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# **Food Safety and Public Health situations in the Former Yugoslav Republic of Macedonia**

**Note**

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## EXECUTIVE SUMMARY

The FYROM Government has been given a list of short-term and mid-term priorities to be completed in the coming years, as part of the pre-Accession phase towards ultimate EU membership. This short report gives an insight into the progress being made on these priorities in the areas of Public Health and Food Safety

In relation to **food safety and veterinary issues**, while there has been considerable progress made in aligning FYROM's laws with the food safety obligations contained in EU Regulation 178/2002 and the 'Hygiene' package, there are considerable difficulties regarding the enforcement of this legislation in the country. HACCP<sup>1</sup> certification is only implemented in a limited number of establishments and is not mandatory for the domestic market which is a major failing of the Government's legislation. Legislation in relation to veterinary border controls still needs to be fully implemented and this will affect the ability of the Veterinary Directorate to deal with an EU-wide/Balkan-wide food crisis

In relation to **phytosanitary issues** the EU Regulations on plant protection products have been transposed but more needs to be done in order for the legislation to be fully enforced.

Despite considerable financial support from the EU and international organisations [UNDP, WHO, OIE and FAO], it is still very difficult to ascertain whether the FYROM Government is capable of dealing with an **avian flu and human influenza** outbreak in the near future.

**Laboratories** for the food safety, veterinary and phytosanitary fields need to be enhanced and strengthened in order to be able to deal with border control checks, food safety inspections, monitoring of foodborne diseases and an EU-style plant protection regime.

With regard to **Health Policy** the FYROM Government has aligned many laws with the EU *acquis communautaire* and initiated a major restructuring of the public health institutions.

The Government has adopted a **National Strategy for HIV/AIDS 2007-2011**, following on from a previous three-year programme. Although HIV prevalence has remained low in FYROM, the Government Strategy is targeted at the most-at-risk populations – injecting drug users, sex workers and prisoners.

The Government has published an **Action Plan on Food and Nutrition** which includes initiatives on breastfeeding, the reduction of micronutrient deficiency and elimination of iodine deficiency.

Finally, with regard to **mental health**, the Government adopted a Mental Health Strategy in 2007. The Strategy has established a number of community mental health centres and initiatives throughout the country, but progress is still slow in reforming this sector due to a lack of trained staff and financial resources.

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<sup>1</sup> HACCP (Hazard Analysis and Critical Control Points)

## **1. Food and Food Safety**

### ***Competent authorities***

With respect to foodstuffs, the competent authorities are the Ministry of Health and the Ministry of Agriculture, Forestry and Water Economy. Within these ministries there are bodies supervising the application of national regulations regarding specific issues related to foodstuffs:

- the Ministry of Health – Food Directorate;
- the Ministry of Agriculture – the Veterinary Directorate, the Plant Protection Administration and the State Agriculture Inspectorate; and
- the Laboratories – Faculty of Veterinary Medicine (Skopje); Public Health Institute Laboratories (with network of 10 regional laboratories); State Phytosanitary Laboratories.

### ***General Food Safety Obligations***

In the Former Yugoslav Republic of Macedonia [FYROM], food safety is regulated according to two major pieces of legislation:

1. Food Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs (2002)
2. Amendment Law to the Law on Safety of Foodstuffs, and Products and Materials in Contact with Foodstuffs (2007)

Both these laws, in particular the Amendments Law, transpose the main food safety obligations contained in Regulation (EC) 178/2002 of the European Parliament and of the Council on General Principles of European Food Law, establishing the EFSA and re-orientating the Rapid Alert System (RASFF). In that case, for the first time in the country obligations throughout the food chain *'from farm to fork'* to produce safe food as well as to have traceability systems are in place. Equally, the obligations on the FYROM authorities have been clarified in relation to their role to ensure food safety, consumer protection, instigate food inspections, prosecute persons and participate in the RASFF. This Amendment Law was published in conjunction with a National Food Safety Strategy (2007) following-on from a previous Strategy document published in conjunction with the 2002 Food Law. The new Strategy emphasis is on aligning FYROM's food safety laws and especially its food control system with EU norms.

### ***Codex Commission***

The Codex Commission was established in 2004 under the 2002 Law on Food Safety. The Minister of Health established the Commission, as an advisory body, consisting of representatives of the Ministry of Health, Ministry of Agriculture, Ministry of Economy and Ministry of Environment and Urban Planning, as well as renowned academics, experts and representatives of consumers' organisations. The Commission reviews the issues governed by FYROM's membership of the *Codex Alimentarius*, the methods of food analysis based on international scientific standards and advises on these matters in line with international practice while taking into account the specific requirements of the country.

### ***Co-operation with EFSA***

The FYROM Food Law 2002 and Amendments Law 2007 do not cover those parts of Regulation 178/2002 dealing with the accession to the European Food Safety Authority (EFSA) and the committee rules of the Standing Committee on the Food Chain and Animal Health (SCFCAH) consisting of Member State government officials. In this context, under the Instrument for Pre-Accession (IPA), the EFSA is implementing an action programme “*Preparatory Measures for the Participation of the Former Yugoslav Republic of Macedonia, Croatia and Turkey in EFSA*”, financed by the European Commission. The objectives of this programme are:

- to prepare the competent bodies in beneficiary countries active in the fields relevant to the work of EFSA, the European Commission and Member States for their future participation in EFSA networks;
- to help create communication and information exchange systems that will enable future participation of the three candidate countries in EFSA networks;
- to transfer knowledge on methodologies used in the fields within the remit of EFSA, in particular on risk assessment and data collection; and
- to support the beneficiary countries in their communication activities linked to risk assessment.

In 2008, the emphasis is on in-depth workshops and seminars in the various areas of EFSA’s expertise. The aim is to enable competent authorities in beneficiary countries to better understand the basic elements of the EU food safety system and gain insight into the work of EFSA in order to integrate efficiently into its activities post-accession. Macedonia is benefiting from this programme for the first time. The seminars cover the following subjects: Bovine Spongiform Encephalopathy (BSE) and other Transmissible spongiform encephalopathy (TSEs); EFSA Advisory Forum and Management Board; Handling a Food Crisis; GMOs; EU Institutions and Food Safety; Microbial Risk Assessment.

### ***Food Safety Laws***

The FYROM Government has adopted laws on flavourings, fortified food, foods for particular nutritional uses, ionising radiation and quick-frozen foodstuffs. The Food Directorate though has not yet established registers for fortified food, food for particular nutritional uses, food additives and mineral waters. In the area of food hygiene a Rulebook has been adopted covering foodstuffs not of animal origin in the marketplace in line with Regulation (EC) 852/2004.

Legislation on food contact materials, food supplements, and implementing legislation on novel foods and GMOs has not yet been adopted.

The Food Safety Directorate established in 2005 has three departments:

- Food Standards including quality assurance;
- Inspections [with units in Skopje, Tetovo, Bitola, Stip, Strumica]; and
- Risk analysis – risk assessment, communication, international issues.

A new organisational structure has been introduced in 2007, with two new units for consumer protection and for administrative and legal issues in the Food Standards Department. It is difficult at present to ascertain whether these changes are sufficient to ensure that the Food Directorate is capable of dealing with a major food crisis.

## *Veterinary Issues*

The FYROM Government has adopted a Law on Veterinary Health which details the functions of the Veterinary Directorate at the Ministry of Agriculture in relation to food safety, in particular the very important issue of food hygiene. It sets the framework for five other specific laws:

1. Veterinary Public Health (meat, milk & other products of animal origin);
2. Feeding stuffs and animal nutrition;
3. Animal Welfare;
4. Animal waste/animal by-products; and
5. Veterinary Medicines.

The first of these areas is the most important for food safety issues as it covers all the EU rules contained within the Hygiene Package in particular Regulations (EC) 853/2004 and 854/2004 covering food products of animal origin. The Veterinary Directorate has also prepared rules on *control systems in the internal market* and on *control systems for imports* in line with Regulation 882/2002. Legislation on veterinary border controls whilst it has been adopted still needs to be fully implemented and the slowness is due to administrative/financial issues. Lastly, with regard to legislation on the identification and registration of animals, this has been completed in relation to goats and sheep but there are delays with other animals including bovines.

In the food hygiene area specifically – while rules have been adopted covering most aspects of the Hygiene Package [Regulations (EC) 852/2004, 853/2004, 854/2004 and 882/2004] there are major problems in relation to their implementation. A Government aid scheme for Hazard Analysis and Critical Control Point (HACCP) certification for exported products was effective in 2006 and 2007. HACCP certification is only implemented in a limited number of establishments. It is not mandatory for the domestic market which is a major failing of the Government rules adopted to implement the Hygiene package. The Government has promised to establish a strategy for enhanced implementation of the HACCP system from 2009. The country still does not have a programme for upgrading food-processing establishments to meet EU requirements. Allied to this are the difficulties already mentioned in relation to the capacity of the Food Directorate to deal with a food safety crisis.

The EU funded a programme between April 2007-April 2008 “*Improving Food Quality and Safety*” [464,000€]. The project included support for the enforcement of the EU acquis-compliant legislation in this area, raising awareness of officials and producer organisations on the EU food hygiene package, improving the skills of personnel in the institutions and ensuring compatibility of operations of the Food Directorate of the Ministry of Health and the Veterinary Directorate of the Ministry of Agriculture. The project has provided inspectors, managers, laboratory personnel and food business operators with valuable information about the legal basis and practical implementation of food safety controls based on the EU norms. Thirteen training courses were conducted with 206 persons attending the programme. Further assistance should be given to the FYROM authorities to assist in implementing adequate food safety controls throughout the food chain, rather than simply assisting in writing laws and aligning with the EU *acquis communautaire*.

### ***Phytosanitary policy***

The EU Regulations on plant health (harmful organisms), plant protection products and quality of seeds and propagating material have been partially transposed in primary legislation and in some implementing legislation. FYROM has a monitoring programme for surveillance of seed and seed materials. The registers of operators and plant protection products have not yet been established. It is difficult to ascertain whether the Phytosanitary Directorate has sufficient capabilities to enforce an EU-plant protection regime. The laboratory capacity of the State Phytosanitary Laboratory needs to be enhanced, especially in order to deal with border control checks and to be in line with EU norms.

### ***Conclusions – Food Safety, Veterinary and Phytosanitary Issues***

Although much has been done in relation to transposition of legislation, more needs to be done to enhance the capacity of both the Veterinary and Food Directorates to enforce the obligations throughout the food chain contained in Regulation (EC) 178/2002 and in particular the Hygiene Package. Equally, more work needs to be done in relation to the enforcement of an EU-style regime for plant protection products, which is crucial to food safety and consumer protection. Lastly, considerable work needs to be done to ensure that the various food safety laboratories are brought up to ISO standards and that they have sufficient resources to complete the work necessitated by an EU-style food safety regime.



## 2. Avian Flu

In October 2005, there were concerns that an outbreak of avian flu had emerged in FYROM. The Government was advised to be ever-vigilant following outbreaks of avian flu in Greece, Bulgaria, Italy and Slovenia. The Veterinary Directorate of the Ministry of Agriculture informed the FAO and EU authorities that they had dispatched teams throughout the country equipped with the necessary diagnostic kits to take samples from domestic and wild birds.

Later in the month many birds died near the city of Bitola and as a precautionary measure the Government ordered the killing of all poultry in a 2km radius of the village Orovcanec, near Bitola. Approximately 10,000 birds were killed. Other incidents of dead birds were notified but the Government stated that they were not cases of bird flu. Some commentators believed that the Government's response was too slow and that the 1M€ allocated for the defence against avian flu was inadequate. Samples were sent for testing at the European Union Reference Laboratory in Weybridge, England, but were found to be negative.

The Veterinary Directorate at the Ministry of Agriculture subsequently adopted general measures for the control of avian flu to deal with the scenario of an outbreak of the disease in FYROM. In 2006, the UN funded the establishment of an Avian Influenza Theme Group which developed a contingency plan for Avian Influenza and a Human pandemic. The Theme Group also prepared a UN contingency plan and implemented a Public Awareness Campaign and provided training for medical workers. Presently, the UNDP has established a programme to assist avian flu preparedness in Bosnia Herzegovina, FYROM and Ukraine.

The United Nations Pandemic Influenza Contingency (PIC), places FYROM in the same division as its neighbours Serbia and Bulgaria in terms of planning, coordination, communications and its national preparedness plan, which are all important parts of the international guidelines suggested by the UN, WHO, OIE<sup>1</sup> and FAO.

Despite this, it is very difficult to ascertain whether the FYROM Government would be truly capable of dealing with an avian flu and human influenza outbreak in the near future.

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<sup>1</sup> OIE, World Organisation for Animal Health

### **3. Health Policy**

#### ***Competent Authorities***

The Ministry of Health is responsible for the national health care system; the Health Insurance Fund (HIF) coordinates health insurance for the population; and the Ministry of Finance sets the budget for the Ministry of Health's vertical 'public health' programmes. The Macedonian Chamber of Physicians is responsible for the licensing of medical doctors. FYROM has one central Health Protection Institute and 10 regional bodies charged with collecting health statistics. The findings of these agencies are collected and published in the annual "Health Map" for the country. The health insurance coverage rate in FYROM is close to 100%, while the number of private patients is low.

#### ***Health Policy Laws***

The FYROM Government has adopted new amended laws on healthcare, patients' rights and health insurance in order to improve the quality of health services, and increase transparency and accountability. The Government also adopted a National Healthcare Strategy. The Ministry of Health initiated a major restructuring of the public health institutions. Some institutes and services were privatised, and some were put out to tender under public-private partnership management programmes. The allocation of resources to the hospital sector is still higher than the allocation for public health and primary healthcare. Lack of a proper operational structure and adequate finances are major obstacles to the implementation of public healthcare programmes like those for Nutrition and AIDS/HIV

#### ***National Strategy for HIV/AIDS 2007-2011***

This Strategy is a follow-up to a previous programme 2003-2006 which was strongly focused on those most vulnerable to HIV infection, and included a monitoring and evaluation framework, incorporating core indicators for reporting on progress in implementing the 2001 UN Declaration of Commitment on HIV/AIDS. The 2003-2006 Strategy was funded by the FYROM Government as well as many international organisations, Member State Governments and the Global Fund to Fight Against HIV/AIDS. A major consequence of this Strategy is that a strong government/civil society partnership has been established which provides a solid foundation for the National HIV/AIDS Strategy 2007-2011.

HIV prevalence has remained very low in Macedonia, including among populations considered most-at-risk. In 2006, there were 96 people in total identified as infected with HIV. [69 were cases of AIDS]. Almost three quarters of reported cases (70%) were among men. The highest number of new cases (16) was reported in 2006 since the figures for HIV/AIDS were collected. However, it is most likely that the increased number is at least partly due to increased and earlier diagnosis of HIV due to greater availability of voluntary confidential counselling and testing services in the country.

The overall goal of the National Strategy is to maintain the low prevalence of HIV/AIDS in FYROM over the five-year period of the programme. This goal will be achieved by programme and policy actions in the following five strategic areas:

- Prevention from HIV infection by the most-at-risk populations e.g. injecting drug users, sex workers, prisoners;
- Other prevention strategies/activities – voluntary confidential counselling and testing services;
- Provision of treatment, care and support to people living with HIV/AIDS;
- Collection and use of strategic information; and
- Coordination and capacity building.

### ***Food and Nutrition Action Plan***

The FYROM Government published a National Action Plan on Food & Nutrition in 2004. The goal of the Action Plan is to protect and promote health and to reduce the burden of food-related diseases, while contributing to socioeconomic development and a sustainable environment [e.g. through the promotion of local food production]. The Plan promotes healthy living by means of a well balanced diet and the avoidance of nutritional deficiencies. The Ministry of Health is assisted in implementing the Plan by the National Committee for Food & Nutrition consisting of government officials, stakeholders and academics.

Particular initiatives included in the Plan are:

- Promotion of breastfeeding in line with the WHO Code;
- Improving the nutritional status of the population in particular pregnant women, children and the elderly;
- Reduction of micronutrient deficiency in the population possibly by means of food fortification;
- Elimination of iodine deficiency – a particular problem in FYROM;
- Public health campaigns to encourage the reduction of total fat intake; and
- Approximation of national legislation with international standards and EU Law.

### ***Mental Health Reforms***

In the Yugoslav period, people with serious mental illnesses were traditionally viewed as unable to participate in community life. Independent living and having a job and a social life were considered beyond their capacities. It was also believed that they needed prolonged treatment in a psychiatric hospital. The FYROM Government introduced mental health reforms in 2000 in an attempt to shift policy away from custodial care towards treatment in the community.

The WHO funded a mental health project in support of those reforms. The mental health reforms established community mental health centres in four cities: two in Skopje and one each in Tetovo, Prilep and Gevgelija. For the first time in FYROM, protected apartments were created to enable people with long-term illnesses to live with their neighbours in the community. Allied to this in 2003, the National Commission for the Protection of Mental Health, was established, consisting of Government officials and stakeholders, as a means of furthering these reforms.

The FYROM Government adopted a Mental Health Strategy in 2007, which defines and protects the rights of persons with mental health. While progress has been made concerning the establishment of community mental health centres there still exists a shortage of adequately qualified and trained staff combined with financial resources. There is also need for improvements in the institutional care of the socially vulnerable and people with disabilities.

#### 4. Recommendations

The following recommendations may provide ideas for a debate/discussion session with the FYROM's institutional authorities:

- Could we get further information on the latest situation regarding the implementation of the Government's National Food Safety Strategy 2007? Previously the Government discussed the possibility of establishing a National Food Agency/Authority – do such plans still exist?
- Do you believe that the Food Directorate has the capacity to deal with a major food crisis? Have you any plans to further co-operation with the EFSA beyond what exists at present in the context of the Instrument for Pre-Accession (IPA) programme?
- Having transposed the most important aspects of the Hygiene package when do you plan to adequately enforce this legislation so that HACCP certification is the norm in all food establishments? Why is HACCP not mandatory for all food establishments in the domestic market? How do you propose to highlight the need to implement HACCP systems amongst all stakeholders in the food chain in line with the new national laws on the Hygiene package?
- What EU assistance do you envisage you will need following the completion of the “*Improving Food Quality & Food Safety*” programme in April 2008? In particular:
  1. Can you inform us about the outcomes of other EU assistance in the food safety, veterinary & phytosanitary fields?
  2. Do you need assistance to upgrade your border veterinary controls in order to be operational to EU standards?
  3. What kind of further assistance would be beneficial in order to implement your laws on plant protection products so that the regime will be in line with EU norms
- In relation to Avian Flu can you demonstrate that the Veterinary Directorate, Ministry of Agriculture has adequate plans and resources, in line with international guidelines, to deal with an avian flu and human influenza outbreak in the near future?
- What is the latest position regarding the implementation of the five strategic areas highlighted in the Government's National Strategy for HIV/AIDS 2007-2011?
- Concerning the Government's Food & Nutrition Action Plan what have been the results in relation to the promotion of breastfeeding, reduction of micronutrient deficiency and elimination of iodine deficiency.
- With regard to the Government's Mental Health Strategy (2007) what progress has been made towards developing community-based services?