Customs Barriers in the Way of Progress in Biotechnology

S. Sinyavskaya, specially for Acta Naturae

Scientific research in the field of Life Sciences is impossible without international cooperation, which means that no research is possible without foreign equipment, reagents, laboratory animals and biological materials. Yet, customs regulations in the field of biotechnology are raising more and more questions from scientists. Passing customs control takes up a lot of time, energy and funds. Can these bureaucratic procedures be simplified for the international transportation of goods for scientific research?

The 21st century is the century of biotechnology; these technologies are the foundation for the 6th technological stage. The importance of this field of knowledge for the development of modern society is understood by the government: *living systems technologies* were deemed priorities in scientific and technical development in 2002 and 2006; a presidential modernization committee has designated *medical technology* as one of the five priorities in economic development; the FTP (Federal Target Program) Research and Development in Priority Fields for the Development of the Russian Scientific and Technological Complexes in the years 2007-2012 and the field of Living systems are among the leading fields in the country. More than 30% of funds in this program are directed into this particular field.

It is clear that as the government favors this field of knowledge among others, it needs to create specific work conditions that will promote effective usage of the funds of scientific organizations and the time of their employees. If such a requirement is not met, then hardly any results adequate to the allocated funds can be expected. Work environment issues are precisely the ones that hamper the work of Russian life sciences researchers most of all. One of the most annoying problems is customs barriers, which prevent Russian science from integrating the worldwide network of scientific and agricultural interactions. In the words of corresponding RAS member **Alexander Gabibov**, an "artificial iron curtain" seems to have been put in place. An international parcel can seldom pass through customs on time and legally, and for a reasonable amount of money.

For instance, if you engage the services of a company which specializes in shipping equipment, reagents, and other goods, then the cost of the goods (and these can be very expensive materials) increases approximately 2.5-3 fold. Under these conditions, all the work needed to clear customs control is outsourced by the scientific organization. Obviously, this path is seldom chosen, as purchasing of equipment and reagents takes up from 10 to 50% of grant money as it is. Most often, scientists go through customs themselves or engage the services of a shipping company. In the latter case, not only do you have to pay for the shipping company's services and customs duties, but also to collect the appropriate documentation which is needed to pass customs. For instance, shipment by DHL requires the following:

– a letter requiring the release of the shipment;
– a translation of the invoice into Russian;
– a detailed description of the goods;
– a copy of the free release agreement between the sender and the recipient;
– registration with the Sheremetyevo or Moscow Customs Office (this can be done by DHL using the provided documentation);
– approval documents, the number of which depends on the specific code of the goods to be imported. The code is selected based on the detailed description (permission from the Ministry of Health and Social Development or a veterinary certificate may be needed, depending on the description).

Importing biological materials for scientific research requires permission from the Ministry of Health and Social Development and the government's Drug Control Department, and these papers are very difficult to obtain and take up a large amount of time (the list of documents requested is shown in appendix 1.2).

The amount to be paid in customs duties is calculated according to the following guidelines:

– the import customs duty ranges from 0%-20% (depending on the code of the goods) of the customs value of the goods (the customs value is the price of the goods according to the invoice + shipping);
– VAT of 18% of the customs value + customs duty;
– the minimal customs duty for a corporation or any other legal entity is 500 rubles;
– the minimum price charged for broker services is 7,000 rubles (without VAT; it is a standard tariff if the goods will be shipped via the DHL Express network with doorstep delivery), and

Svetlana Senotrusova, Doctor of Biological Sciences, Professor at the Organization of Customs Control department at the Russian Customs Academy.

Are the difficulties in the import of compounds needed for scientific research warranted in your opinion?

– I think that the existing procedures for customs regulation of the import of chemical reagents are to some extent warranted, since this is a special group of goods which can be extremely poisonous. Separating the import of goods for scientific purposes and for other needs may be a difficult task, since most of the import is accomplished by intermediary companies.

Spokespeople from the scientific community have been talking about the need for a single code (3822 00 000 0) for goods used only for research and development purposes, which is by the way how it is done in Europe and the USA. Why does not Russia introduce a single code for this group of goods?

– Group 3822 000000 includes reagents for diagnostics or laboratory use mounted on a support sheet, ready-made diagnostic or laboratory-use reagents with or without a support sheet, excluding goods which fall under the 3002 and 3006 categories; certified etalon materials. Goods that fall under this category are indeed not import-restricted. But even this category is burdened by the need for a number of supporting documents. But two other large groups of goods, which include organic and inorganic chemical compounds, rare-earth metals, radioactive elements and their isotopes cannot be folded into the 3822 group, since this may be harmful to national security. The majority of these chemicals and compounds require the use of nontariff means of control. A thorough diversification of the goods in groups 28, 29, and 38 of the Goods Nomenclature for the Foreign Trade is required.

The nomenclature lacks classification for many types of biological materials used in scientific research. Here is an example: a plasmid with all the required support documentation was sent from La Sapienza University in Rome via TNT express-mail. However, customs officials could not find the appropriate code and thus had to send the plasmid back to Rome.

– Of course the nomenclature lacks classifications for some types of biomaterial used in scientific research; this is not news, since science develops much faster than changes in the Nomenclature can be made. Declaration of such goods requires a qualified approach, especially from a foreign economic entity, a customs control specialist, or a broker. Unfortunately, the qualification of experts in the customs control of special-group goods is currently insufficient. Indeed, the declaring entity has priority in establishing the code of the goods and thus the amount to be paid in customs duties, and customs authorities only oversee this process. In the case of the returned plasmid, the mistake was due to the declarant and the customs broker. Such situations do no occur very often.

What changes should be made to the statutes to simplify customs control for research purposes?

My view is that optimizing customs duties which involve reagents for scientific research would be effective, since this will not affect the fiscal functions of the customs tariff of the Customs Authorities but will promote the development of science in Russia. Another import-optimization issue may be reducing the number of importers of these types of products; however, exemptions or simplifications of customs control procedures are out of the question.

Goods which can easily spoil are prioritized during customs control. These goods include living animals and the like (art. 67 of the Russian Customs Code). This prioritization must be carefully used.

Changes in the legislation aimed at the simplification of the export and import of goods used in scientific research require very thorough substantiation, which in turn requires significant, time-consuming work. We are working on this issue, but the problem is a difficult one.

the amount also depends on the need for additional services.

In theory, a shipment can be processed without professional assistance; however, customs services do not give consultations on the telephone. You need to show up and to present a 10-digit code for the goods in question (which is pretty difficult to figure out on one's own) in order to get the complete documentation package. Here, more difficulties await an applicant on his journey as an unassisted customs check:

– The longest delays usually occur when obtaining the so-called "refusal letters" issued by five government departments: the Ministry of Health and Social Development, Ministry of Agriculture, Governmental Drug Control Department, Russian Technical Supervision Department, and the Federal Technical and Export Control Department. The letters must acknowledge that the imported goods are not listed as medical or veterinary drugs, narcotic or potent drugs, dangerous waste or dual-use goods, and that they do not require certification or licensing. Obtaining this type of documentation can take up to 2-3 months.

– Combersome customs declaration process.

– Currently, because of the ill-conceived set of customs codes, the legal import of animals and biomaterials into the country is very difficult. This includes cell lines, DNA (such as plasmids), and bacteria. The nomenclature also lacks many of the biomaterial types which are commonly used in scientific research.

– Customs duties are not designed to tell the difference between goods shipped for sale or for scientific research. Because of this, scientists need to prepare lots of documentation that confirms their "good intentions."

Getting only one permission from the Ministry of Health and Social Development, which is valid for 30 days, requires an extensive package of documents (see more in Appendix 1), which includes a permission from the permanent committee on drug control for the export (import) of biological materials (the list of documents for a review of this committee is presented in Appendix 2).

– Moreover, it must be noted that some types of biological materials may spoil if the transportation and storage requirements in the customs storage

Alexander Gabibov, head of the Biocatalysis Laboratory at the M.M. Shemyakin and Yu. A. Ovchinnikov Institute of Bioorganic Chemistry (IBC RAS), corresponding member of RAS, Doctor of Chemical Sciences, professor:

During Soviet times, we used to order reagents from abroad a year ahead. Nowadays, some reagents take more than a year to arrive. Also, these reagents cost much more after passing through customs than they are for users in western countries. How can we even discuss priorities, market development and progress in nano- and biotechnology when we use up to 50% of our grant money on purchasing equipment? Can any world-class research take place when both animals and derivatives (such as human or animal blood) are virtually impossible to import legally? For instance, we need to transport certain genetic lines of mice into our Pushchino branch of IBC. We can only transport them as a present. However, we have to pay large sums of money to transport companies and customs authorities even for this "present." This is why we much prefer to conduct our animal experiments in our branch laboratories in Israel and France. This means that, even though we have all the technology, the administrative restrictions are so excruciating that we are forced to move our operations to western countries. Also, western researchers can transport animal blood, while Russian scientists need to obtain permission from the Drug Control Committee, which has to certify that the blood is free of narcotic compounds. But the thing is we carry blood in miniscule amounts, so drugs could not be extracted even if the blood did have drugs in it. It is unacceptable to prevent us from working just because bureaucratically it is easier to restrict than to allow. For example, we need spider toxins for studying cellular electric potentials. A western researcher can buy these compounds after signing several papers that state that the toxins will be used for such and such purposes. A Russian researcher just cannot cross the border with these toxins. Also, we cannot buy any spoilable reagents, even though companies such as Fedex and DHL ship these reagents all over the world in dry ice. The reason for this is that Russian customs control takes so much time that everything will thaw before it is released.

In order to open this "iron curtain" a whole series of legislative acts needs to be drawn up and the scientific community needs to be involved in their drafting. My opinion is that customs officials, who are highly qualified specialists, need to work on a single-window basis. Also, the veterinary service could be located inside the customs offices as opposed to being located in the other part of the city.

facility are not observed (for instance cell lines need to be stored in dry ice or at -80°C).

As we can see, obtaining materials for scientific research takes months, lots of efforts, and a large amount of funds.

We were unsuccessful in trying to play this game on our own; i.e., trying to pass customs control without assistance, and we could not get any broker or company to agree to do their job in the presence of reporters by the time this issue went to print, even though we did have preliminary arrangements. We also could not get any answers from the Federal Customs Authorities, who claimed to be busy with signing the Customs Agreement between Russia and Kazakhstan, and thus declined to comment. In short, all our attempts to prepare an objective article on the customs control of biological materials were very much reminiscent of the stories of the scientists who attempted to get their materials through customs.

However, we were able to find someone with a different opinion. Prominent lawyer Sergei Zhorin says that most of the problems associated with customs control can be avoided if "the performance of the appropriate tasks is not procrastinated." "Scientific research is usually conducted according to a plan, which means that a) knowing that certain materials will be needed during the following 3-6 months, one needs to consult customs authorities on the documentation needed for successful customs processing; b) the appropriate documents can be obtained at a reasonable pace with no rush; c) the goods should be pre-declared, which means that a customs declaration is filed before the goods arrive on the territory of the Russian Federation; d) after which the sender is notified that the recipient is ready to receive the previously ordered goods. In such a case, the completion of customs formalities will not take a large amount of time."

One way to ease customs formalities for scientists would be to assign a single code to all the goods needed in scientific research (3822 00 000 0), which is the case in Europe and the United States. According to Sergei Zhorin, the issue of putting certain goods in a specific position in the Goods Nomenclature (GN) is the sole domain of the Government of the Russian Federation. Zhorin himself believes that "the current concept for developing the customs authorities of the Russian Federation warrants the creation of a specialized customs post (or customs department) which would perform customs registration of these goods in the shortest possible time."

According to customs broker **Andrei Kirienkov**, the government will probably not assign a single code to this group of goods, since different goods have appropriate duties and customs in western countries are "much more oriented at targeted usage than the customs authorities in our country." The main problem is that scientific facilities have no priority over any others: "Such preferences need to be won as a first step. Then some other things can be fought over. The Federal Customs Authority does have a practice of granting privileges and permissions, scientific institutions need to team up and lobby their interests and solve this problem on their own and not put all their hopes into the government."

However, in this case the government then should not put too much hope into getting adequate results from the money it puts into biotechnology.

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Appendix 1

MINISTRY OF HEALTH
OF THE RUSSIAN FEDERATION

LETTER
Dated October 17, 2000, N 2510/11197-32

ON THE IMPLEMENTATION OF A TEMPORARY PROCEDURE FOR THE IMPORT (EXPORT) OF BIOLOGICAL MATERIALS

This material is forwarded as a guideline and procedure for the temporary procedure of document review, as submitted by organizations (institutions) to the Ministry of Health of the Russian Federation, for obtaining permission for import into the Russian Federation and export abroad of biological materials during the course of international scientific cooperation. This temporary procedure was approved on October 12, 2000, in accordance with the Decree of the Ministry of Health of the Russian Federation dated July 14, 2000, N 259.

This temporary procedure regulates the documentation process involved in the import and export of biological materials in the course of international cooperation in various aspects of medical science and creates a single organizational and methodological basis for the fulfillment of this task.

First Deputy Minister of Health
Of the Russian Federation
A.I. Vyalkov

Hereby Confirm
First Deputy Minister of Health
Of the Russian Federation
A.I. Vyalkov
October 12, 2000

THE TEMPORARY PROCEDURE OF DOCUMENT REVIEW, AS SUBMITTED BY ORGANIZATIONS (INSTITUTIONS) TO THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION, FOR OBTAINING PERMISSION FOR THE IMPORT INTO THE RUSSIAN FEDERATION AND EXPORT ABROAD OF BIOLOGICAL MATERIALS DURING THE COURSE OF INTERNATIONAL SCIENTIFIC COOPERATION.

This temporary procedure is implemented in accordance with the Decree of the Ministry of Health of the Russian Federation dated 07.14.2000 N 259 (art. 1.7) in order to regulate the issue of permissions for organizations (institutions) for the import into the Russian Federation and export abroad of biological materials during the course of international scientific cooperation.

I. General provisions for the drawing up of documentation by organizations (institutions) for the import (export) of biological materials

1. The organization (institution) must send a petition addressed to the administration of the Ministry of Health of the Russian Federation drafted according to the attached form and with the required package of documentation as listed in Section II of this temporary procedure.

2. Notarized originals of the documents or, in specific cases, their copies (also notarized) must be presented. Documents which have more than one page must be sewn together. Documents which have not been notarized or do not have all the required signatures will not be accepted. Documents (agreements, contracts, conventions, etc.) must be signed and have printed names under the signatures, and also bear clear seals of the involved parties.

4. Documents must be submitted in the Russian language. Documentation in foreign languages must have an attached translation signed by the head of the organization (institution) according to the established procedure, which also indicates the person who performed the translation.

5. Permissions for the export of biological materials can only be granted to Russian organizations (institutions) which have the legal right to conduct scientific and/(or) technical research in cooperation with foreign legal entities.

6. A permission from the Ministry of Health of the Russian Federation is a single-use document and is to be obtained for each instance of export (import) of biological materials used in the course of international scientific cooperation and is issued to the applying organization (institution).

7. Permission for the import (export) of biological materials is issued to the organization (institution) as a single copy and cannot be passed on to other organizations (institutions).

8. The permission document (permit) for the export (import) of biological materials is valid for 30 days from the date set by the registration number of the Ministry of Health of the Russian Federation.

9. The original of the permit issued by the Ministry of Health of the Russian Federation is presented by the organization (institution) to the customs authority of the Russian Federation at the place of registration, according to the procedure set by the National Customs Committee of the Russian Federation.

10. Changes in the legal status of the organization (institution), changes in the agreement (contract, convention) between the parties require a new application with a full set of documentation.

11. The person who signed the documents is responsible for the truthfulness of the information and correctness of the data presented to the Ministry of Health of the Russian Fed-

eration in the course of the procedure for obtaining a permit for the export (import) of biological materials in the course of international scientific cooperation, in accordance with laws of the Russian Federation.

12. The Ministry of health has the right to deny an organization (institution) an export (import) permit for biological materials in the following cases:

12.1. Incorrect drafting of the documentation by the organization (institution).

12.2. Incomplete presentation of the required materials, and also failure to conform to the requirements set by this temporary procedure.

12.3. False or distorted information in the documentation.

II. Documents required from the organization (institution) in order to obtain a permit for the import (export) of biological materials.

1. An application from the organization (institution), drafted according to the attached form.

2. Agreement [contract, convention, grant (a description of the grant and its main points must be included)] stipulating international scientific cooperation.

Scientific research performed in collaboration under intergovernmental agreements is to be documented by a copy of the appropriate document or an extract, certified in due manner.

3. Corporate charter and registration documents of the applying organization (institution).

4. Copies of the licenses of the parties named in the agreement (convention, contract), confirming their rights to conduct scientific research in the biological and medical fields.

5. A conclusion from the administration of a medical institution confirming that the subjects from which the biological samples were obtained did not have any infectious illnesses.

6. Documents from the cooperating party which state that the biological materials in question will be used only for scientific purposes, and that these materials will not be passed on to any third party without prior consent from the Russian party named in the agreement.

Note. This document must be drafted only if the above-said condition is not addressed in the agreement (contract, convention).

7. A foreign party importing biological materials into the Russian Federation must present an official letter of confirmation from the appropriate Health Ministry (Department) that the biological materials in question do not bear any infectious agents, addressed to the Ministry of Health of the Russian Federation.

8. Scientific research in the fields of infectious diseases (AIDS, HIV, hepatitis, etc.) must provide to the Ministry of Health of the Russian Federation a permit (consent) of the appropriate Health Ministry (Department) of the country into which the biological materials in question will be imported.

9. Biological materials that need to be imported into the Russian Federation to be used in scientific research in the field of infectious diseases must be reviewed in advance by the Ministry of Health of the Russian Federation, which makes the appropriate decision.

10. A permit for the import (export) of biological materials from the Permanent Drug Control Committee.

11. Reports on the conducted scientific research and a list of publications in Russian and foreign journals.

Head of the Medical Scientific
Research Facility Control Unit
S.B. TKACHENKO

Appendix to the temporary procedure of document review, as submitted by organizations (institutions) to the Ministry of Health of the Russian Federation, for obtaining permission for the import into the Russian Federation and export abroad of biological materials during the course of international scientific cooperation.
October 12, 2000.

I. APPLICATION FROM THE ORGANIZATION (INSTITUTION)

1. The application must be drafted on the organization's (institution's) official letterhead signed by the head of the organization (institution) and have the contact telephone and fax numbers of the executor, together with his/her last name. The application must include:

1.1. The location (country, city) and full title of the organization (institution) to which the biological materials will be exported in the course of international scientific cooperation.

1.2. Type of exported biological material (blood or blood fractions, serum, urine, spittle, other biological fluids, bioptates, etc.).

1.3. Number of units for each type of biological material.

1.4. Packaging type.

1.5. Mode of transportation:

a) package – mode of shipping must be described;

b) hand carry – full name of the person to transport the biological material, number of his foreign passport.

II. AGREEMENT (CONTRACT, CONVENTION)

Agreements (contracts, conventions) must have the following articles:

1. Subject of the agreement.

2. Agreement conditions.

3. Responsibilities and liabilities of the parties in the agreement.

4. Results of the scientific research and their use by the parties.

5. Duration of the agreement.

6. Description of the experiments to be conducted, and work plans and timetables of the research should be presented as an attachment to the agreement (contract, convention).

Appendix 2

List of documents to be submitted by the applicant for the expert assessment procedure in issuing a permit for the import/export of biological materials

A letter from the applicant to the Head of the Federal Agency for Healthcare and Social Development Control (Roszdravnadzor) requesting a permit for the import (export) of biological materials. The letter must be on the applying organization's letterhead, indicating the address of incorporation, and signed by the head of the organization – 1 copy.

An appendix to the above-mentioned letter with a list of the biological materials to be imported (exported), signed by the head of the organization, bearing a note from the Permanent Drug Control Committee certifying that there are no narcotic or psychotropic drugs or their precursors in the biological materials to be imported (exported), whose circulation is controlled by the Russian Federation (if the Appendix is more than one page, then each page must bear this note) – 2 copies.

A copy of the contract [agreement, convention, grant (the grant must be indicated by its full title and have a brief description of its main points)] on international scientific cooperation, certified by the applying organization's seal – 1 copy.

Copies of the founding and registry documentation of the applying organization, notarized – 1 copy.

Extract from the charter of the organization confirming that the organization is involved in research and development activities, notarized by the applying organization's seal – 1 copy.

Conclusion from the administration of a healthcare institution certifying that the person(s) who provided the samples does (do) not carry any infectious diseases – 1 copy.

Document from the cooperating party certifying that the biological materials will be used only for scientific purposes and that they will not be passed on to third parties without prior permission from the Russian party in the Agreement (this document is required if this issue is not covered in the contract).

A foreign party importing biological materials into the Russian Federation is required to supply an official confirmation from the appropriate Healthcare Ministry's (Department) that the biological materials in question do not harbor any infectious diseases.

In case of studies involving infectious diseases (AIDS, HIV, hepatitis, etc.), Roszdravnadzor requires a permit (consent) from the appropriate Healthcare Ministry's (Department) of the country into which the biological materials in question will be imported.

Import of biological materials for studies involving infectious diseases involves a review procedure by Roszdravnadzor, which decides whether or not to grant its consent.

Reports of the conducted scientific research and a list of publications in Russian and foreign journals.