SUMMARY

of the report on the impact assessement of the Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market implementation for the biocidal products producers and governmental institutions of Lithuania

perfromed within the framework of the National Programme on assessement of social and economical changes regarding Lithuania accession to EU

The aim of the assessement – to evaluate possibile Directive implementation impact on the different groups of society of Lithuania and to offer the suggestions on appropriate implementation measures to assure complete and well–timed implementation of the Directive requirements providing conditions to reveal the most positive impact and to reduce possible negative one.

The investigation has been performed according to the **Recommendations** on Law Acts Impact Assessement, provided by European Committee under the Government of Republic of Lithuania.

The Directive of Biocidal products is one of the most complex and problematic legal acts among those issued by EU. At the beginning of the investigation the main problematic statements of the Directive according to the existing legal basis of Lithuania have been identified: definitions of biocidal products and types of biocidal products are not transposed or do not correspond to those presented in the Directive, the European authorization procedures of the active substances are not legalized and there are no experience of their application, mutual recognition of national authorizations is not legalized, the resourses of the competent authorities of Lithuania to assure this procedure have to correspond to the level of conformable institutions of the EU countries; the requirements for the dossier formation and assessement are extremely high and are not transposed yet, European procedures of Commission and Committees, monitoring and information exchange are not legitimated and there is no experience of their application. The first and essential step for the Directive implementation has not yet been done – the Competent Authority is not appointed, the application for Lithuania of part of considerable transitional measures is not defined by EU law acts.

Regulations on the Letter of consent, commercial secret protection, taxes, poisoning control are less problematic because Lithuania has the experience in transposition and implementation of the statements of other directives.

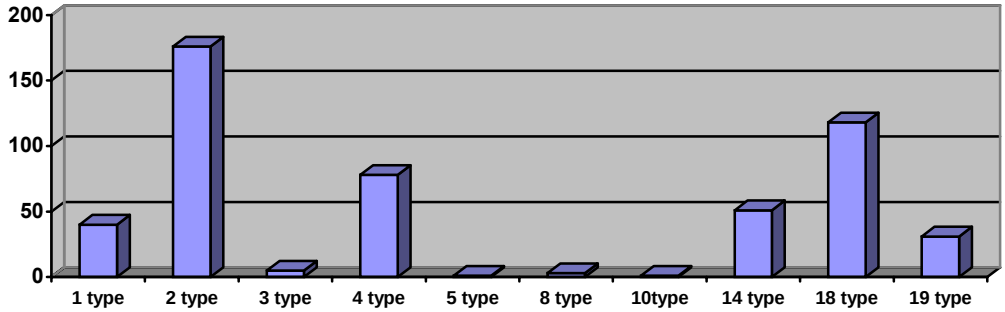
Other legal acts of Lithuania (Law on Prevention and Control of Human Communicable Diseases, Law on Product Safety, Law on Chemical Substances and Preparations, Law on Poisons Control, Negotiation Statement of Republic of Lithuania "Environment", Resolution of the Government on the appointment of authorized institutions to set up obligatory requirements of product safety, order of Minister of Health On the rules of the obligatory decontamination (desinfection, desinsection, deratization) of the environment approvement and others) correspond to the concrete statements of the Directive in 5 – 7%. The order of Minister of Economy and Minister of Health on the rules of biocidal product registration, the only legal act, which in some way corresponds to the Directive requirements, will not be in force from the 1st of January 2001.

The protocol decision of the Government from the 6th September, 2001 has authorized Ministry of Health to approved all legal acts transposing requirements of the biocidal products Directive before the end of February, 2001.

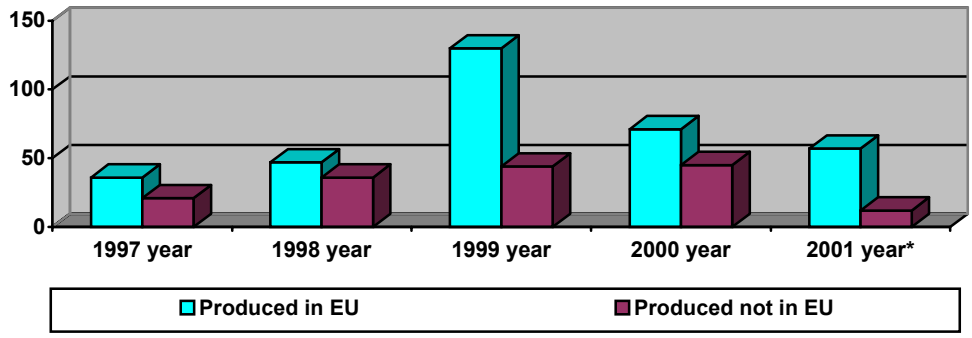
The subjects of the investigations and investigation of the impact on them purposfulness have been selected according the main identified problematic statements of the Directive. The opinion of the stakeholders as well as the uncertainty of data obtained during the whole investigation mainly depend on the fact that requirements of the Directive are not transposed yet.

According to the law acts now in force only 10 types of biocidal products are registered in Lithuania (out of 23 types set down in the biocidal products Directive). Since the beginning of the year 1997 up to the November, 2001 499 biocidal products have been registered, their distribution according to the type is presented in the scheme 1.

Scheme 1. Distribution of the registered biocidal products according to their types (in absolute numbers)



More than 92% of registered biocidal products belong to the 1, 2, 4 14 and 18 type of biocids, there are biocidal products which are the most actual for the assuarance of the safety of primary and public health. The number of the registered biocidal products and their proprotions have been changing during the period of analysis. Changes of the proportions and amouns are presented in the scheme 2.



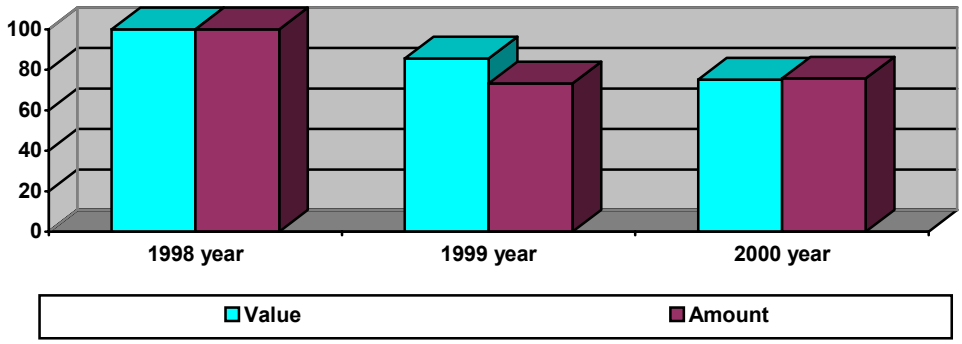
Scheme 2. The dynamics of the number of the registered biocidal products

Number of biocidal products produced not in EU (including those produced in Lithuania) has fluctuated from 25 to 43 % of all registered biocides, with the exception of the year 2001, when number of biocidal products produced not in the EU has been only 17% of all registered biocides.

The volume of all biocidal products' market according to the opinion of EU experts makes up about 1512 million EUR. Lithuanian market of biocidal products including the import for internal use (about 51 million Litas) and those for internal use produced in Lithuania (about

1,23 million Litas) makes up about 52 million Litas per year, which is about 95% of average EU level (estimated according by analogy). The main share in the Lithuanian market of biocidal products (about 98% of value) belongsto the imported products, their volume and value changes during the period of 1998 - 2000 are presented in the scheme 3.

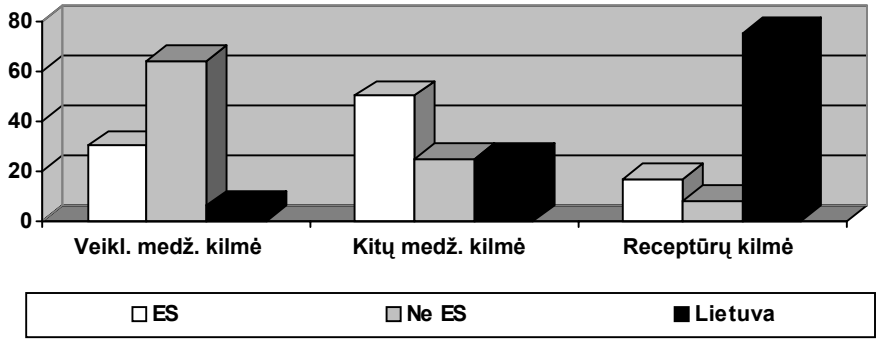
Scheme 3. Changes of biocidal products import to Lithuania during the period 1998 – 2000 (% rom the level of the year 1998)



It is clear that there is a tendency in the imported biocidal product volume and value to decrease while the average price of imported products remains stable.

The possibility to remain on the market for biocidal products produced both in EU as well as in Lithuania after the implementation of the requirements of the biocidal products Directive depends on the application of standard product prescription, notification, identification and authorization procedures of active and other substances. Products that correspond to the mentioned criteria and, accordingly, their suppliers to Lithuanian market will have the most favourable competition conditions. The conditions of biocidal products' producers of Lithuania according to the mentioned criteria are presented in the Scheme 4.

Scheme 4. The functional dependence of Lithuanian producers by the origin of active and other substances and product prescription (%)



While evaluating the possible impact on Lithuanian producers one should take into account the forecast that more that 50% of all active and other substances and only small part of product prescription in use will remain on the market after the requirements of the biocidal Directive requirements will be fulfilled. The forecast for the substances produced outside EU to remain on the market is about 5 – 10%. That means that Lithuanian producers will be forced either to refuse or to replace about 80% of active and about 70% of other substances and almost all products prescription. The main negative impact for Lithuanian producers

might be performed by additional expenses for authorization procedure. The estimated value of the additional expenses is presented in the Table 1.

Table 1. Estimated expenses for the Lithuanian biocidal products producers for the Biocidal products Directive implementation (from the year 2004, with the precondition, that number of authorized biocides per year is constant)

Type of activity	Value of expenses per year
Expenses for the authorisation of active substances*	increase 192 – 432 million. Lt*
Expenses for the authorisation of biocidal products	Increase 1,34 – 18,24 million. Lt.
* The authorisation of active substances is not feasible	

Because of expenses for the authorization of active substances Lithuanian producers of biocidal products will have no possibilities to authorize them. Only feasibility of the authorization of biocidal products is realistic, with the significant decrease of the number of authorizations and increasing the volume of authorised products.

Economic impact on the Lithuanian market of biocidal products will be experienced not only by producers whose comparative weight is very small but other participants of the market as well. The main and bigest impact will hit importers of biocidal products. Calculations of the main economical impact for the participants of the market are presented in the Table 2.

Table 2. Indirect economical impact of the implementation of the Biocidal products Directive (with the precondition, that number of authorized biocides per year is constant)

Time	Indicator of the activity	Volume of the market	Value of the impact
Short-term period (2002 – 2003 year)	Biocides produced in Lithuania and placed at the internal market	At the moment 1,23 million Lt. per year without VAT and other taxes	Decrease by 80 – 150 thousand. Lt per year due to changes in the production processes
	Import from EU	At the moment 34 million Lt per year (estimation according to the nomenclature of the biocides)	Increase by 1 – 1,5 million Lt per year due to market growth to EU average, and increase by 4 – 7 million due to changes in the market strucure
	Import from other countries	At the moment 17 million Lt per year (estimation according to the nomenclature of the biocides)	Decrease by 4 – 8 million Lt per year due to market restructuring
Long-term period (2004 – 2010 m.)	Biocides produced in Lithuania and placed at the internal market	0,93 – 1,07 million Lt per year without VAT and other taxes (forecast for the year 2004)	Decrease by 0,2 – 0,8 million Lt within six years

	Biocides produced in EU (excluding Lithuania)	44 – 51 million Lt per year (forecast for the year 2004)	Increase by 1 – 8 million Lt within six years
	Import	2 – 10 million Lt per year (forecast for the year 2004)	Decrease by 0 – 8 million. Lt within six years

The comparison of data presented in the Table 1 and Table 2 shows that forecasted value of biocides produced in Lithuania per year will be less than expenses of the Lithuanian producers of biocidal products for the authorisation procedure of biocides. From the economical point of view this is unbearable, therefore Lithuanian producers of biocides will be forced to decrease significantly the nomenclature of biocides, to increase prices, to try keeping the volume of production and to search for new markets.

There will be changes in the structure of the import when in Lithuanian market biocides produced in the EU will replace, up to 90 –95%, the biocidal products produced in other countries.

The biggest negative impact will be experienced by relatively small group of stakeholders – namely by Lithuanian producers of biocidal products. If appropriate measures are not taken they will suddenly and irreversibly loose their positions at the market. Due to differences related to the origin of the imported products of the suppliers the impact on them will differ and depend on their supplies orientation at the present. Positions of those who place on the market the biocides produced not in the EU will become significantly weaker and their place in the market will be overtaken by suppliers offering biocidal products produced in EU. Other groups of stakeholders will experience positive impact. Environment, first of all nature, will become an absolute winner. The improvement of the environment will have one of most significant impact on the life conditions' improvement for every person and the whole society. Implementation of the Biocidal products Directive will provide conditions to obtain immediately the political and later – economic benefits for the Government as well as conditions to protect national interests at EU in a better way.

To prepare itself to implement the requirements of the Biocidal products Directive in time and in proper way the Government should finance the institutional building of the existing Lithuanian institutions and to assure proper fulfillment of new functions.

The needs for the additional financial resources are presented at the Table 3.

Table 3. Additional financial resources needed for the governmental institutions to implement requirements of the Biocidal products Directive for the year 2002 – 2003

Type of activity	Institution	Investment	
		volume	Purpose
Authorisation, registration, consultation	State inspection of veterinary preparations	365 thousand Lt	Offices, equipment, new staff, training
Authorisation, registration, training, guidance and manuals, monitoring, data management, poisoning information and control	State Public Health Center or State Public Health Service under the Ministry of Health	640 thousand Lt or 1340 thousand Lt	Offices, equipment, new staff, training
Control and monitoring at the working places	State Labour Inspection	1447 thousand Lt	Offices, equipment, new staff, training

Household biocidal products control and monitoring	State Non Food product Inspection	201 thousand Lt	equipment, new staff, training
Control and monitoring at the places of animals housing and feeding	State food and Veterinary	1225 thousand Lt (as public health centers)	Offices, equipment, new staff, training (as public health centers)
Control and monitoring at the health care, social care and education institutions	Public Health Centers	1230 thousand. Lt	Offices, equipment, new staff, training
Total	5108 – 5808 thousand Lt		

All essential governmental institutions to implement all requirements of the Biocidal products Directive are in place already. There is no need to establish new institutions. Existing institutions have necessary experience to performe appropriate activities related to other products.

Estimations made according to the functions of institutions described in the draft order of the Minister of Health *On the approvement of the regulations of the authorization and registration of biocidal products* show that Lithuania has the possibilities to be ready to join the EU at the 1st of January 2004 and to performe all obligations related with the membership.

During the investigation the new aspect of the problem has been cleared out – Lithuania needs to make the inventory of biocidal products which are placed on the market. Approvements of that action have been submitted by all governmental institutions involved in the investigation.

According to the data obtained the report contains the proposal presented in the operogramme for the optimal way of the volumes and terms of the Lithuanian legal basis, institutional building and of the activities of the market subjects improvement.