

Planning Export Compliance for Cross-Border Growth

by S. Revelle Gwyn

Business or research groups planning to expand research, manufacturing, sales, or distribution activities beyond the United States should plan for compliance with US and international export and import rules and understand how these rules apply to various technologies. Export and import requirements can be complex and highly technical. Failure to allow for the long lead times needed to frame and implement internal export policies and procedures as well as engage third-party export services can lead to additional expenses, delayed export schedules, financial penalties, and criminal charges. Recent aggressive enforcement of US export laws have resulted in civil penalties amounting to >\$100,000 against several companies engaging in unlicensed exports and re-exports.

INITIAL CONSIDERATIONS

Specialists must plow through lengthy and complex commercial export rules and packing, labeling, and shipping requirements. A general understanding of such rules in the United States (as well as related costs) is essential to determine how, where, and to whom biological materials, chemical substances, technology, data, and services may be exported. To achieve this understanding, you should have a solid grasp of

- the identity and nature of the exported item, technology, data, or services
- the identity and location of the recipient



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- the intended use of the exported item, technology, data, or service
- the export license exception (if any) that pertains to the export transaction,
- the relevant packing, shipping, and transport rules
- the ultimate destination country and its import, packing, shipping, and labeling and other requirements
- the transshipment or import requirements of any intermediate country and its packing, shipping, and labeling requirements.

Failure to account for and properly use this information may result in financial and criminal penalties.

Here are some basic concepts, reminders, and traps to consider during export planning. The information here is not complete, nor is it a substitute for detailed, fact-

specific planning or implementation. That depends on the specific types of technology, specific regulations, and each exporter's circumstances.

OVERSIGHT

Technology does not always take the form of consumer goods, commodities, parts, or supplies. Biological materials, chemical substances, technology, and technical information, data, and services are subject to various US export laws, foreign government import regulations, and international requirements. The emphasis here is on "various" because there is no one group of statutes, rules, or regulations applicable to all US exports.

In the United States, the Commerce Department's jurisdiction extends to the export and re-export of several

commercial items and technical services, including biological items (human, plant, and animal). The US State Department oversees military or defense articles and applications, technical information, data, and services (which should not be assumed to be limited to munitions). US Treasury Department oversight includes exports to certain embargoed destinations. And the State Department and Treasury Department purviews extend to poor export conduct.

Other nations have their own respective laws, regulations, and practices. So cross-border strategic planning is incomplete without identifying the countries intended as the ultimate and intermediate destinations for exports. Such planning also should include integrating related specific requirements into internal export planning, policies, and procedures.

Because biological materials and chemical substances are subject to various special packing, labeling, and shipping rules, their export and shipment must comply with other US regulations (such as those imposed under the Toxic Substance Control Act [www.epa.gov/lawsregs/laws/tsca.html] and by the Department of Transportation [www.dot.gov]) in specific cases. Such exports also must comply with United Nations guidelines for shipping hazardous materials in domestic and international transport.

Export transactions require disclosure of a sales price or value of the exported item or service. Even though the exported items or services are not being sold to the recipient, the export paperwork requires an invoice containing the name and address of exporter and recipient, a value and description of the exported item or service, and the intended use of the item or service (the reason for the export).

Export recordkeeping and compliance requirements are complex, detailed, and massive. Third-party export service providers (such as freight forwarders) and appropriate software should be considered to shorten lead time and cost of hiring and training internal staff. Nevertheless, there is no substitute for

EXPORT PLANNING

Allow substantial planning and lead time to

- become familiar with all import, export, and transshipment basics and apply them to an exporter's specific circumstances
- educate and train internal research, business development, sales, and manufacturing groups about specific US export rules; labeling, packing, and shipping rules; and destination country requirements pertaining to an exporter's specific activities
- plan for the time and costs to obtain required export licenses or comply with conditions of export license exceptions and to prepare and maintain the required export records
- develop relationships with experienced service providers to provide information or training and to handle certain export activities (no need to re-invent the wheel).

a strong internal knowledge base and consistent compliance.

EXPORTS AND TRANSACTIONS

An *export* includes any item or service that is transported across a US border to a foreign destination. Other than shipping, packing, and labeling matters, the method by which biological materials and chemical substances (or related technology, technical information, data, or service) are crossing the border generally is not an issue. Disclosure to unauthorized individuals in the United States also may constitute an export.

Exporter responsibilities include determining whether a specific export transaction requires an export license or qualifies for an export license exception. If an export license is required, then an exporter must obtain it. Although help desks at various federal offices will provide assistance, ultimately an exporter must make the decision. The US commercial export rules contain classifications for specific types of items and services. Accurate classification of an exported item is the basis for determining whether an export license is needed or an exception is available. For example, certain training, maintenance, repair, implementation, instructional manuals, equipment, or other exported items may qualify for export license exceptions.

Be alert, however, to penalties for failing to obtain an export license if one is required as well as for failing to obtain the correct export license. Penalties can include seizure and confiscation of exported items (usually at the US border), delays in shipment, self-reporting, monetary penalties, and

(in worst cases) criminal charges and fines against individuals involved.

Research and nonresearch transactions are subject to export rules. Research conducted with non-US collaborators outside the United States may require an export license for items, technical information, data, services, or technology that are being transferred. US export requirements contain exceptions, however, for fundamental research (information resulting from basic and applied research activities that are ordinarily published and shared broadly in the scientific community) and information in the public domain. This information is broadly shared and free from publication restrictions.

Intracompany transfers of technology, technical information, data, information, and other exported items for use in a foreign country (as well as such transfers to affiliates in a foreign country) generally are made under a special export license for applicable purposes. Although discussions continue regarding the scope and use of an intracompany export license exception, such an all-purpose exception is not currently available.

A deemed export includes the disclosure of technology or technical information, data, or services that are otherwise subject to US commercial export rules to a person who is not a US citizen or resident alien. Technology is "released" for export when it may be visually inspected (e.g., plans, drawings, designs, technical specifications) by an unauthorized person, when it is exchanged orally, or when it is made available by practice or application by a knowledgeable person.

For example, the disclosure of biological materials or chemical substance technology in the United States to international visitors during a facility or site visit may require an export license or compliance with an appropriate export license exception (such as the fundamental research exception).

You should not overlook deemed exports when managing visits, research meetings, or collaborative or strategic alliance reviews. The unintended consequence of noncompliance may be a contract breach or inability to issue a certificate, representation, or warranty regarding export compliance. Although many research disclosure activities may fall within the fundamental research export license exception, you should adequately plan in advance to identify and use another exception or obtain an appropriate export license for the specific technology disclosure activities.

Temporary stay export transactions involve items such as biological materials, encryption software, data, or other information stored on a computer and demonstration equipment that leave the United States for use in a foreign country and then return. Such items used temporarily for trade shows, conferences, sales events, demonstrations, sales, or personnel training, and for personal use while in a foreign country may be granted this type of exception.

Exports also include items that arrive in the United States for a temporary stay and then are returned to their country of origin or are sent on to another foreign location. Trans-shipments through the United States are considered temporary stays. A temporary stay in the United States and re-export to a foreign destination also includes goods that are held in a foreign trade zone for modification, the addition of a special part or element, or some other type of special handling and then forwarded to their ultimate destination.

PACKAGING AND SHIPPING

Exports that include biological materials (e.g., diagnostic specimens or chemical substances) must comply not only with US export rules but also US

and international packing, labeling, and transport requirements. For example, shipments containing or possibly containing pathogens or toxins are subject to additional packing and shipping regulations under Transportation Department rules and United Nations guidelines adopted and implemented in International Air Transporters (IATA) regulations.

IATA rules address international shipments of hazardous materials, including toxins, infectious substances, and genetically modified microorganisms. As a general rule, diagnostic specimens are not considered hazardous materials unless the source patient or animal has or may have a serious communicable disease for which effective treatment is not usually available. In such a case, caution and concern for public health and safety should prevail, and you should consider consulting with liability insurance carriers and treating diagnostic specimens as hazardous materials.

Shipments that are refrigerated, frozen, or stored in liquid nitrogen or dry ice also must comply with specific packing and transportation rules. An exporter should not overlook the special requirements that shipping vendors or other third parties having custody or shipping management of those items may impose. Some shipping vendors do not accept infectious substance shipments or any items containing or using radioactive substances.

An exporter should recognize that personally carrying certain items (such as, toxins or infectious materials) on airplanes will result in criminal penalties, including imprisonment and fines.

DESTINATION

Although a company may have determined that an export requires US export license or qualifies for an exception, the final destination country and intermediate countries have their own import rules and restrictions. Not all exports can be sent to, delivered in, or trans-shipped through all countries. Early attention to this matter may save substantial time and prevent penalties, fines, and confiscation.

Embargoed countries such as Cuba and North Korea periodically receive

media attention. Countries deemed to pose a threat of terrorist activities also are subject to export restrictions. US commercial export rules contain country lists and other information needed to determine whether exports in specific classifications can be exported to certain countries for specific purposes. Whether an item can be exported depends on its intended use, the recipient's identity, and its final and intermediate destinations. Items such as those in certain chemical and nuclear categories are subject to worldwide restrictions. Seizure, confiscation, delays, and monetary or criminal penalties may be the fate of illegal exports, imports, or other non-compliant activities.

Security: Each export must have a final recipient. An exporter's obligations include knowing that recipient's identity and location. Exports to warehouses and similar facilities are likely to be delayed or seized by customs officials. With the heightened concern regarding national security and the export and import of materials and technology to alleged or suspected terrorists or other criminal groups, each exporter has a responsibility to ensure that an export recipient is not listed on any US list of restricted entities or individuals engaged in criminal activities (e.g., terrorism, narcotics trafficking, or proliferation of weapons of mass destruction) or identified as having violated export laws.

Exporters who are solicited or contacted by restricted persons or entities regarding an export transaction, delivery to a suspect foreign destination, or for a suspect purpose or use should report this to an appropriate US agency. Typical suspect export requests include those for delivery where use of the exported item or service is highly unusual or unlikely or with recipients who are not the person or entity named in the export invoice.

PENALTIES

Export transactions involving people or entities on a restricted list or who have been denied US export privileges may result in a federal investigation, fines, criminal charges, and the loss of export privileges. No one wants to manage such penalty

activities and related federal investigations and untoward publicity. Developing a process for frequent reviews of unauthorized recipients lists, obtaining accurate current information regarding delivery destinations, and being alert to export scams are essential parts of strategic planning for biological and chemical exports.

Similarly, export transaction schemes for making an end run around US export restrictions are severely penalized without regard to the type of industry involved. Recent civil monetary penalties include those against Cryostar (France) and Reson A/A (Denmark) as well as criminal fines of \$500,000 against other companies for alleged unlicensed exports and reexport activities.

Exportation is replete with traps for the unwary. Companies should be aware of the array of regulations. Such requirements include those to self-report errors; prepare and maintain a substantial volume of records; and comply with various packing, labeling, shipping, and other transportation rules (see “Export Planning” box). Exporters also should take into account the possibility that the jurisdiction of an unanticipated US agency over an export transaction may cause costly delays and require a restart of export transaction and license applications.

Disclaimer: This article is for information purposes only. It is not intended and should not be used or relied upon as a substitute for careful review and compliance with US export requirements, US and international packaging, labeling, and shipping rules, and all other applicable laws and requirements and their application to specific circumstances. 🌐

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