

POLICY PULSE



IN THIS ISSUE

- **MACRO-ECONOMIC SNAPSHOT**
- **POLICY BRIEF**
 - CDS CO EXTENDS MEDICAL DEVICE COMPLIANCE DEADLINES TO 2021
 - INDIA'S DRAFT CHEMICAL INVENTORY AND REGISTRATION PLAN
- **FTA/WTO UPDATES**
 - INSIDE THE WTO: RUN-UP TO NUR-SULTAN 2020
- **MARKET UPDATES**
 - US FDA RECOGNIZES ISO 14971 AS MEDICAL DEVICE CONSENSUS STANDARD
 - COSTA RICA NOW REQUIRES IN-COUNTRY TESTING OF CELLULAR PRODUCTS
 - INDONESIA'S LAW ON E-COMMERCE
 - ARGENTINA'S ENERGY EFFICIENCY RESOLUTIONS TAKES EFFECT IN 2020
 - EAEU SIGNED AGREEMENT ON HARMONIZATION ON EXCISE DUTIES ON TOBACCO PRODUCTS
 - CHINA'S STATE COUNCIL PASSES OVERARCHING COSMETICS REGULATION
 - NEW YORK TO REQUIRE LABELS FOR LEAD IN CHILDREN'S JEWELLERY
 - UPDATES ON CHINA'S DRAFT EXPORT CONTROL LAW
- **SERVICE SECTOR UPDATES**
 - GROWING TRENDS OF SERVICE STANDARDS
- **OFF BEAT**
 - GO PRO WITH PROBIOTICS
 - PESTICIDE USAGE IN INDIA VIS-À-VIS EU STANDARDS

In This Edition

This edition focuses on policy overview, market scenario and insights of the World Trade Organization (WTO) proceedings for the 12th Ministerial Conference in Nur-Sultan, Kazakhstan. The section on Policy brief covers the decision of Central Drugs Standard Control Organisation (CDSCO) on medical devices and the adoption of Globally Harmonized System (GHS) of classification and labelling of chemicals by Ministry of Environment, Forest and Climate Change (MoEF&CC). The market updates section highlights the regulatory reforms that were introduced in different sectors across the globe. The offbeat section covers the situation of pesticides in India vis-a-vis European Union and status of probiotic market across the globe.

MACRO-ECONOMIC SNAPSHOT

Global Economy

As per World Bank's report, "global growth is projected at 2.5 percent in 2020, just the post-crisis low growth registered last year amid weakening trade and investment—and edge up further over the forecast horizon. While growth could be stronger if reduced trade tensions mitigate uncertainty, the balance of risks is to the downside. A steep productivity growth slowdown has been underway in emerging and developing economies since the global financial crisis, despite the largest, fastest, and most broad-based accumulation of debt since the 1970s. These circumstances add urgency to the need to rebuild macroeconomic policy space and undertake reforms to rekindle productivity."

It also says that "the outlook for emerging market and developing economies (EMDEs) has weakened significantly. As trade and investment firm, EMDE growth is projected to pick up to 4.1 percent in 2020—0.5 percentage point below previous forecasts—and stabilize at 4.4 percent in 2021-22, with the pace of the recovery restrained by soft global demand and structural constraints, including subdued productivity growth. The near-term rebound in EMDE growth will be mainly driven by a projected pickup in a small number of large countries. Per capita income growth will remain well below long-term averages, making progress toward poverty alleviation and development goals more challenging".

Indian Economy: Performance of Eight Core Industries

The Eight Core Industries comprise 40.27 percent of the weight of items included in the Index of Industrial Production (IIP). The combined Index of Eight Core Industries stood at 133.2 in December, 2019, which increased by 1.3 percent as compared to the index of December, 2018. Its cumulative growth during April to December, 2019-20 was 0.2 percent.

- Coal production (weight: 10.33 percent) increased by 6.1 percent in December, 2019 over December, 2018. Its cumulative index declined by 3.8 percent during April to December, 2019-20 over corresponding period of the previous year.
- Crude Oil production (weight: 8.98 percent) declined by 7.4 percent in December, 2019 over December, 2018. Its cumulative index declined by 6.0 percent during April to December, 2019-20 over the corresponding period of previous year.

- The Natural Gas production (weight: 6.88 percent) declined by 9.2 percent in December, 2019 over December, 2018. Its cumulative index declined by 3.8 percent during April to December, 2019-20 over the corresponding period of previous year.
- Petroleum Refinery production (weight: 28.04 percent) increased by 3.0 percent in December, 2019 over December, 2018. Its cumulative index declined by 0.6 percent during April to December, 2019-20 over the corresponding period of previous year.
- Fertilizers production (weight: 2.63 percent) increased by 10.2 percent in December, 2019 over December, 2018. Its cumulative index increased by 4.7 percent during April to December, 2019-20 over the corresponding period of previous year.
- Steel production (weight: 17.92 percent) increased by 1.9 percent in December, 2019 over December, 2018. Its cumulative index increased by 5.2 percent during April to December, 2019-20 over the corresponding period of previous year.
- Cement production (weight: 5.37 percent) increased by 5.5 percent in December, 2019 over December, 2018. Its cumulative index increased by 0.7 percent during April to December, 2019-20 over the corresponding period of previous year.
- Electricity generation (weight: 19.85 percent) declined by 1.6 percent in December, 2019 over December, 2018. Its cumulative index increased by 0.5 percent during April to December, 2019-20 over the corresponding period of previous year.

POLICY BRIEF

CDSCO Extends Medical Device Compliance Deadlines To 2021



India's medical device and pharmaceutical regulator, the Central Drugs Standard Control organization (CDSCO), has issued an extension for several types of medical devices to register for market authorization.

The CDSCO extension means that the following device types, originally expected to register under India's Medical Device Rules, 2017 by January 1, 2020, now have a January 2021 registration deadline:

- Nebulizers
- Blood pressure monitoring equipment
- Digital thermometers
- Glucometers

In addition, CDSCO will extend compliance deadlines for several types of imaging and other devices to April 1, 2021:

- Implantable devices
- CT scan equipment
- MRI equipment
- Defibrillators
- Dialysis systems
- PET equipment
- X-Ray machines
- Bone marrow cell separation devices

CDSCO had initially set a December 2019/January 2020 deadline for registration of these devices. The extension by CDSCO provides manufactures of such devices more time to prepare and ensure for compliance and maintain commercialization in India.

India's Draft Chemical Inventory And Registration Plan



Under the draft National Action Plan for Chemicals (NAPC), the Ministry of Environment, Forest and Climate Change (MoEF&CC) is considering an inventory and registration scheme for chemicals to adopt the Globally Harmonized System (GHS) of classifying and labelling chemicals. The proposed "policy framework" will additionally require phasing out chemicals in the short and long term, based on their risk to human health and the environment.

The plan has been prepared by the National Coordination Committee (NCC) – a chemical committee set up by MoEF&CC, which is responsible for drawing up chemicals legislation in the country. It makes the following three recommendations:

- compile a national chemicals inventory;
- analyse and assess the risks of those chemicals; and
- develop risk mitigation strategies, policies and regulations

The plan is dated December 2018 but it has not been publicly released. MoEF&CC is still discussing it before it publishes an official draft for public comment.

Compiling the inventory

The plan proposes that the ministry compiles a list of hazardous chemicals handled by manufacturers, traders and importers, within a recommended time frame of 6 to 12 months after publication of the plan.

The plan will require companies to submit only "minimal data" such as the names of the chemicals and quantities handled. Chemicals listed must also include hazard classification and labelling information to "set the groundwork for implementation of the GHS, which India needs to adopt", the document says. The ministry will develop a "user-friendly" online portal to help companies submit this data. When received, it will analyse it in-house or outsource it to an agency.

To initiate the process, the NCC recommends using the model inventory of 4,600 substances developed by Chemicals Export Promotion Council (CHEMEXCIL)

and its related software. The inventory will include all of the 684 substances listed in the Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, which currently govern industrial chemicals in India. When it has finished compiling the inventory, the ministry will amend the MSIHC Rules to provide a provisional time frame of six months for companies to notify the ministry if they are using any of the 684 chemicals listed.

When drafting the inventory, the ministry will take into consideration that there are a large number of small and medium-sized companies (SMEs) operating in India that do not have the required technical expertise on regulatory issues.

Registration scheme

According to the plan, within two years of completing the inventory, an expert panel will prepare a registration scheme. Chemicals expected to require registration are the 684 substances on the MSIHC Rules, chemicals "registered under REACH relevant to Indian context" and additional ones that may emerge following the compilation of the inventory. Potentially, this could mean a large number of substances will require registration. Importers and manufacturers registering chemicals will be required to provide data on the hazardous properties of substances, including data on flammability, toxicity and carcinogenic, mutagenic and reproductive toxic substances (CMRs).

Other proposals

The plan recommends that the MoEF&CC will review existing legislation in India and will set out measures to consolidate chemicals laws. For example, it suggests the MSIHC Rules should be merged with those of the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules to streamline the legislation. This would result in more effective implementation and safer handling of hazardous chemicals throughout the country. The MoEF&CC will take the lead in establishing a "regulatory framework" for chemical substances and appoint an expert group to start the initial groundwork for preparing a national inventory.

After this, it will prepare and introduce proposed legislation and table it for parliamentary approval – or adopt an executive order, which allows it to proceed without such approval – after a consultation process. The expert group will conduct

training across the country to familiarise agencies with the requirements and procedures.

The plan also proposes to create a separate body like “European Chemicals Agency (ECHA)” for all future chemical legislations and administration purposes. For the time being, however, the Central Pollution Control Board (CPCB) will act as the technical body responsible for implementation of the legislation, along with state pollution control boards and third-party inspection bodies.

FTA/WTO BRIEF

Inside The WTO: Run-up to Nur-Sultan 2020

The World Trade Organisation (WTO) is a multilateral system governing international trade. The decision making power in the WTO may be understood as a multi-level structure with the Ministerial Conference (MC), a biennial congregation of the members, at the very top. In preparation for the 12th Ministerial Conference to be held in Nur-Sultan, Kazakhstan in June 2020, several Council and Committee meetings are underway with the aim of reaching a consensus on, and providing recommendations for key issues on the agenda for discussion at the upcoming MC.

A special session of the Informal Committee on Agriculture (CoA SS) and a meeting of the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) were among the ongoing preparatory meetings.

With the trade ministers of member countries set to update the WTO rulebook on agriculture at the 12th MC, discussions on domestic support, market access, export competition, export prohibition/restriction, cotton, public stockholding and Special Safeguard Mechanism were held at the CoA-SS.

Domestic Support

As members of the Cairns Group (an interest group of major agri-export countries not including India) jointly announced their framework for negotiation to address disparities in global agri-food markets at the World Economic Forum, they also sought the resolution of domestic support issues in agriculture at the 12th MC. To achieve their goal of reducing the sum of trade-distorting domestic support entitlements by at least half by 2030, the group called for the reduction on all forms of trade-distorting domestic support, including those currently allowed under Article 6 of the Agreement on Agriculture of the WTO.

In response to this, trading members such as the EU and Norway have expressed apprehension over this proposal and suggested focusing on the most trade-distorting subsidies rather than the entire Article 6. This is further echoed by Switzerland (representing G10), which has asked members to take into consideration the need to subsidize sensitive products for non-trade reasons. Indonesia and Egypt, representing the G33 and the African Group respectively, further reiterated this by stating that subsidy reductions should not target

clauses allowing developing countries additional flexibilities in providing domestic support but only focus on the Aggregate Measure of Support.

India, for its part, has supported China's per-capita based argument for calculating subsidies and noted that big land holder farmers in main developed members exported most of their products, therefore the subsidies they received from government constitute de facto export subsidies. China was of the further opinion that there should be no uniform rules applicable on members at different development stages.

As it stands, members of the Cairns Group are proposing a reduction in all forms of trade-distorting domestic support measures. This move is expected to receive significant pushback from the EU, African countries and other developing members such as India and China. The USA was non-committal in its approach as it questioned whether there is enough time to resolve differences on domestic support issues before the upcoming MC.

These developments are significant and could have the potential to impact India's subsidies. India recently lost the case on export subsidies against USA as a WTO Dispute Settlement Panel upheld the USA complaint that India's export subsidy programmes violated provisions of the trade body's subsidies and countervailing measures (SCM) pact. India has appealed against the decision.

Additionally, in March 2019, Guatemala raised a dispute at the WTO against India, concerning domestic support measures allegedly maintained by India in favour of producers of sugarcane and sugar (domestic support measures), as well as all export subsidies that are allegedly provided for sugarcane and sugar (export subsidy measures). Australia, Brazil, Canada, China, Colombia, Costa Rica, El Salvador, European Union, Honduras, Indonesia, Japan, Panama, Russian Federation, Thailand and the United States are third party observers in this case. However, given the fact that the Appellate Body of the WTO is in a "lockout" state due to a lack of judges because of repeated blocking from the United States, the dispute settlement process is likely to be on hold.

Nonetheless, there are indications from the United States that it may reconsider its stance on the appellate body crisis. At a recently held meeting of the TRIPS council, discussions were held over the moratorium on non-violation and situation complaints under the TRIPS Agreement. A decision is set to be taken on the extension or expiration of the moratorium at the upcoming Ministerial

Conference. An expiration of the moratorium, which is the US agenda, would mean that countries would have the right to bring dispute cases to the WTO if they consider that another member's action or a specific situation has deprived them of an expected benefit under the TRIPS Agreement, even if no specific TRIPS obligation has been violated. This could be dangerous for countries like India, which have been targeted for perceived lack of protection of Intellectual Property Rights in heretofore informal processes like the Special 301 Report. Interestingly, if the moratorium is lifted, then the Dispute Settlement Body and consequently, the Appellate Body of the WTO would have to be functional. As USA has been the main reason for the paralysis of the Appellate Body, a turnaround in its stance could be imminent if the moratorium is lifted. Further discussions of the TRIPS Council, the Committee on Agriculture and other committees will set the tone for the next Ministerial Conference. These discussions and the eventual decisions taken may determine the course for India's trade in the future.

(This article has been prepared by Ms. Aishwarya, Research Associate, RV-VeKommunicate)

MARKET UPDATES

US FDA Recognizes ISO 14971 as Medical Device Consensus Standard

The US Food and Drug Administration (US FDA) has granted Recognized Consensus Standard status to the third edition of the ISO 14971 risk management standard for medical devices and in-vitro diagnostic (IVD) products. FDA's recognition of ISO 14971 Third Edition 2019-12 will entail a transition from the standard's previous edition, ISO 14971 Second Edition 2007-03-01, through late 2022.

ISO 14971 declarations of conformity and FDA pre-market submissions: Accordingly, the agency will accept declarations of conformity to ISO 14971 2nd edition included in medical device and IVD pre-market submissions until December 25, 2022; from that point on, FDA medical device and IVD registrants will be required to provide declarations of conformity to the standard's third edition.

ISO 14971 general scope: In general, the ISO 14971 standard applies risk management requirements across all stages of a device's lifecycle, although without identifying acceptable risk levels or requiring quality management system implementation by manufacturers.

Costa Rica Now Requires In-Country Testing of Cellular Products

As of 2019, Costa Rica's homologation process no longer accepts outside test reports for cellular products to be imported or commercialized in Costa Rica. Any product utilizing cellular technology (data or voice; 2G, 3G, or 4G) must undergo testing at an accredited lab within Costa Rica.

After testing, reports will be submitted with other documentation to SUTEL (Superintendencia de Telecomunicaciones), the Agency responsible for radio frequency management in Costa Rica. In addition to in-country testing of a specific cellular product, any company (or brand) seeking approval to sell cellular products in Costa Rica must also be registered with SUTEL. Examples of cellular products that require testing in Costa Rica include, cellphones, tablets, laptops, telematic devices, mobile payment terminals,

The major cellular communications companies operating in Costa Rica are Claro, Movistar, and Kolbi.

Indonesia's Law on E-Commerce: Clear Guidelines and Compliance by November 2021



In 2019, Indonesia introduced its long-awaited law on e-commerce to improve the governance of internet-based and electronic trading activities in addition to ensuring tax compliance among e-commerce businesses. The regulation is applicable to domestic and international internet companies, defines the type of entities that can engage in e-commerce. Additionally, the regulation addresses the specific set up requirements businesses will need to comply with, as well as the framework for online contracts and transactions, and the provisions for consumer right protection. Businesses will have until November 2021 to adhere to the new provisions.

a) Entities allowed to engage in e-commerce:

The law addresses the types of entities that are permitted to engage in e-commerce activities. These are:

- Business practitioners;
- Consumers;
- Non-business individuals; and
- Government agencies

The term 'business practitioners' can be divided into the following categories:

- Merchants (sellers)–business entities or individuals who conduct trade through an 'electronic system' which they own or manage directly or through a third party;
- E-commerce providers (PPSME)
 - any business entity, individual, or government agency that provide facilities or business models that enable e-commerce transactions. These can include, online retail websites; online classified ads; price comparison websites; and daily deal websites.
- Intermediary service providers –business entities or individuals that provide search engine services, hosting services, or caching services.

b) Requirements to set-up e-commerce entities:

As per the new regulation, businesses and individuals (domestic or foreign) engaging in e-commerce activities must adhere to several new requirements. This includes obtaining:

- A business license –This is done through the government's Online Single Submission System (OSS);

- A tax identification number;
- A technical license; and
- A business identification number.

Another key provision is to prioritize the trade of domestic goods or services, improve their competitiveness, and facilitate a special section or area to promote such goods or services on online marketplaces.

c) Related Services: Online marketplaces must also store their data (subscribers, payments, complaints, contracts, shipments etc) in local data centers in addition to having domain names that 'reflect' Indonesia (i.e. dot id). Online marketplaces are asked to retain financial data for up to 10 years and non-financial data for five years.

d) Foreign e-commerce entities: Foreign e-commerce businesses or internet companies that have a significant economic presence in Indonesia will be classified as having a permanent establishment in the country, and as such, deemed as an Indonesian tax residence. These entities would need to satisfy the following criteria:

- Reach a certain number of transaction volumes;
- Achieve certain transaction values;
- Achieved a certain volume of packages shipped; and
- Achieve a certain volume of traffic accessing who accesses the businesses' platform

Businesses that do fulfill the categories must also appoint a local representative in Indonesia and adhere to all applicable tax regulations.

e) Tax compliance: Online sellers must now adhere to prevalent regulations regarding income tax. Online businesses classified as small or medium enterprises (SMEs) must pay 0.5 percent in income tax while large companies pay the 25 percent corporate tax rate. Additionally, individual taxpayers who are earning at least 4.8 billion Rupiah (US\$342,000) from their online business must charge their customers value-added tax (VAT).

f) Consumer protection: E-commerce businesses must respect consumer protection and rights. Furthermore, the regulation addresses more specific protection framework regarding personal data protection, consumer complaints, and dispute resolutions.

g) Personal data protection: Online marketplaces and e-commerce businesses who collect personal data must follow the data protection standards set out in GR 80, 2019. These include:

- Obtaining personal data in a legal manner;
- Personal data must be accurate and up-to-date, providing the data owner with the opportunity to change the information;
- The personal data obtained must be relevant to what is described in the online marketplace;
- Parties that store personal data must use the appropriate security system to prevent breaches or other illegal uses;
- The personal data collected is prohibited to be utilized or controlled beyond the estimated utilization period; and
- The data collected is prohibited from being transferred or sent to other countries unless the said country has the same standards of data protection as Indonesia.

h) Consumer complaint services: The law states that e-commerce businesses must provide a complaint service for consumers. This must include at least:

- The proper procedures that set out the process on how consumers can complain;
- An address and contact number to file complaints;
- Staff that are competent in handling complaints;
- Follow-up procedures for complaints; and
- The time period for resolving complaints.

i) Electronic contracts: The law recognizes two types of electronic contracts: purchase agreements and license agreements. For the agreement to be deemed valid and binding, they must abide by the following requirements:

- Must contain information stated in the electronic offer (an offer can be made through emails, websites, and other electronic media);
- Must include the information of the parties involved;
- The contract must be in the Indonesian language
- Include transaction value;
- Payment terms and conditions;
- Details of shipment terms and conditions; and
- Exchange and cancellation policies.

j) Payments: Online marketplaces are permitted to cooperate with online payment service systems that are authorized by Bank Indonesia (the central bank). Payment service operators are required to maintain the highest standards of security for electronic systems, which is regulated by the Financial Services Authority, the State Cyber and Cryptography Agency, and the central bank.

k) Import tax: From January 2020, Indonesia has lowered the import tax threshold value on consumer goods sold via e-commerce platforms. Goods now worth at least US\$3 will be liable for import tax; the threshold was previously at US\$75. This new rule is aimed at controlling the number of cheap foreign products entering the country in addition to protecting domestic firms. Additionally, there will be different tariff rates for imported textiles, shoes, and bags. Textiles will be subject to 15-20 percent in import duties, as are bags, while shoes will be subject to a 25-30 percent rate. This is also before applying the 10 percent VAT and 7.5 percent in income tax.

Argentina's Energy Efficiency Resolutions Will Take Effect in 2020

Starting in 2020, manufacturers and importers of LED lighting and of electric pumps in Argentina must certify the energy efficiency of their products, in compliance with two new resolutions.

a) Resolution 795, dealing with general-purpose LED lighting, takes effect in stages over time.

- Starting May 30, 2020, importers must have proof from the local certification body that they have started the energy efficiency certification process for the LED lamps they wish to sell in Argentina.
- Starting Aug. 28, 2020, importers must have a valid energy efficiency certificate for omnidirectional LED lamps.
- Starting Dec. 2, 2020, importers must have a valid energy efficiency certificate for unidirectional and bi-directional LED lamps.
- Starting Mar. 1, 2021, importers must have a valid energy efficiency certificate for tube-style LED lamps.

b) Resolution 800, concerning electric pumps from 0.18kW to 5.5kW, is also rolled out over time.

- Starting May 31, 2020, importers must be able to prove that they have started the energy efficiency certification process for their pumps.
- Starting May 26, 2021, importers must have a valid energy efficiency certificates in hand.

EAEU Signed Agreement On Harmonization On Excise Duties On Tobacco Products

In December 2019, members of the Eurasian Economic Union (EAEU) countries signed an Agreement on the principles of tax policy in the field of excise taxes on tobacco products. The Agreement will enable harmonizing the rates of excise taxes on cigarettes and thus lay the groundwork for operation of the EAEU tobacco market. Since 2024, when

calculating national excise rates on cigarettes, the EAEU countries will proceed from the indicative rate of €35 per one thousand cigarettes with an upward or downward deviation of no more than 20%. The years 2020-2024 are defined as the period for achieving the indicative rate in order to adapt the business to these new requirements.

The gap in excise rates is the main reason for the growing flow of illegal tobacco products in the Union countries. Gradual and phased harmonization of excise rates on cigarettes will enable to restrain the development of illegal tobacco market. The harmonization also creates good conditions for increasing the volume of mutual trade in tobacco products, promotes equal competitive conditions for business and growth of budget revenues from excise taxes and improves conditions for legal turnover. The introduction of an indicative rate on tobacco products and the establishment of a five-year period for its achievement will contribute to business planning in the midterm.

China's State Council Passes Overarching Cosmetics Regulation

China's State Council has passed the Cosmetics Supervision and Administration Regulation. However, the Council has not yet confirmed a date for implementation. It will form the overarching law for cosmetics and replace the regulations concerning the Supervision and Hygiene of Cosmetics.

Experts are of the view that the new regulation contains only minor changes because it has already been through several stages of approval before reaching the State Council. The WTO draft of the regulation in general reduces the data requirements for cosmetic ingredients and products and simplifies many processes.

New York To Require Labels For Lead In Children's Jewellery

New York Governor Mr. Andrew Cuomo has issued a law to regulate lead content in children's jewellery, which will take effect on 1 January 2021. Introduced in February 2019, the bill amended the state's environmental conservation law to require a warning statement on jewellery with lead content greater than 40 parts per million (ppm) but less than 600ppm, which is the maximum level permitted under federal standards. The label can either be placed on the jewellery itself or on its immediate packaging.

The bill has some exemptions on product's lead-containing parts which are inaccessible to a child. The law defines children as those under the age of 12 and put stringent controls on the amount of lead in jewellery are necessary to protect public health, especially the health of children.

Violations of any of the law's provisions will result in a civil penalty of up to \$500 for the first violation and up to \$2,500 for any subsequent violation. In October, State of California also adopted legislation on lead in jewellery, with more stringent restrictions on products intended for children. However, the state did not introduce labelling requirements. Instead, it lowered the allowable lead levels for children's jewellery from the 600ppm limit prescribed by the federal standard to 100ppm, and to 90ppm by weight for surface coatings.

Updates On China's Draft Export Control Law

On 28 December 2019, the National People's Congress (NPC) of the People's Republic of China (PRC) released a new draft of the Export Control Law (ECL) ("2019 Draft"), an update from the 2017 version circulated by the Ministry of Commerce. The 2019 draft, if enacted, the ECL will be China's first comprehensive and consolidated export control legislation, aimed at upgrading the country's existing regime consisting of multiple regulations.

Key Changes

a) Retaliatory Measures: One of the most controversial points arising from the 2017 Draft was the power for the Chinese authorities to implement retaliatory measures against discriminatory measures taken by other countries against the PRC. This provision has been removed from the 2019 Draft. At this stage, there is no clear indication as to whether the "Unreliable Entity List" announced earlier, if implemented, would be integrated into the export control legislation or would be enacted independently.

b) Re-export: The definition of “re-export” (i.e. the export of items containing above a de minimis amount of PRC controlled content from one foreign country to another foreign country) has been removed from the 2019 Draft, but reference to “re-export” is still included in respect of transshipment and transit activities.

c) Catch-all: The catch-all provision previously provided for controls in relation to unlisted items which may endanger national security, present risk of circulation or be used for terrorism purposes. This provision is now clarified to cover items which may be used in the design, development, production or use of Weapons of Mass Destruction (WMD) and their means of delivery, or used for nuclear, biological, or chemical terrorist purposes.

d) Determination by the Authorities: An exporter may make an inquiry to determine whether an item is subject to control under the ECL. The 2019 Draft clarified that the scope of the determination includes technologies and services, and it now requires the authorities to respond to such inquiry in a timely manner. Unfortunately, the draft does not further clarify what constitutes “timely manner” and whether the determination is binding on the authorities (similar to customs rulings under customs law generally).

e) End-Use/End User Statement (EUS): The submission of EUS as supporting document for an export permit application is now mandatory (previously where required).

f) Approval and Notification when Changing End-User or End-Use: Under the 2017 Draft, where there is a change of end-user or end-use for an item, the importer is required to obtain approval from the authorities. In practice, this may not be feasible as the importer may not necessarily have knowledge of such change upon delivery of the item to the end-user. Under the revised draft, the end-user is required to obtain such approval. Additionally, where the exporter or importer finds out that the end-user or end-use for the item may change, the exporter or importer is required to immediately report such change to the authorities. Previously, this requirement only applied to the exporter.

g) Permit Application Timeline: Under the previous draft, the application timeline for dual-use items is limited to 45 days subject to possible extension due to special circumstances. The 2019 Draft clarified that such extension is for an additional 15-day period.

h) Increased Penalties: Under the 2019 Draft, the prescribed penalties for a number of offences have increased significantly and new categories of offences are introduced. More interestingly, the provision relating to penalty mitigation in the case of voluntary disclosure has been removed. It remains to be seen whether provisions relating to penalty mitigation and power to compound offences and issue administrative penalties would be introduced in the implementing regulations and guidelines.

SERVICE SECTOR UPDATES

Growing Trends Of Service Standards

The role of standards has evolved over decades. There is an increase in motivation to develop internationally accepted standards to achieve better quality than before. Standards are essential to facilitate global commerce, and strengthen positions in world economy.

Services are becoming crucial in countries' economic growth with their increasing importance in the global economy. From smallest to the largest economies of the world, the service sector is escalating dynamically. The expansion of the services sector's output has led to employment growth and is by far the biggest employer in majority of the world's economies. From international trade perspective, service standards play an important role in enhancing the trade prospects of a service entity.

Consumer expectations are continually rising when it comes to the service they receive from organizations. The services sector, in parallel with such growth need standards to establish good practice, encourage consistently high service quality and build consumer confidence. Services industry is diverse, from utilities, IT and finance to tourism, healthcare, education and retail.

Manufacturing sectors also include a significant services component from training to transit, logistics to customer satisfaction.

International Organisation for Standardization (ISO) and European Committee for Standardisation (CEN) lead the way in the development of standards for services. Their work covers both horizontal standards, having broad application across the services sector, and vertical standards, those applied to specific service domains such as tourism, finance, market research, etc.

Service Sector across the globe

Some examples of service standards developed in various countries are:

- Africa - service standards are most often used in the tourism and finance sectors in Africa where they have made a huge difference. These are the two fastest-growing sectors, attracting substantial external investment also influencing the development of the media, especially newspapers, electronic media and digital information. One of the East African Countries, Rwanda proposed a draft standard concerning code of practice for travel and tour operation at the

World Trade Organisation (WTO). This Rwanda standard prescribes the guidelines to ensure the quality and professionalism in the services provided by all travel and tour operators in Rwanda.

- Canada - Passport Canada, Human Resources and Skill Development Canada and the Canada Revenue Agency have developed services standards in their respective areas to ease the process and benefit the consumer.
- European Union - has a service package which includes balanced measures for companies and professionals to provide services to a potential customer base. The package includes regulation for European services e-card and related administrative facilities. It is a simplified electronic procedure that will make it easier for providers of business services (e.g. engineering firms, IT consultants, organisers of trade shows) and construction services to complete the administrative formalities required to provide services abroad. There is also commission guidance on standardization in services which sets out measures that will help prioritise and incentivise the development of voluntary European service standards, reduce obstacles stemming from national standards and certification schemes, and improve information to service providers.

Service Sector in India

An Export Promotion council Services in the name of Services Export Promotion Council (SEPC) is set up by the Ministry of Commerce and Industry, Government of India, with a view to give proper direction, guidance and encouragement to the Services Sector. SEPC has been mandated to promote export of services in the following sectors:-

- Healthcare Services
- Legal Services
- Accounting and auditing services
- Hotel and tourism related services
- Environmental Services
- Entertainment Services
- Maritime transport related
- Distribution services
- Architectural services
- Educational Services
- Advertising Services
- Consultancy Services
- Marketing Services
- Printing and publishing services

Also, there is a **Service Sector Department in the Bureau of Indian standards (BIS)** to formulate Standards on service sector including Banking and Financial Services, Education Services, Tourism Services, Accounting Services, Legal Services, Environmental Services, Communication Services, IT Services, Health related and Social Services, Business Services and Logistics Services and other related areas. As per the BIS website no Service Sector Standards are published in India.

(This article has been prepared by Ms. Anjali Chauhan, Research Analyst, RV-VeKommunicate)

OFF BEAT

Go Pro with Probiotics

Key Points

- Probiotics improves gut health and thus the overall health
- Demand for probiotics is increasing with increasing lifestyle disorder
- Probiotics market is expected to reach USD 50 billion by 2023
- Yeast will be the most used ingredient for probiotics
- Food and Beverage captures the maximum share

Consuming a probiotic is what the body demands together with healthy food. As gut health has profound effect on overall health, probiotics can play a significant role for providing what the changing lifestyle demands. Probiotics are the “live microorganisms which when administered in adequate amounts confer a health benefit on the host”. In order to be labeled a probiotic, scientific evidence for the health benefit would have to be documented. (World Health Organization, WHO)

Probiotics are attracting consumers and covering larger market share due to the increasing health concerns, growing risk of lifestyle disorder, increasing amounts of disposable income and standards of living. Globally, the industry has the potential to attract USD 50 billion by 2023 (International Probiotics Association (IPA) 2019).

The Probiotic Market Segmentation is done based on:

- Ingredients (Bacteria and Yeast)
- By Application (Food Beverage, Dietary Supplements and Animal Feed)
- By Function (Regular, Preventative Healthcare and Therapeutic)
- By End User (Human and Animal Probiotics)
- By Geography (North America, Europe, Asia- Pacific and LAMEA)

As per the report 2019, yeast is the fastest growing ingredient globally while for application segment the food and beverage captures the maximum share. In addition to this, liquid probiotics will dominate the market. While the Asia- Pacific is the fast growing geography in the probiotic market (marketandmarket.com).

In India, the product is attracting largest revenue because of its popularity among youth. The major revenue is generated from North India followed by South and Central part of the country.

The market players for this product are Mother Dairy, Amul, Danone Yakult, Herbalife and Nestle India. (India Probiotic Market Forecast and Opportunities, 2019).

Regulatory Regime in India for Probiotics

A regulation covering probiotics, “Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016” has been issued by FSSAI, Government of India.

The regulation is applicable from 1 January 2018. It provides the list of the type of microorganisms that can be used with limit for the viable organisms that can be incorporated, food additives that can be used and the labelling requirements for the probiotic foods.

Recent Probiotic Product Launch

- **Simply Probiotic (Herbalife):** A powdered probiotic product that can be added to beverages which can increase the growth of beneficial bacteria in gut. The product do not contains no added flavor, color, sugar or sweeteners with non-GM ingredients.
- **Probiotic Fruit Bar (That’s It):** The product is available in 3 flavor namely mango, blueberry and banana. The company claims that the fruits act as prebiotic which aids the bacterial culture in growth.
- **b-active probiotic curd (Mother Dairy):** The product is launched in Delhi last year. The product is incorporated with dietary fiber to have Synbiotic effect and make it a healthier option.
- **Materna Opti-Lac (Nestle):** A food supplement launched for lactating mother. It is a probiotic solution which relieves breast pain and mastitis.

(This offbeat article has been prepared by Ms. Himani, Research Analyst, RV-VeKommunicate)

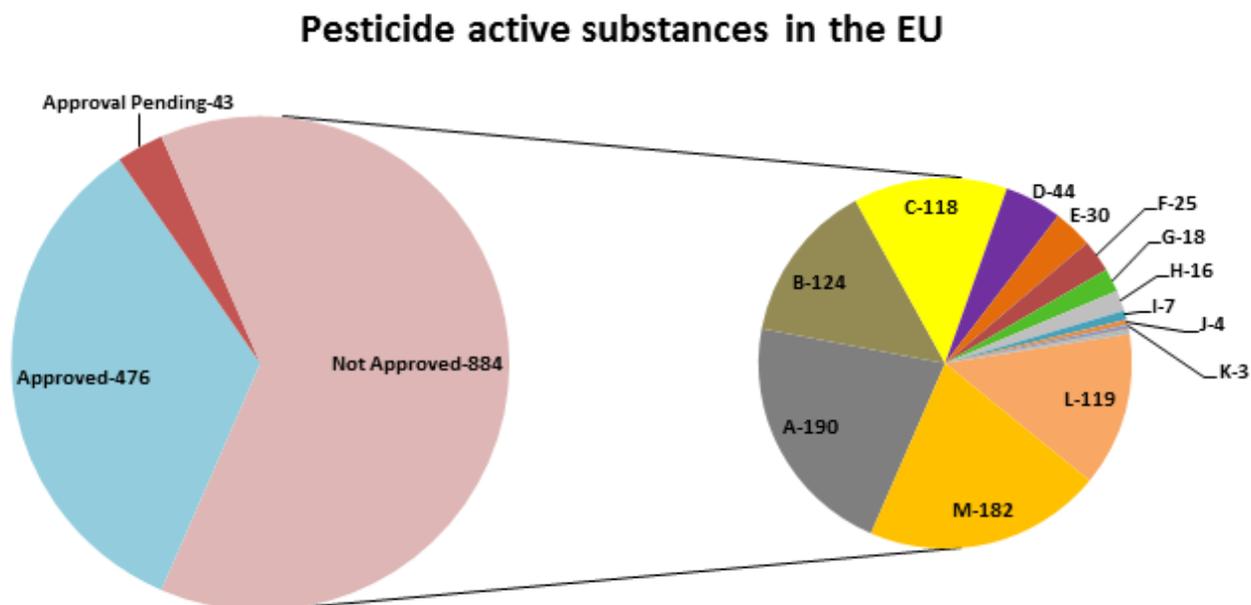
Pesticide Usage In India vis-à-vis EU Standards

India is among the top five agricultural producers of the world and is also among the leading pesticide consuming countries of the world. With news reports indicating that a Pesticides Management Bill is set to be tabled in this session of the Parliament, India seems to be moving towards a more regulated market for pesticides and other agro-chemicals.

In such a scenario, it is important to understand if India's pesticide use is up to global standards. As it is universally acknowledged that the European Union (EU) has some of the most stringent pesticide regulations in the world, this article takes a look at the use of pesticides in India vis-à-vis EU.

1. Pesticide active substances in the EU

As of February 2020, out of the total 1,403 pesticide active substances registered in the EU for use in Plant Protection Products (PPPs), 884 are no longer approved for use. These have been categorised as shown below.



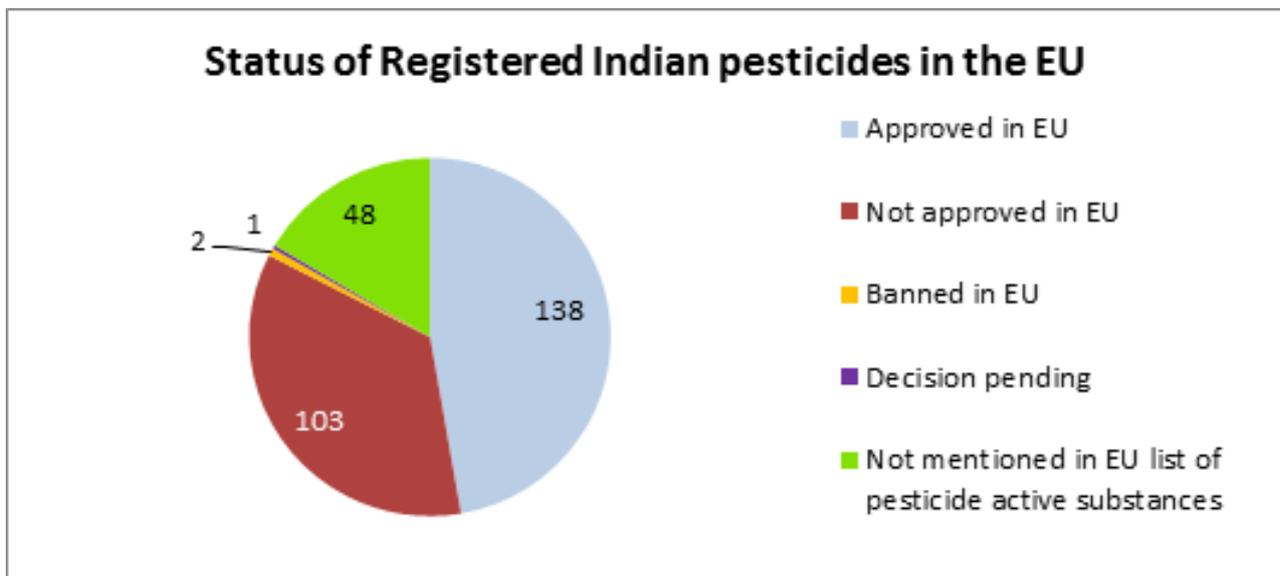
A-Herbicide, B-Insecticide, C-Fungicide, D- Plant growth regulator, E-Rodenticide, F-Attractant, G-Acaricide, H-Repellant, I-Bactericide, J-Nematicide, K-Pruning, L-Multiple categories, M-No categorization

Source: EU Pesticides Database - Active Substances

Of the 884 active substances which are not approved for use in EU, approval for 48 substances was revoked within the last 15 months (since the last quarter of 2018).

2. Registered pesticides in India which have been banned or restricted in the EU

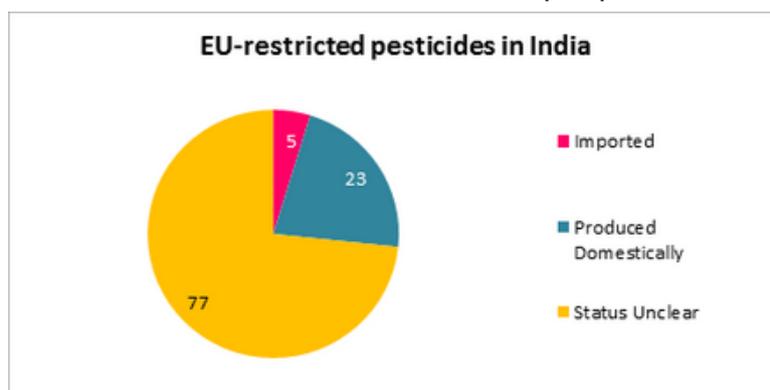
As of 31 October 2019, 292 pesticides are registered under section 9(3) of the Insecticides Act, 1968 for use in India. Of these, 103 pesticide active substances are not approved for use in the EU, meaning that the maximum residue level for these pesticide active substance is set at the limit of detection in all products, i.e 0.01 parts per million. This is a significant hurdle for the exporters as product consignments may be rejected by the EU, a major trading partner, if the pesticide limits are not complied with. Further details are shown below.



Source: EU Pesticides Database - Active Substances

3. Import/Indigenous production of pesticides in India

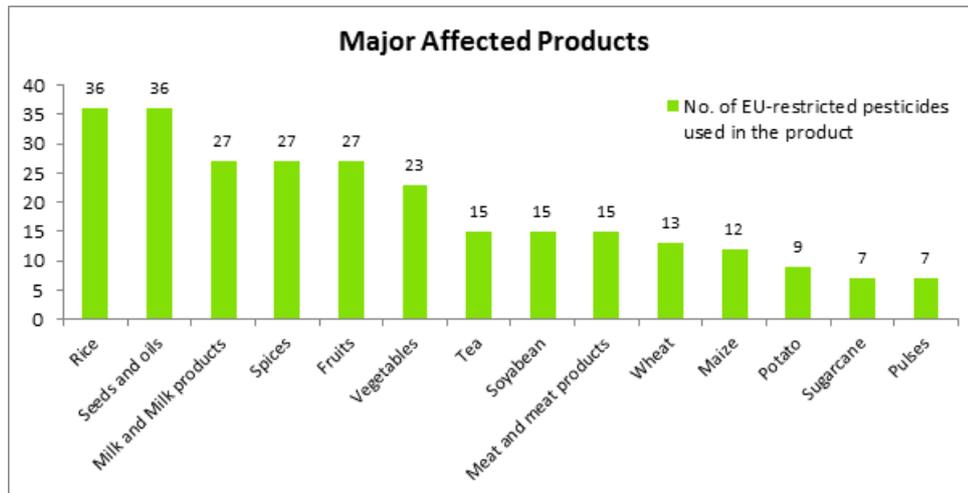
Pesticides in India are produced domestically as well as imported. This subsection gives details of whether the pesticides restricted in the EU are produced domestically in India or are they imported. Data on a total of 105 pesticides which are registered in India was studied for this purpose. The results are shown below.



Source: Directorate General of Commercial Intelligence and Statistics (DGCI&S), Kolkata and Department of Chemicals & Petro-Chemicals, Ministry of Chemicals & Fertilizers

4. Major affected products

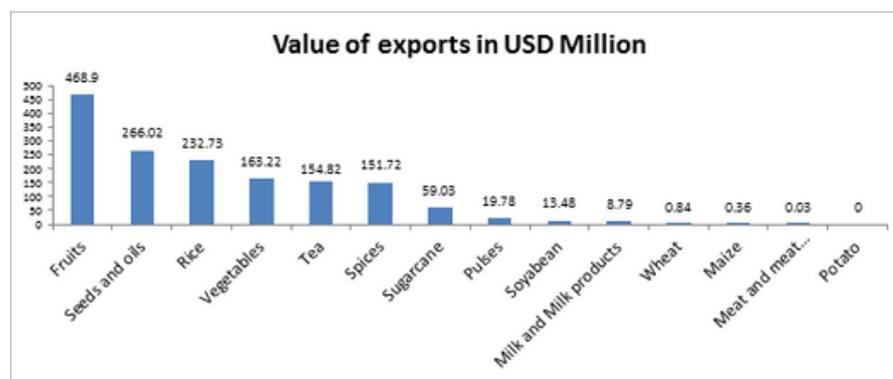
The 105 pesticides which are restricted in the EU are used in India in a number of different agricultural commodities. The use of these pesticides in the products is regulated by domestic limits set by the Food Safety and Standards Authority of India (FSSAI). An analysis revealed the major affected commodities to be as shown below.



Source: Central Insecticide Board & Registration Committee (CIBRC) and FSSAI

5. Export of affected products to EU

Agricultural produce is one of the major exports to European Union and it being a high-value market is of immense significance to Indian exporters. As understood so far, 13 sub-categories of agricultural products have been identified which, as per FSSAI data, are sprayed with pesticides which are restricted in the EU. The export of these products to EU in 2018-19 is given below.



Source: ITC Trade Map

With India looking to renew talks of a Free Trade Agreement (FTA) with the European Union, it would be useful to try and bridge the gaps in the scientific assessment of pesticides and their permitted levels in different products between India and EU.

(This article has been prepared by Ms. Aishwarya, Research Associate, RV-VeKommunicate)



**Global Business Communication Partners in
Advocacy & PR, Reputation & Crisis Management,
Research & Economic Data Analysis, with in-depth
knowledge of Legal, Trade and Regulatory Affairs,
specialising in various industries such as Mining,
Manufacturing, Agriculture, Automotive, Pharma &
Healthcare, Consumer Affairs and Tourism.**

**Based in India, working across various
international regions:**

Asia, EMEA, North and South America

**VeKommunicate
1212 12th floor
Tower B, Emaar Digital Greens
Gurugram 121202**

For Further Information:

**T S Vishwanath: +91 9810977551;
vishwanath@vekommunicate.com**

**Krishnan Ramalingam: +91 9810042540;
krishnan.ramalingam@vekommunicate.com**

**Gracelle Gerber: +91 9650586622;
gracelle@vekommunicate.com**