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Bio sector in India



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ICP Guidance for Bio Sector in India



Government of India's National Biotechnology Development Strategy (2015) emphasizes the "generation of biotech products, processes and technologies for enhanced efficiency, productivity and cost-effectiveness in the areas of agriculture, food and nutritional security; affordable health care and wellness; environmental safety; clean energy, biofuel, bio-manufacturing etc." and the government is committed to "engage with all stakeholders as we move forward in our journey to make India a US$100 billion bio-economy by 2025" (http://dbtindia.gov.in/about-us/secretarys-message).

Reaching this lofty target is laudable but requires steady attention to many underlying challenges. International collaborations, joint R&D initiatives, exports and imports of bio-pharma products and bio-production technologies have accelerated significantly in the past decade. Accompanying these developments is the acknowledgement that many of the materials, technologies and expertise available in the Life Sciences sector are inherently "dual-use," i.e. they have legitimate commercial uses but can also be adapted for use as biological weapons and lethal toxins. Responsible governance, therefore, requires a focus on not just safety, but also security, of these "inputs" in any bio-economy.



Stakeholders in a bio-economy are many and varied, based on their expertise and profile of activities: government agencies, laboratories, universities, manufacturing companies, exporters/importers, traders, transporters and shippers. It is imperative that all stakeholders understand if, when, how, and why, government controls apply to the trade in bio-products, materials, technologies, and services.

Government of India maintains a robust set of laws, policies and implementing guidelines, as well as a unified control list of dual-use and munitions items, which cannot be exported without a license. This control list, called **SCOMET** (**S**pecial **C**hemicals, **O**rganisms, **M**aterials, **E**quipment and **T**echnologies), enumerates all biological items, precursors, and equipment that are tightly regulated to prevent their use in developing biological weapons by irresponsible actors. Similar national regulations apply to bio sectors in almost all of India's major trading partners as well.

Failure to comply with SCOMET requirements may result in the delay of shipment release, confiscation of the goods, administrative penalties and even criminal prosecutions.

The items of concern for bio industry are primarily found in

Specific SCOMET Categories:



Category 2 : Microorganisms and Toxins

Category 3 : Materials, Materials Processing Equipment and related technologies.

As such, stakeholders are expected to put in place checks within their internal procedures to prevent the diversion of such items to destinations and end-users of concern. These procedures are referred to as Internal Compliance Programs or ICPs.



The basic premise of an ICP for bio items is that an export license is required if:

1. The material(s) could help a country or a sub-state actor in the development of a biological weapon, its precursors, or equipment to test such a weapon, or to deploy/disseminate it.
2. There are concerns about one or more of the entities involved in the transaction (manufacturer/exporter, customer, shipper, banker, broker) and the ultimate end-use of the item.



Crucial Elements of an ICP

1. Explicit commitment by the management (owner, CEO, proprietor) that compliance with SCOMET is mandatory company policy. Further, that violations by employees, regardless of their position within the company, will be penalized.
2. Designation of a Trade Compliance Office within the company as being responsible for ensuring SCOMET compliance, and its designated head would be legally responsible for clearing items for export. The Compliance Office would
   - Establish Standard Operating Procedures for Screening Transactions
   - Maintain all Records Relating to all Licensed Transactions
   - Regularly Train Employees and Vendors
   - Solicit Feedback from Employees about Possible Improvements in Procedures
   - Communicate with the Licensing Agencies Regarding Policy Updates and Changing Requirements
3. Management would establish the requirement for routine external and internal audits and share some of the aggregated results with the Board of Directors as well as the employees. It will also direct the Compliance Office to address the gaps identified by the audits.

Example of Standard Operating Procedures for Screening an Order

What is the item and is it licensable?

- What is it generally used for?
- Where does it appear in the SCOMET list?

Where is it going?

- Destination Country - is it under prohibition (by the UN or any other country/grouping)?
- Your Customer - is it listed as an entity of concern (by the United Nations, any multilateral body, by the United States, EU or any other country/grouping)?

What is the stated purpose/activity?

- Is your Customer a bonafide business?
- Is your Customer directly involved in the activities stated on the license application or buying it on behalf of another customer in the importing country?

Are there any anomalies in the Customer's Order - unusual or suspicious patterns?

Examples of Suspicious Patterns in an

Export Order

- The customer's address is a PO Box or a residential address, or is the business location shared with other companies
- A freight forwarding firm is listed as the ultimate consignee.
- The customer or purchasing agent is reluctant to offer specific and detailed information about the end-use of the item.
- The item ordered is incompatible with the technical level of the country (or company) to which it is being shipped, e.g., a reaction vessel with inside-coating of tantalum alloys, destined for a private research facility in Botswana.
- The item's capabilities do not fit the Customer's line of business, e.g. an order for an expensive, large capacity, freeze-dryer for use by a dried-foods trader with small annual turnover.
- The customer is willing to pay cash for a very expensive item when the terms of sale would normally call for bank financing and payments in instalments.
- The bank underwriting the transaction has been publicly implicated in money-laundering or supporting terrorist-sympathizers.
- The customer declines routine installation, training, or maintenance services which are typically built into the supply contract at no additional charge.
- The shipping route is abnormal for the product and destination.
- When questioned, the buyer is evasive and especially unclear about whether the purchased product is for domestic use, export, or re-export.



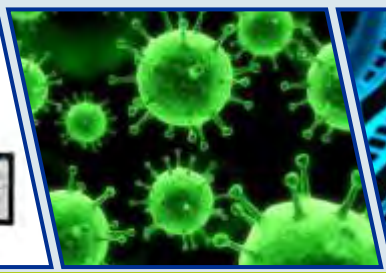
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A non-government, not-for-profit organization, FICCI is the voice of India's business and industry. From influencing policy to encouraging debate, engaging with policy makers and civil society, FICCI articulates the views and concerns of industry, reaching out to over 2,50,000 companies. FICCI serves its members from large (domestic and global companies) and MSME sectors as well as the public sector, drawing its strength from diverse regional chambers of commerce and industry.

The Chamber with its presence in 14 states and 10 countries provides a platform for networking and consensus-building within and across sectors and is the first port of call for Indian industry, policy makers and the international business community.

The Henry L. Stimson Center is a nonpartisan policy research center working to protect people, preserve the planet, and promote security and prosperity. For the past 30 years, Stimson's experts have sought to understand and illuminate complex issues and transnational threats that include the proliferation of weapons of mass-destruction and illicit small arms, terrorism, environmental security, the protection of civilians in conflict, UN reforms, and new applications of emerging technologies. By engaging national policymakers, international organizations, industry and non-government experts, Stimson crafts recommendations that are actionable and effective. Stimson's Trade, Technology, and Security Program examines the growing intersection of trade and security challenges. From technology transfers and additive manufacturing, to global non-proliferation efforts — the program develops public-private partnerships, pinpoints win-win opportunities, and fosters norms, systems, and institutions that durably promote security and prosperity.

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