ensures the immediate transfer of information between NKT, contact points in institutions involved in the RASFF, persons authorized to carry out official controls and sources of information through the RASFF. The Ministry of Agriculture, as the body responsible for the coordination of official controls in Croatia, is responsible for preparing national multi-annual plans of official controls and reporting. It is also responsible for the formulation of a crisis management plan for food and feed safety, as well as for the preparation of contingency plans in the event of the occurrence of animal and plant diseases or food crisis.

Risk management

19. The Ministries of Agriculture and Health are responsible for risk management, with annual monitoring plans in the areas of animal health, plant health and food safety being developed and adopted, with funding for their implementation. To achieve the required protection of human life and health, food safety regulations are based on risk analysis, including risk assessments, risk management and risk communication. Until January 1, 2019, the scientific risk assessment was organized under the responsibility of the Croatian Food Agency and the Plant Protection Institute (pesticide residues). Both institutions are now part of the newly formed Croatian Agency for Agriculture and Food.

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20. An integrated approach to food safety is achieved by a system with three levels of control: 1) The European Commission has an obligation to review the control systems of Member States and countries exporting to the EU and verifies whether they are efficient; 2) Member States or in the case of imports into the EU, the competent authorities of the exporting country in which the food business operates shall establish official control systems to check the effectiveness of self-control system, and 3) Food business operators and farmers are responsible for compliance with regulations and the establishment of a self-control system.

21. The European Food Safety Authority (EFSA) is responsible for EU level risk assessment and provides independent scientific advice on food-related risks. Member States at the national level establish their risk assessment bodies as Focal Points to EFSA. From January 1, 2019, the Croatian Food Agency (HAH in Croatian) was abolished as an independent body and joined the Croatian Center for Agriculture, Food and Rural Affairs, constituting a new risk assessment body for Croatia - the Croatian Agency for Agriculture and Food (HAPIH in Croatian). HAH became HAPIH’s Food Safety Center. The Agency is funded from the state budget\(^5\) and from fees for some services it provides to entities in the agri-food supply chain.

22. The State Inspectorate, adopted by law in December 2018 and operational on April 1, 2019, is an administrative entity that concentrates the control of food safety, plant and animal health and welfare into one institution. An advantage of this restructuring is the consolidation of risk assessment into one institution with qualified staff and laboratories, especially when dealing with residues of pesticides in food. A potential disadvantage can be temporary reduction of functionality given the time needed for establishment of fully functional processes under the new setting. Sources of funding could potentially influence the independence and transparency of the risk assessment process.

**Cross-compliance implementation**

23. Croatia has fully implemented the system of cross compliance for the 2013-2020 programming period. SMRs for animal identification and registration have been applied since 2015, SMRs for food safety, animal diseases and plant protection products have been applied since 2016, while animal welfare SMRs began in 2018. The Agency for Payments in Agriculture, Fisheries and Rural Development is responsible for the administration and control of cross-compliance in the field. A field inspection report is used for verification of cross-compliance, with inspections carried out by certified inspectors of the Ministry of Agriculture.

24. Regarding the proposed new conditionality system for the new programming period 2021-2027 and two new SMRs related to animal health and the sustainable use of pesticides, the

\(^5\) At the time of writing this paper, it was not clear what the operating budget for this Agency is.
agricultural sector in Croatia should be able to easily internalize and implement them since these requirements already exist in regulatory acts.

**Veterinary policy**

25. National legislation in the field of veterinary and food safety is based on the European framework. By adopting a new EU legislation, whose application is expected to start in early 2020, as well as specific measures planned to be introduced at the EU level, the challenge for Croatia would be to maintain and improve its national systems for meeting the high EU standards in the field of animal health and food safety.

26. The Veterinary and Food Safety Directorate veterinary service of Croatia is currently organized in a pyramid structure, as in most veterinary services globally. The chief veterinary officer (CVO) is the head of the service with central part and the base of the pyramid being the system of laboratory diagnostics and analytics and private veterinary organizations (clinics) with various forms of veterinary activity. This hierarchical structure is being modified with the creation of the State Inspectorate, a new, independent body that among other functions will undertake veterinary inspection. This may also bring about changes in the oversight over registers, such as the register of domestic animals (cattle, sheep, goats, dogs), with the Veterinary and Food Safety Directorate no longer being responsible for the identification and registration of animals.

**Information Systems**

27. Each Member State has the obligation to ensure the management of the various data and records required by veterinary legislation. For that purpose, the Central Veterinary Information System was established in 2013 by the Veterinary Act (Official Gazette No. 81/13) as a unified system of registers and information regarding animal health and welfare and the implementation of veterinary public health measures. The System is still not fully functional, with some of the envisaged units still not developed, and big part of the data, that Croatia is obliged to collect and provide to the EU, is still handled “manually” in MS Word and Excel.

28. Implementation and monitoring of veterinary and food safety measures by each Member State requires substantial financial resources. An upgraded IT system that enables the effective control of financial resources will enable the tracking and planning of the funds spent and funds planned for the implementation of all veterinary and food safety measures. Moreover, certain activities and programs are co-financed by the EC. The possibility of co-financing is realized only after Croatia has implemented a program, invests its own funds in its realization and after submission to the EC of a detailed report (technical and financial) on the results achieved by the program. Thus, establishing of the fully functional electronic system for data collection and monitoring the expenditure of financial resources would significantly improve the process of refunding by the EC.

**Antimicrobial resistance**

29. Through the newly adopted Regulation on veterinary medical products and Regulation on medicated feed, Member States are obliged to continue being proactive in reducing antimicrobial resistance (AMR), which is directly linked to the quantities of use of veterinary medicinal products (VMP). Globally, the appearance of resistant microbes, due to excessive use of antibiotics in the treatment of animals, as well as its use as a growth promoter in animals for food production is significantly increasing. Continuous discovery and introduction in the application of new antimicrobial agents have led to a constant change of bacteria by producing
genotypic and phenotypic resistance strains to certain antimicrobial agents. Therefore, it is important that the Croatian veterinary service continues with the improvement of the system of monitoring of the quantity and type of VMP used on annual base. Adequately collected data on quantity and type of VMP used could serve as a tool for planning of future activities that will reduce the use of VMP in breeding of domestic animal and accordingly influence on the reduction of AMR.

**Phytosanitary policy**

30. The main challenges that Croatia faces in phytosanitary policy are similar to those in other EU countries. Global trade increases the risk of introducing harmful organisms into new areas. Climate change makes it even more possible. Entering, spreading and damage from harmful organisms is steadily increasing in Croatia, as well as in other EU countries, which endangers the safety of agricultural production, the stability of yields, and threatens farmers, especially the small ones. Modern plant quarantine mechanisms increasingly appear to be ineffective in preventing the introduction and spread of foreign harmful organisms. The level of phytosanitary control in different EU countries is different and achieving harmonization remains a challenge.

31. The use of plant protection products needs to be rationalized according to the principles of sustainable use of pesticides. At the same time the standards of market quality of agricultural products are prescribed, which are not easily achieved without the intensive use of agrochemicals. More stringent requirements for the approval of active substances and plant protection products affect the development of the European chemical industry. Despite the common legislative framework, harmonization on the common market for plant protection products in the EU has not yet been achieved. Evaluation and approval of plant protection products is still significantly different between countries.

32. Croatia has the necessary infrastructure capacities and started exploring opportunities for co-financing phytosanitary measures by the EU, investing in human resources development, correctly detecting certain problems, and improving the system of official controls related to plant health and plant protection products. However, according to available information, national implementation of phytosanitary policy has sometimes been marked by the lack of evaluation of the effects of certain measures, inadequate staffing, lack of communication between stakeholders linked to phytosanitary policy and insufficient participation in EU bodies. Going forward, the phytosanitary policy of Croatia can benefit from past experience and focus on eliminating the shortcomings, further improvement of the elements of the system that proved effective and strengthened communication between competent national bodies and agricultural producers.

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6 With change in temperature, humidity and other related conditions, new organisms can appear in the areas where they are not usually noticed.
## Summary

### Strengths

- Established Integrated Food Safety system and Official Control is in compliance with EU requirements
- Long-term experience in the field of independent, scientific risk assessment
- Fully implemented system of cross-compliance with beneficiaries of support under the CAP 2014 – 2020
- Many years of experience in preparing a monitoring program in the field of food safety, veterinary and phytosanitary policy
- Educated and experienced staff in the implementation of plant protection products
- Secured funds in the state budget for oversight and official control
- Good functioning of the RASFF system in Croatia
- Good coordination of official controls and cooperation between the authorities responsible for legislation and food safety policy
- Good coordination of the competent bodies (within control and inspection) for the implementation of all measures for protection of human and animal health
- Developed laboratory infrastructure and capacities

### Weaknesses

- Insufficient number of IT specialists to help upgrade existing or future required databases and their connectivity
- Slow decision-making
- Lack of results evaluation
- Average age and educational level of farmers
- Slow introduction of modern technologies
- Less experience in EU (youngest MS)
- Variety of climates suitable for the establishment of harmful organisms
- Insufficient knowledge of farmers on future conditionality requirements (new SMRs in the area of animal health and sustainable use of pesticides)

### Opportunities

- Integration of risk assessment process in the new body (HAPIH) into a separate organizational unit - Food Safety Center
- There is no barrier to free trade and trade in live animals and food of animal origin
- Strengthen inter-institutional cooperation for minimizing food-related frauds
- Strengthen cooperation with other EU countries
- Develop digital technologies for food safety and SPS
- Decentralize functions and funding
- Improve transparency and efficiency in decision-making
- Safeguard natural resources (soil, water and forests)

### Threats

- Departure of educated and experienced staff from the system due to restructuring of ministries and agencies
- Weak coordination of official controls due to adaptation period after upcoming changes
- Reduction of the effectiveness of the existing risk management system in the area of food safety, veterinary and phytosanitary policy because of adaptation to upcoming changes
- Inability to recruit additional staff in state administration (with particular emphasis on IT experts)
- Inadequate financial resources from the state budget for the future development of the services
- Increased pressure of harmful organisms in plant production and emerging diseases
- Climate change
- Increased risks from global trade
- Borders with third countries
- Depopulation
Questions for strategic vision and potential actions?

- **How can the functionality of the existing Central Veterinary Information System (SVIS) and Phytosanitary Information System (FIS) be improved?** This includes the use of existing software programs - epidemiological, registration, networking with other institutions, establishment of an electronic system for collecting, exchanging and processing data as monitoring and control, residual Veterinary Medicine Products, monitoring and controlling expenditure of financial resources for all services that are paid from the state budget.

- **Can a system for food safety control at the market level be improved?** Specifically, through the implementation of mandatory monitoring programs by the competent authority (Ministry of Agriculture - Veterinary and Food Safety Directorate) and through the registration of food business operators who sell food via internet.

- **Can and should administrative capacity in the field of biomedical, biotechnical sciences and food biotechnology be strengthened?** Organizational units responsible for the implementation of food safety policy within the Ministry of Agriculture require an adequate number of experts, competent and motivated staff with experience and skills.

- **Is more IT capacity required for the development of information systems?** Only provision of adequate conditions for civil servants in the IT industry can motivate IT professionals to take part in the civil service and participate in the digitization of Croatia’s agriculture by applying specific knowledge and IT skills.

- **How could linkages with relevant EU institutions be strengthened?** It is advisable to invest in educating the employees of the Ministry of Agriculture, to provide a suitable budget for participation on the meetings in EU institutions, as well as to clearly assign the duties, tasks and responsibilities of staff responsible for representing or representing Croatia in EU bodies.

- **Is there space for increase of funds for urgent measures?** Emergency measures imply sudden and often unpredictable situations

- **Is it possible to enable all manuals, standard procedures, brochures and novelties related to food safety policy to be available on the web site, in one place?**

- **Is there a need for investment in the development, equipment and human resources of the Croatian Agency for Agriculture and Food (HAPIH)?** HAPIH needs sufficient number of professional staff involved in the implementation of phytosanitary activities, such as evaluation of plant protection products, monitoring of harmful organisms or laboratory analysis of plant material.

- **Should the system of control of quarantine of harmful organisms in Croatia be upgraded?** The monitoring should be aimed at preventing potential damage to agriculture, but also to support the competitiveness of domestic producers of seed, planting material or other crops, plant and plant products exporters or market-oriented producers’ associations.

- **Can the system for evaluation and registration of plant protection products be improved?** Sufficient number of evaluators from all areas need to be provided, which is important to support and invest in risk evaluation agencies, such as the Croatian Agricultural and Food Agency.

- **Can the monitoring program for pesticide residues in food be improved?** With increase in the number of plant products imported from third countries and the increase in the number of plant products produced within the organic production, effective control of plant products coming from third countries can contribute to competitiveness of domestic agriculture.