The Activities of the Health Protection Inspectorate in Approval of Enterprises and in Supervision of Adherence to the Food Act

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Summary

Food processing – the preparation, sales and catering thereof – is permitted only at approved enterprises. There are more than ten thousand retail or catering enterprises operating in Estonia (the first ones outnumber the latter by almost one-third). These enterprises are approved and the adherence of the organisation of their activities to the Food Act and to the requirements established on the basis of the Food Act is evaluated by the Health Protection Inspectorate, which is in the area of government of the Ministry of Social Affairs. The State Audit Office analysed the organisation of the respective operations of the Inspectorate and its activities in conducting the supervision of food businesses. The audit was organised on the basis of the work schedule of the State Audit Office.

The objective of the audit was to assess whether the legal regulation of the organisation of approval of food businesses and supervision conducted over their activities and the organisation of work of the Inspectorate are rational and effective, and to give recommendations, if necessary. The organisation of all the activities of the Inspectorate was not assessed.

Material observations and conclusions

Over the past two years the Health Protection Inspectorate has done a great job in explaining the requirements of the state to the employees of food businesses and in assessment of the adherence of such businesses to the requirements. In less than two years, an internal control program has been started by almost all the enterprises supervised by the Inspectorate.

The Inspectorate has approved approximately 5 percent of all the enterprises for a specified term (for up to one year), i.e. it has not assessed them to be fully in conformity with the requirements. Most of the food businesses that have been approved for a specified term operate in state and municipal institutions: in schools and other childcare institutions and in prisons. With regard to state and municipal institutions, the Inspectorate has been more flexible and lenient in supervision and imposition of sanctions than with regard to private businesses.

The European Union has given a relatively free hand to the Member States in the regulation of retail businesses and catering enterprises, and several requirements necessary to ensure food safety have not yet been established with regard to such enterprises.

The decisions of the Health Protection Inspectorate are very much based on the right of discretion, as the state has not established all the requirements qualitatively. Businesses and the state have accepted a good hygiene practice, which should specify the meaning of the terms "sufficient," "satisfactory," "necessary," etc., that are used in the regulations established by the government (the application of such a document is enabled by the Food Act and by the requirements of the European Union), but such instructions are still under preparation. The microbiological requirements for groups of foodstuffs were repealed by the government as of May 2004, as no specific requirements had been established to this regard in other Member States of the European Union. The government has also cancelled the requirement that the employees engaged in food processing have to undergo medical examination once every two years – only periodic medical examination is required now.

Enterprises do not have to pay any state fee for passing a decision on approval. However, they have to pay an annual state fee for the Health Protection Inspectorate to conduct supervision over them (approximately 5 million kroons in total according to the assessment of the State Audit Office). Not all the enterprises have paid that fee (according to the assessment of auditors, the state has annually lost about 2.5 million kroons). The Inspectorate has not paid enough attention to the payment of fees, and the Ministry of Social Affairs and the Tax and Customs Board have not verified the receipt of these fees (the obligation to check derives from the State Fees Act).

Main proposals of the State Audit Office

To the Minister of Agriculture

- To take measures to accelerate the preparation of the instructions on good hygiene practice referred to in § 26 (5) of the Food Act, which would take into consideration the specifics of catering enterprises.
- In case the microbiological requirements for food, which are being prepared by the Commission but do not yet exist, are not ready and effected within this year, the Minister should consider developing quickly, in cooperation with the Minister of Social Affairs, and applying on a temporary basis the respective internal requirements up until the EU requirements are established.

To the Minister of Social Affairs

- To decide on the necessity to establish more specific requirements for the employees processing food with regard to medical examination and the regularity thereof, and to make a proposal to the Minister of Agriculture to initiate a respective amendment to the Food Act.

- To take measures to ensure that the management of the Health Protection Inspectorate
    - issues an order to the employees of the Inspectorate not to make any concessions to state and municipal institutions in the assessment of the conformity of catering enterprises to the requirements and not to approve them for a specified term, if the Inspectorate is not convinced that after the expiry of the term of approval such catering place will have eliminated the omissions which can endanger human health;
    - requires the employees of the Inspectorate to apply all the measures available to the Inspectorate to prevent unapproved food businesses from operating without making its decisions dependent on to whom such businesses belong (to treat state enterprises and local government enterprises just as strictly as private enterprises). If, in the opinion of the Inspectorate, omissions in the property base or organisation of work of the enterprise endanger human health, such enterprises have to be prevented from operating with all possible means;
    - establishes more specific decision-making criteria for supervision officials, and makes the internal control system of the Inspectorate more effective to ensure that such criteria shall be met;
    - supplements the accounting and internal control system of the Inspectorate in such a manner that it ensures a continuous overview of the payment of fees and of the measures applied with regard to those who have failed to pay the fees in due time for the management of the Inspectorate;
    - ascertains the enterprises that have failed to pay the state fee for supervision and initiated collection of such outstanding fees.

To the Minister of Finance

- To decide whether it would be necessary to establish a fee for passing a decision on the approval of an enterprise in the State Fees Act, and if it is regarded as reasoned, to make a proposal for supplementing the State Fees Act.
- As the applicable legal acts do not prescribe any sanctions with regard to the enterprises that fail to pay the annual fee for supervision activities and as the administration expenses of such relatively small fees are quite high, to consider cancellation of such fees.

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The Minister of Social Affairs agreed with the conclusions and proposals of the State Audit Office and submitted a plan of action for the application of the same. The Ministry has prepared a draft of the Act on Amendment of the Public Health Act and Respective Amendment of the Food Act, Communicable Diseases Prevention and Control Act, which specifies the regulation of the order of medical examination of employees in order to prevent communicable diseases. A directive obligates the Health Protection Inspectorate to ascertain the enterprises that have not paid the state fee for supervision. Proposals are made to the Health Protection Inspectorate to eliminate the omissions that turned up in the course of the audit. The Minister supported the proposal of the State Audit Office of shedding the state fee for the supervision activities and establishing payment of state fee for making a decision on approval.

In his reply, **the Minister of Economic Affairs and Communications, acting for the Minister of Finance**, called attention to the fact that the basis for payment of state fees has to derive from the law of the respective area, which regulates the operations or provision of services taxable with the state fee

(at the time being, the Food Act does not prescribe payment of a state fee, and payment of a state fee for supervision activities is set forth in the State Fees Act). Therefore, according to the assessment of the Minister of Finance, the Food Act certainly needs to be amended on the initiative of competent ministries. The Ministry supports the necessity for establishing a state fee for passing decisions on approval of food businesses, and development of the respective legislative amendments is in the competence of the Ministry of Agriculture and Ministry of Social Affairs. It is the task of the Ministry of Finance to check adherence to the principles of establishment of state fees in drafting laws.

In his reply, **the Minister of Agriculture** stressed that the objective of the Food Act and the legislative acts issued on the basis thereof was to set the boundaries that ensure the safety of food, if they are observed in one's operations. The food business itself is responsible for its operations and has to ensure that the food processed by it is safe for the health of the consumer. The Ministry supports in every way the development of good hygiene practice instructions that take into consideration the specifics of catering businesses. The draft of microbiological requirements that is being prepared by the Commission is in its last stage of preparation and it is planned to enter into force as of 01.01.2006 – therefore the Ministry does not consider it expedient to start preparing temporary local requirements for the interim period.

The Director-General of the Health Protection Inspectorate gave notice of the measures already taken and to be taken for the implementation of the proposals made.

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