APRIL 2020 VOL.9

POLICYPULSE

IN THIS ISSUE

FOREWORD

COVID-19 has had a devastating effect on countries across the world. Even countries with the most modern health facilities are reeling under the onslaught of a virus that has taken the world by storm. Even as countries are battling to save human lives and safeguard health, the economy in most countries is on a downward spiral providing no hope of a recovery in the near future.

Most importantly, for companies and world trade the global and regional value chains that have come to represent the Just-in-Time business model is under pressure. Even the most ardent supporters of globalization are now advocating that countries need to build domestic capacity for most products that are essential. The large-scale unemployment that countries may face in the aftermath of the crisis may lead to far more closure of borders.

Surely, the coming months will show how the existing model of cooperation and coalition across countries may get disrupted and new models may emerge. Policy Pulse will continue to closely monitor the developments across the globe and will keep you updated on changes that may have an impact on the companies and sectors.

We will continue to follow regulations and policies that will aid or impede economic growth and trade. This edition of the newsletter looks at some of the issues that have been a fallout of the current world situation and also other issues of importance to industry.

MACRO-ECONOMIC SNAPSHOT

COVID-19: Key Global Economic Indicators

The impact of COVID-19 touches every part of the economy, and can largely be divided into three categories:

- Demand Shock, as quarantines, travel restrictions, and global disruption have impacted the consumer goods & services, tourism, hospitality industries, and more.
- Supply Shock is the most complex as the global supply chain has stopped without a clear resolution point.
- Financial Shock, as lack of cash flow and liquidity threaten to sink vulnerable enterprises in a downward economic environment.

Global Trade

Besides its worrying effects on human life, COVID-19 has significantly slowed down the global economy. Over the last two decades the push for improved productivity has driven manufacturing, as well as many service industries, towards minimizing costs. Two key elements of this have been just in time delivery which meant firms holding minimum stocks and inventories; and outsourcing to reduce costs, which meant long supply chains.

The crisis has brought to the fore the vulnerability of both these processes. With disrupted supply chains and low stocks, firms are already finding it hard to maintain operations. As per “Trade and Development Report Update” issued by UNCTAD in March 2020, overall, the most impacted economies are the European Union (machinery, automotive, and chemicals), the United States (machinery, automotive, and precision instruments), Japan (machinery and automotive), the Republic of Korea (machinery and communication equipment), Taiwan Province of China (communication equipment and office machinery) and Vietnam (communication equipment).

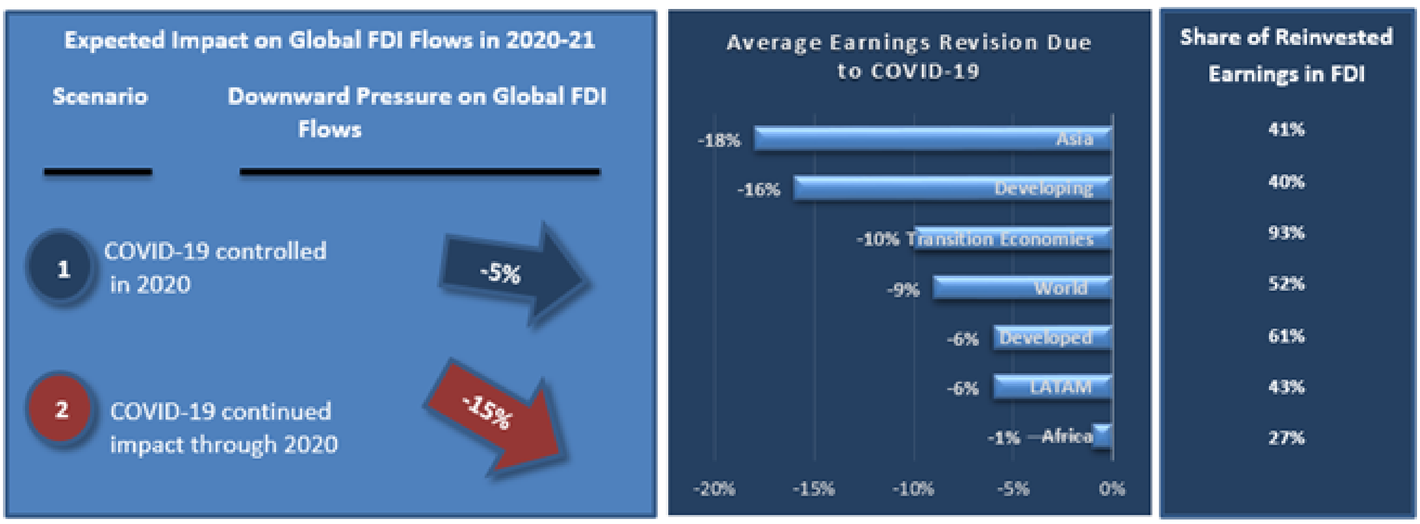
Foreign Exchange

The outbreak of the COVID-19 pandemic has been unprecedented, and its impact to world markets has been reflected in foreign exchange. Trends show that many currencies have lost its value against the US Dollar, such as Mexican Peso, Australian Dollar, New Zealand Dollar, Indian Rupee, Icelandic Krona, Turkish Lira, Belarusian Ruble, Israeli Shekel, Ukrainian Hryvnia, Colombian Peso, Russian Ruble, Uruguayan Peso, Brazilian Real, South African Rand and pegged currencies, Zambian Kwacha, Sudanese Pound, Kazakhstani Tenge, Indonesian Rupiah, Norwegian Krone, Chilean Peso, etc. While the crisis in other countries has spurred demand for US dollars, in Myanmar it has resulted in less demand due to reduced import/export activities. In early March, the Central Bank of Myanmar held currency auctions to temper the currency's appreciation. This led to a brief bounce back, but the currency continues on a trend of appreciation in Myanmar.

Foreign Direct Investment (FDI)

As per Investment Trends Monitor report issued by UNCTAD in March 2020, the outbreak and spread of Coronavirus (Covid-19) will negatively affect global foreign direct investment (FDI) flows. With scenarios of the spread of the epidemic ranging from short-term stabilization to continuation throughout the year, the downward pressure on FDI will be -5% to -15%. The report says that:

- The impact on FDI will be concentrated in those countries that are most severely hit by the epidemic, although negative demand shocks and the economic impact of supply chain disruptions will affect investment prospects in other countries.
- The outbreak of Covid-19 will slow down capital expenditures of multi-national enterprises (MNEs) and their foreign affiliates. Production locations that are closed or that operate at lower capacity will temporarily halt new investment in physical assets and delay expansions.
- Greenfield projects, M&As are generally long-term commitments to overseas markets. Greenfield investment projects that are already ongoing will also be affected by this. Announcements of new Greenfield projects could be delayed. Similarly, mergers and acquisitions (M&As) could also see a slowdown.



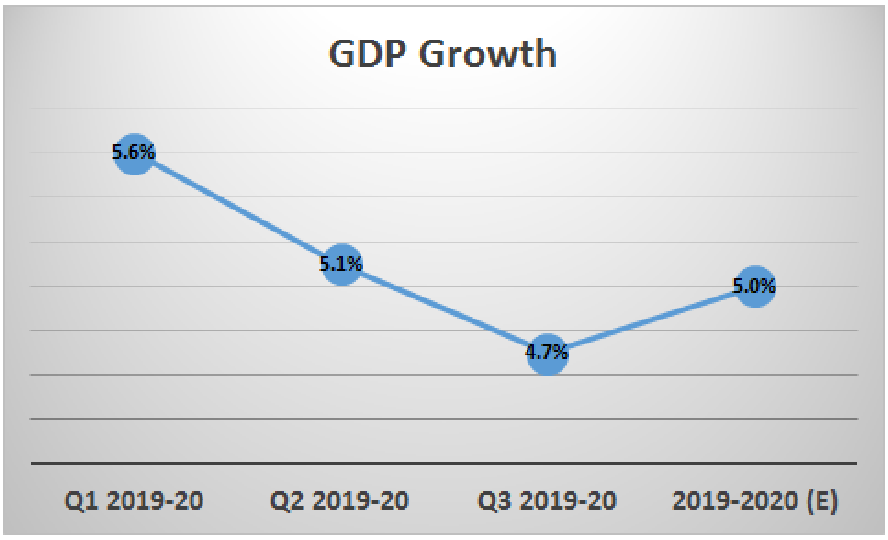
Source: UNCTAD

Key Economic Indicators of Indian Economy

As per the Monthly Economic Report issued by the Department of Economic Affairs, Ministry of Finance for the month February 2020:

Gross Domestic Product (GDP)

The growth of GDP in 2019-20 is estimated at 5.0 percent (second advance estimates) as compared to 6.1 percent in 2018-19. The growth of GDP was 4.7 percent for the third quarter (Q3) of 2019-20, as compared to the growth of 5.6 percent and 5.1 percent in first quarter (Q1) and second quarter (Q2) respectively of 2019-20.

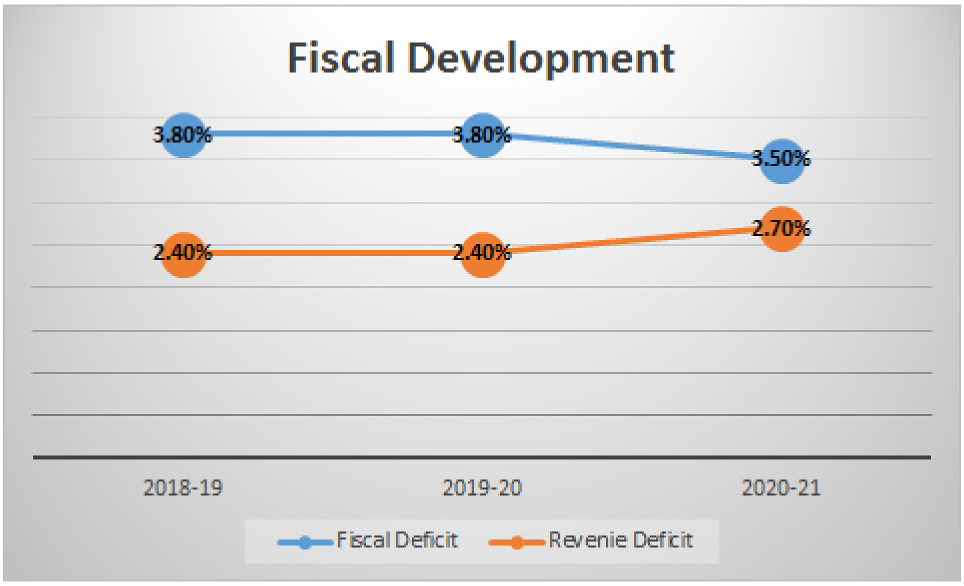


Inflation

- The consumer price inflation stood at 7.6 percent in January 2020, as compared to 7.4 percent in December 2019.
- Food inflation based on Consumer Food Price Index (CFPI) decreased to 13.6 percent in January 2020 as compared to 14.2 percent in December 2019, mainly due to decrease in inflation of vegetables.
- CPI inflation for fuel stood at 3.7 percent in January 2020 as compared 0.7 percent in December 2019 and 2.1 percent in January 2019.
- CPI core inflation (non-food non-fuel) stood at 4.2 percent in January 2020 as compared 3.8 percent in December 2019 and 5.2 per cent in January 2019.
- Inflation based on CPI (industrial workers) for January 2020 decreased to 7.5 percent as compared to 9.6 percent in December 2019. Inflation based on CPI (agricultural labourers) and CPI (rural labourers) stood at 11.0 percent and 10.6 percent respectively in January 2020.

Fiscal Development

- The fiscal deficit as percentage of GDP for 2020-21 has been set at 3.5 percent, as compared to 3.8 percent in 2018-19
- The revenue deficit as a percentage of GDP for 2019-20 was 2.4 percent, same as compared 2018-19. The revenue deficit for 2020-21 is budgeted to be 2.7 percent of GDP.



Merchandise Trade

- Merchandise exports and imports (in US$ terms) declined by 1.9 percent and 8.1 percent respectively in April-January 2019-20. Oil imports declined by 9.2 percent and non-oil imports declined by 7.7 percent in April-January 2019-20.
- Merchandise exports and imports (in US$ terms) declined by 1.7 per cent and 0.7 per cent respectively, during January 2020 over January 2019. During January 2020, oil imports increased by 15.3 per cent and non-oil imports declined by 6.7 per cent respectively over January 2019.

Balance of Payment

- India’s current account deficit (CAD) was 0.9 percent of GDP (US$ 6.3 billion) in Q2 of 2019-20, as compared to 2.9 percent of GDP (US$ 19.0 billion) in Q2 of 2018-19. The contraction of the CAD in Q2 of 2019-20 was primarily on account of lower trade deficit.

Foreign Exchange Reserves

- Foreign exchange reserves stood at US$ 476.1 billion as on 21st February 2020, as compared to US$ 412.9 billion at end-March 2019.

Exchange Rate

- The rupee depreciated against the US dollar, Pound sterling and Euro by 0.11 percent, 0.1 percent and 0.13 percent respectively in January 2020. However, it appreciated against and Japanese Yen by 0.02 percent in January 2020

External Debt

- India's external debt stood at US$ 557.5 billion at end-September 2019, recording an increase of 0.5 percent over the level at end-June 2019. Long-term debt was US$ 448.4 billion at end September 2019, as compared to US$ 447.3 billion at end-June 2019. Short-term external debt (by original maturity) was US$ 109.1 billion at end-September 2019, as compared to US$ 109.7 billion at end-June 2019.

Sectoral Growth

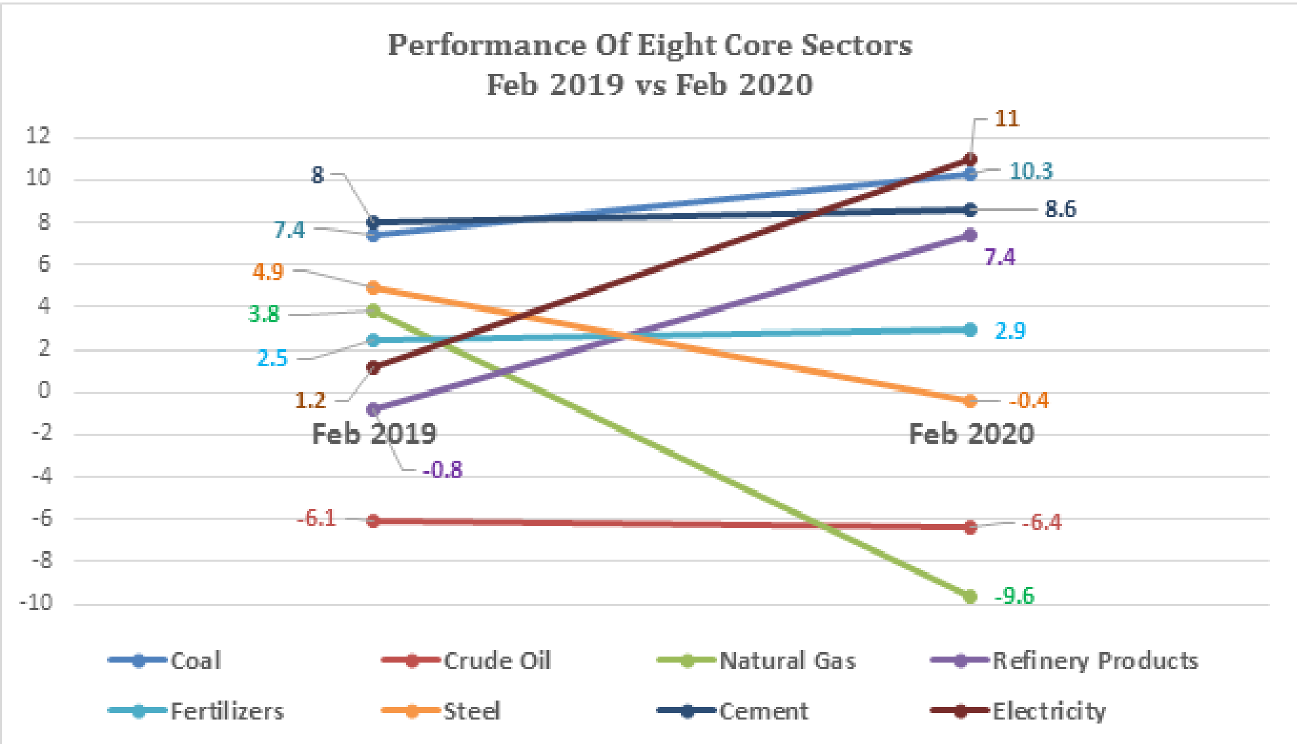
- Real gross value added (GVA) growth of agriculture and allied sectors is estimated at 3.7 percent in 2019-20, as compared to 2.4 percent in 2018-19.
- Real GVA growth of industry sector in 2019-20 is estimated at 1.8 percent, lower than 4.9 percent in 2018-19

Tax Collection

- The gross GST revenue collected in the month of March, 2020 is Rs. 97,597 crore of which CGST is Rs. 19,183 crore, SGST is Rs. 25,601 crore, IGST is Rs. 44,508 crore (including Rs. 18,056 crore collected on imports) and Cess is Rs. 8,306 crore (including Rs. 841 crore collected on imports).

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 132.9 in February 2020, which increased by 5.5 percent as compared to the index of February, 2019. Its cumulative growth during April to February, 2019-20 was 1.0 percent.
- Out of the eight core industries, coal, refinery products, fertilizers, cement and electricity sector have witnessed a positive growth in February 2020 in comparison to the rate of growth in February 2019. Other sectors such as steel, natural gas and crude oil have witnessed negative growth in February 2020.

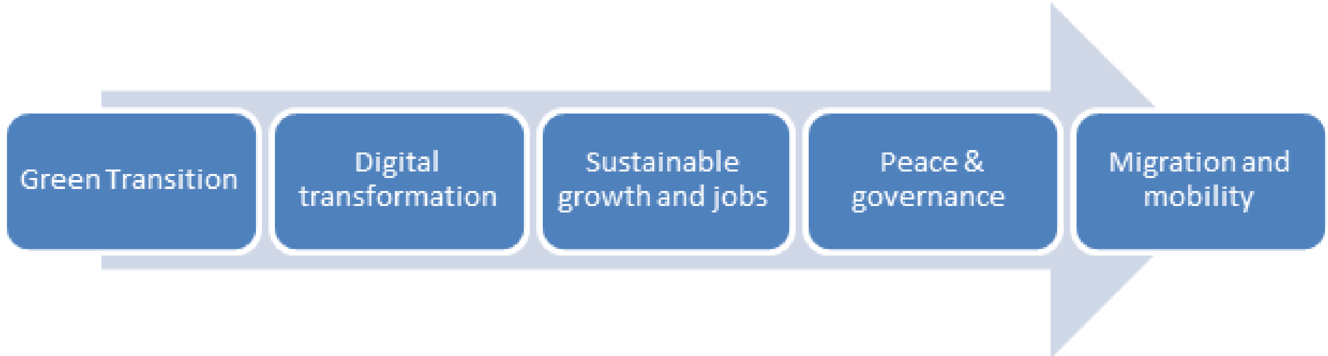


FTA UPDATES

EU's New Comprehensive Strategy For Africa

In order to strengthen the EU's strategic alliance with Africa, the European Commission has proposed a strategy document 'Towards a Comprehensive Strategy with Africa'. The proposal is a part of the ongoing dialogue between the EU and the African partners and will be discussed in the upcoming EU-AU Summit in Brussels in October 2020. This event will be the occasion to define joint strategic priorities for the years to come.

The strategy proposes to strengthen EU-Africa cooperation through partnerships in five key areas:



A. A partnership for green transition and energy access: To Maximize the benefits of the green transition and to minimize threats to the environment in full compliance with the Paris Agreement

B. A partnership for digital transformation: To boost the continent's digital transformation.

C. A partnership for sustainable growth and jobs:

- Substantially increase environmentally, socially and financially sustainable investments that are resilient to the impacts of climate change; to promote investment opportunities by scaling up the use of innovative financing mechanisms; and to boost regional and continental economic integration, particularly through the African Continental Free Trade Agreement.
- Attract investors by supporting African states in adopting policies and regulatory reforms that improve the business environment and investment climate, including a level-playing field for business.
- Rapidly enhance learning, knowledge and skills, research and innovation capacities, particularly for women and youth, protecting and improving social rights, and eradicating child labour

D. A partnership for peace and governance:

- Adapt and deepen EU support to African peace efforts through a more structured and strategic form of cooperation, with a particular focus on regions where tensions and vulnerabilities are the highest.
- Integrating good governance, democracy, human rights, the rule of law and gender equality in action and cooperation.
- Secure resilience by linking humanitarian, development, peace and security interventions at all stages of the cycle of conflicts and crises.

E. A partnership on migration and mobility: Ensure a balanced, coherent and comprehensive approach to migration and mobility

How Is It Different From India-EU Strategic Partnership?

In 2004, India and the European Union signed a strategic partnership, based on the shared values and principles of democracy, the rule of law, human rights and the promotion of peace and stability. Today, though, free trade negotiations are stalled and the two sides have yet to find common ground to move forward on key issues ranging from digital regulation to climate change. Indian Minister of External Affairs, Dr. S Jaishankar, during his visit to Brussels in August 2019, focused on the three priorities that India would like to work with the EU:

a) Increased mobility, an issue dear to India whose talented and educated youth is eager to gain experience abroad and earn higher wages

b) Improved market access for its growing industry, which is also keener than ever to invest outside India; and

c) Access to the services market, especially in the banking sector The upcoming EU-India Summit was actually slated for first quarter of 2020. However due to outbreak of COVID-19, the discussion got stalled. Please find below some key priority areas highlighted by both the authorities under the strategic document "EU-India Agenda for Action-2020":

<u>A. Foreign Policy and Security Cooperation</u>

- Strengthen foreign policy cooperation, in areas of mutual interest such as Asia, Africa, the Middle East/West Asia, Europe, and other relevant areas including through regular dialogue at appropriate levels
- Identify opportunities for strengthened cooperation and coordination in international fora, including a possible dialogue on gender equality, global humanitarian issues and disaster risk reduction

B. Trade and Investment, Business & Economy

- Continue engagement at multilateral level, notably on global economic cooperation and bilateral level through negotiations on the Broad-based Trade and Investment Agreement
- Implement a mechanism to facilitate investments of EU businesses in India.
- Make full use of the existing institutional mechanisms to resolve trade irritants, IPRs, Geographical Indications (GIs), public procurement, customs and competition policy
- Strengthen cooperation in the area of pharmaceuticals, in particular in the context of regular meetings of the EU-India Joint Working Group on pharmaceuticals, biotechnology and medical devices.
- In the context of India's 'Make in India' Initiative, strengthen exchanges and create favourable circumstances for investment, including public-private partnerships.
- Encourage EU and India business including SMEs to strengthen dialogue

C. Global issues/sector policy cooperation

- Climate Change: Develop cooperation on the implementation of the Paris Climate Agreement, Montreal Protocol and India-EU climate change dialogue
- Energy: Under the aegis of the EU-India Energy Panel and its working groups, expand energy cooperation for “Sustainable Energy for All” objectives, launched by the UN Secretary General
- Environment: Establish and implement an Indo-European Water Partnership (IEWP) programme, effective cooperation between the EU and India on water issues, notably in the context of India’s 'Clean Ganga' flagship programme, work towards promoting resource efficiency, contributing to low greenhouse gas emissions and climate resilient development.
- Research & Innovation: Pursue India-EU Science, Technology and Innovation Cooperation
- Information and communications technology (ICT): Create synergies between the "Digital India" initiative and the EU's “Digital Single Market”, next generation of global communication networks (5G) under the India-EU Joint ICT Working Group.

D. Migration & Mobility: Cooperation on migration and mobility issues of mutual interest, including through relevant recommendations, actions, training and capacity building

A comparison of EU's strategic partnership with Africa with India shows that, there are certain common parameters exist in both the strategic partnerships such as focus on climate change, environment, migration and partnership for peace and governance. The EU's strategic approach for Africa looks one dimensional, whereas, the EU's strategic approach for India covers the interest and opportunities for both parties. The factor which differentiate EU's strategic approach with India from Africa is that, both the EU and India shares equal engagement and market access opportunities. It talks about bilateral trade options and mutual investment opportunities for companies. It also covers major topics like R&D, IPR, ICT, etc, which will give Indian companies a platform to become more competitive. More interestingly, several government run schemes like Make in India, Skill India and Digital India are also covered in the mandate.

POLICY/REGULATORY BRIEF

Section I: Larger Policy/Regulatory Updates

Regulation Of Chemicals In Australia: A Possible Model For India

In a time when global manufacturing is struggling to remain functional and trade has reached dangerously low levels, the importance of raw materials and key inputs for several industries is glaringly evident. Chemicals are one such vital material input for several industries including textiles, paper, paints, cosmetics, cleaning compounds, consumer electronics, pharmaceuticals and agrochemicals. In addition to being the mainstay for these allied industries, chemicals are also an important contributor to India's economy in their own right. Exports of organic chemicals account for 5.5% of India's total exports between April 2019 and January 2020 and was the fifth largest exported commodity of India in terms of value in that period.

The Indian chemicals industry is heterogenous, in that it is composed of large scale units as well as a significant number of small and medium-sized companies (SMEs). Considering this diversity, the wide spectrum of dependent allied industries, the range of manufactured commodities and the international obligations under multi-lateral legally-binding agreements[1], there is a strong case for a unified yet comprehensive regulatory mechanism for this industry.

In this regard, the Indian government has already proposed a National Action Plan for Chemicals under the Ministry of Environment, Forest and Climate Change (MoEF&CC). This new policy

[1] India is a party to the Rotterdam Convention on the Prior Informed Consent Procedure for certain Hazardous Chemicals and Pesticides in International Trade, the Stockholm Convention on Persistent Organic Pollutants, the Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal; and the Strategic Approach on International Chemicals Management which is voluntary in nature.

framework recommends the development of an inventory and registration scheme for chemicals, a system for analysis and assessment of the risks of those chemicals and outlines plans to adopt the Globally Harmonized System (GHS) of classifying and labelling chemicals. Other proposals include the consolidation of India's existing legislation on chemicals and creation of a separate body for the implementation of the legislations and regulation of the industry.

Considering these developments, India may possibly take its cues from existing regional regulations like the REACH in the European Union. This article takes a look at the regulatory environment for management of chemicals in Australia.

Regulation in Australia

Australia adopted a new law- the Industrial Chemicals Act on 4 April, 2019 with an enforcement date of 1 July, 2020. This law creates a new framework for the regulation of imported or manufactured industrial chemicals. This does not include chemicals used in therapeutic goods and agricultural and veterinary chemicals. Common industrial chemicals may include those used in cosmetics, which encompass products such as makeup, soap, shampoo, deodorant, hair dye and other similar products; cleaning and other domestic products; various industries such as mining and metal extraction; fuel and oil; surface coatings; plastics; and engineering.

Accordingly, a new scheme – the Australian Industrial Chemicals Introduction Scheme (AICIS), will replace the current National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

AICIS defines an industrial chemical and requires importers to register their businesses before introducing an industrial chemical into the territory of Australia. Imports must also comply with the requirements of a category of introduction, which are based on the level of risk to human health and the environment from the introduction. There are 5 categories of imports:

1. Listed introductions- industrial chemicals that are already listed on the Australian Inventory of Chemical Substances (AICS). These require no new assessment. Currently, the inventory has over 40,000 chemicals listed in it.
2. Exempted introductions - very low risk chemicals
3. Reported introductions - low risk chemicals which require a pre-introduction report
4. Assessed introductions - Medium-to-high risk imports which must be authorised and require an assessment certificate issued by regulatory authority. Once there is

an assessment certificate for an industrial chemical, it will be listed on the Inventory after 5 years.

5. Commercial evaluations- The introduction is for the purpose of ascertaining the industrial chemical's potential for commercial application and its exposue to general public is controlled.

Companies will be able to continue to secure low volume and control permits for new industrial chemicals until at least 30 June 2022 and the following exemptions will still be allowed until 31 August 2022:

- research and development or analysis – manufactured in a fixed apparatus in a specific location;
- research and development or analysis – import only;
- cosmetic use (no unreasonable risk);
- cosmetic use (no unreasonable risk and non-hazardous chemical); and
- non-cosmetic use (no unreasonable risk).

Additionally, AICIS will establish a new Australian Inventory of Industrial Chemicals (AIIC) to replace the Australian Inventory of Chemical Substances and specify certain record keeping and reporting obligations. AICIS shall also implement a ban on the testing of cosmetics on animals. The AICIS will be supported by a range of offence provisions, which will include fault-based, strict liability and civil penalty provisions.

To act in conjunction with this law, a new legislative framework has also been proposed for environmental management of the industrial chemicals. This includes:

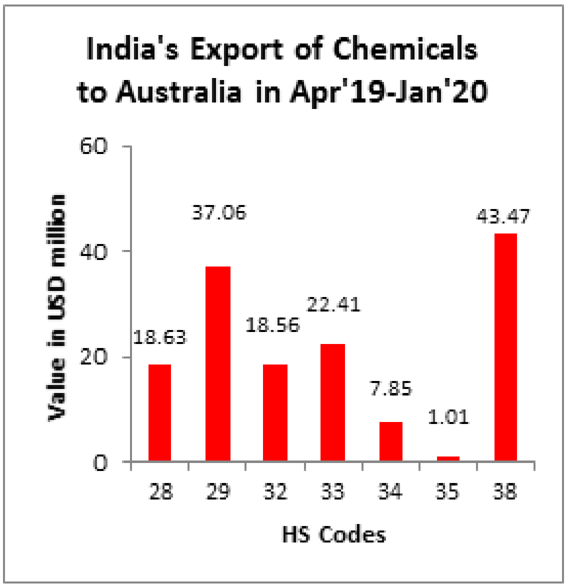
Based on this, a draft of National Standard for Environmental Risk Management of Industrial Chemicals was notified to the World Trade Organisation for consultation on 27 February 2020.

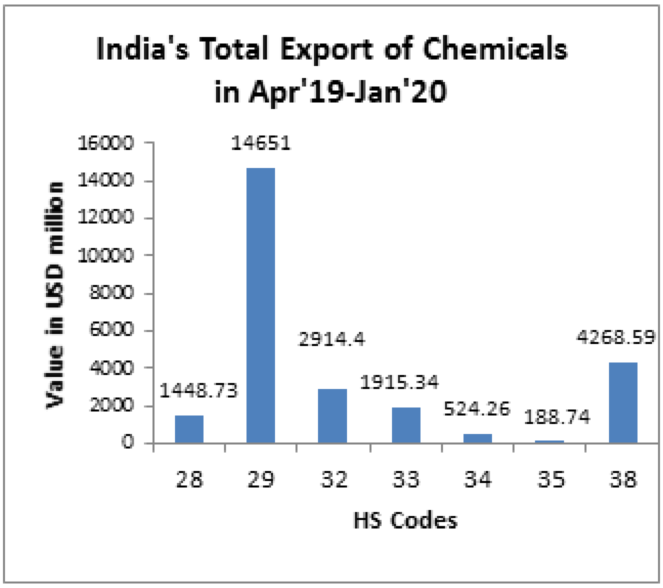
Under the standard, chemicals will be classified into seven "environmental schedules" representing low, intermediate and high levels of concern. A chemical that has a variety of uses may have different risk assessments and would therefore be classified in multiple environment schedules, depending on the level of environmental concern in each case. Each scheduling decision will depend on the scope of the risk assessment undertaken, including the usage and the volume of the chemical used.

When an industrial chemical has been categorised, it will be listed in the relevant schedule of the ICEM Register, along with information on its prohibition or restriction. For each schedule of the ICEM Register, there will be a corresponding pre-defined set of risk management measures that will be appropriate for managing the risks posed by chemicals listed in that schedule. This will allows users to be aware of the types of measures they can expect to be applied to chemicals in each schedule. Some, or all of these risk management measures may be assigned to an industrial chemical or a particular use of that chemical.

These broad reforms in the assessment of environmental risk of industrial chemicals and regulation of their registration and uses may provide greater incentive for importers to introduce greener, safer new industrial chemicals. The development of such regulatory mechanisms may act as a model for India to introduce similar legislative frameworks.

Trade Values





Source: DGCI &S, Department of Commerce

It is clear from the values depicted in figures 1 and 2, that the current export of industrial chemicals from India to Australia is not significant when compared to the total exports of these commodities from India (it is 0.57% share). The new regulatory changes in Australia will establish clarity regarding the rules governing industrial chemicals and may hence act as a facilitator and augment India's exports.

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

Section II: Region/Country Updates

COVID-19 Impacts US Foreign Medical Device Inspections

The US Food and Drug Administration is postponing foreign inspections including for medical device manufacturing facilities through at least April 2020 as multiple countries grapple with the coronavirus pandemic. The FDA move takes immediate effect, and applies to all foreign inspection activities.

For medical device manufacturers based outside the US and dependent on FDA inspections to obtain US market registration, this announcement means delays in premarket application reviews. Furthermore, the agency will conduct random quality system inspections as well as on a pre-announced basis, which may impact foreign companies due to uncertainty. FDA states that in lieu of physical device and manufacturing facility inspections, alternative methods will be utilized, including:

- Denial of entry of unsafe products into the US;
- Physical examinations and sampling of devices at US borders prior to importation;
- Reviewing device manufacturers' previous compliance histories;
- Requesting records and documentation in advance or instead of on-site inspections

USA mainly imports medical devices from Mexico, China, Germany, Ireland, Japan, etc. As per ITC Trade Map, in 2019, US's total imports of medical devices from the world were US$ 96 billion, of which the above top five countries enjoys a share of 56 % of US's total imports of medical devices. Major imported medical devices in the US are instruments and appliances used in medical, surgery, dental and veterinary services, orthopedic appliances, instruments and apparatus for physical or chemical analysis, etc. India's exports of medical devices to the US were US$ 550 million in 2019 and the above mentioned products also feature in India's export basket to the US.

Due to COVID-19, the US FDA has postponed its foreign market inspections, which has caused delay in getting market authorization for new companies and new devices. However, companies which already have a track record of exporting medical devices to the US can reap the benefits of alternative methods adopted by the US FDA and export medical devices to the US. This shows that, Indian exporters which are already exporting medical devices to the US can export their devices by using the alternative methods mentioned above.

COVID-19 outbreak triggers regulatory interventions in Asia-Pacific region

Novel coronavirus has inspired numerous regulatory bodies that govern medical devices to take steps to ease import restrictions and expedite registration processes for needed goods, seeking to ensure that regulations do not block the development or supply of devices that could save lives. Please fine below a roundup of regulatory updates from the Asia-Pacific region pertaining to the outbreak:

<u>Chinese regulatory bodies roll out numerous emergency regulatory changes</u>

- The Chinese National Medical Products Administration (NMPA) announced that they will expedite the registration of medical protective clothing devices that meet relevant standards from the EU, US, or Japan, as well as the Chinese standard GB 19082-2009 (Technical Requirements for Single-Use Protective Clothing for Medical Use), as a temporary emergency measure.
- The Chinese Center for Medical Device Evaluation (CMDE) announced adjustments to their medical device application acceptance and consultation services. The CMDE encourages the use of their online eRPS system and will temporarily suspend on-site acceptance of applications and consultation services.
- The CMDE published two new technical review guidelines on nucleic acid detection reagents and antigen/antibody detection reagents designed for IVDs that will detect COVID-19.
- The CMDE announced extensions for renewals and data correction requests due to delays caused by the COVID-19 outbreak. Extensions for renewal applications can now be filed within three months of the date the outbreak dissipates. Applications that have been notified to submit additional technical reviews or data corrections from February 12, 2019 to the end of the outbreak will be given an additional year to submit the information.
- The CMDE published a guidance document on registering devices that use deep learning technology to identify lung abnormalities. The guidance specifies the basic requirements, as well as the requirements for risk management, software research materials, clinical trials, instructions, and software updates for these devices.
- Due to a shortage of medical masks in Hubei province, the provincial NMPA office will allow importation of unregistered masks as an emergency measure. While the measure is in effect, only an import authorization is needed for qualifying products. Manufacturers will need to work with licensed distributors in Hubei in order to import under this allowance.

Singapore names devices temporarily exempt from registration requirements

- The Singapore Health Sciences Authority (HSA) issued the Health Products (Import, Wholesale and Supply of Medical Devices — Exemption) Order 2020. The Order exempts specified devices (particulate respirators, protective gear, surgical masks, and thermometers for measuring human body temperature) from registration requirements, and it exempts importers and wholesalers of those devices from establishment licensing requirements.
- During the time when the Exemption Order is in effect, the named devices can be imported for commercial (or other non-personal) purposes through a simplified notification route, which is outlined on the HSA website.

Malaysia provides application for face mask registration exemption

- In order to safeguard an adequate supply of face masks, the Malaysian Medical Device Authority (MDA) announced that companies can apply for exemption from registration for these devices through a Notification of Medical Device for Special Access. Devices that have obtained this exemption are not permitted to be advertised.

Australia provides registration exemption for specified goods from authorized laboratories

- Australia's Therapeutic Goods Administration (TGA) issued the Therapeutic Goods (Medical Devices—Novel Coronavirus) (Emergency) Exemption 2020 for devices used for the diagnosis, confirmatory testing, prevention, monitoring, treatment, or alleviation of the novel coronavirus (COVID-19) infection.
- The exemption is available for those devices imported, exported, manufactured, or supplied by a laboratory that is a member of the Public Health Laboratory Network. Devices supplied for purposes relevant to the public health threat posed by the novel coronavirus emergency will circumvent several registration requirements, including the Essential Principles, conformity assessment procedures, and inclusion in the Australian Register of Therapeutic Goods (ARTG).

Thailand reclassifies alcohol-containing gel products as cosmetic goods

- In order to avoid shortages, the Thai Food and Drug Administration (FDA) announced on March 11 that it would remove alcohol-containing gel products such as hand sanitizers from the category of regulated medical devices. These products were formerly regulated as cosmetic goods and will be legally defined as such again. This step will allow such products to reach the public considerably faster.

Gulf GHS Regulation Reached Its Final Stage

The Gulf Standardization Organization (GSO) has shared the final draft regulation on the UN's Globally Harmonized System (GHS) of classification and labelling of chemicals to member countries for approval. The final draft could then be adopted as a technical regulation at a meeting of national standards bodies in mid-November this year. The six countries in the trade bloc the Gulf Cooperation Council (GCC) – Bahrain, Kuwait, Oman, Saudi Arabia, the United Arab Emirates (UAE) and Qatar – would then need to transpose this into their domestic legislation, which could take two to three years.

There have not been significant changes since the draft was published in October last year. But they added that other stakeholders, such as the regional chemical manufacturing industry, chemical logistics sector and a host of fast-moving consumer goods companies, have also endorsed the standard. None of the GCC's members currently follow the GHS and there is no consistent system for classifying and labelling chemicals in the region. However, many large chemicals companies voluntarily comply already because of their trade partners in developed countries, such as the USA and the EU.

India's total chemical product exports to the Gulf countries were US$ 2.2 billion in 2018-19 and US$ 1.8 billion in 2019-20 (April to Jan). India's major export basket of chemical products to the GCC countries organic chemical followed by inorganic chemicals, essential oils, tanning and dyeing extracts, etc. Under the proposed National Action Plan for Chemicals, the Ministry of Environment, Forest and Climate Change (MoEF&CC) has already recommended the development of an inventory and registration scheme for chemicals, which outlines plans to adopt the Globally Harmonized System (GHS) of classifying and labelling chemicals in India. Though, the UN GHS has not been implemented in India, but as per information available, big Indian companies while exporting chemical products are already meeting the UN GHS norms; however, small and medium enterprises need to upgrade their system in order to compete in the market.

US FDA Temporarily Easing Nutritional Labelling Rules To Maintain Food Supply

On 1st April 2020, the US Food and Drug Administration (FDA) has issued temporary policies on nutrition labeling that will make it easier for restaurants and food manufacturers to sell food that was not originally intended for retail sale.

The Federal Food, Drug, and Cosmetic Act requires food that's not labeled for consumer sale can't be sold directly to consumers. Further, restaurants and similar retail food establishments that are part of a chain with 20 or more locations have to provide nutrition information (including calorie declarations) on menus and menu boards so that the information be available to customers when they make their order selections.

Due to the COVID-19 outbreak, restaurants and food manufacturers have large quantities of food on hand that is not labeled for retail sale and cannot be sold in restaurants. As a result, some chain restaurants and similar retail food establishments are temporarily changing their business practices to address the pandemic's impact on operations. For example, some dine-in operations are temporarily switching to a "take away only" or take out only" format, which involves creating new or modified online ordering portals and printed takeout menus for their stores. Additionally, some chain restaurants and similar retail food establishments may be experiencing temporary disruptions in the food supply chain which may impact availability of their standard menu items.

Hence, the US FDA has provided temporary flexibility to chain restaurants and similar retail food establishments to allow sell of food intended for restaurant use directly to retail consumers without providing the nutrition information. The policy change will remain in effect only for the duration of the public health emergency.

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