

# POLICYPULSE



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## Thank You!

Thank you for taking the time to go through this latest edition of **PolicyPulse**. We are so encouraged and enthused by the positive feedback received to date. Please do continue to write to us and let us know if you have any specific topic or industry you'd like us to cover or comment on. We have added in a few new sections based on feedback received. Trust you find these valuable.

Our team at **VeKommunicate** remains committed to providing information that's relevant, topical and based on verifiable industry research and data.

**PolicyPulse** is our monthly newsletter and is sent on a personal basis to key stakeholders like yourself. Hence we value your comments and look forward to hearing from you soon.

Your continued support is highly regarded and appreciated.

Best wishes

**Team VeKommunicate**

# MACRO-ECONOMIC SNAPSHOT

## Global Economy: Growth May Show An Upward Trend In 2020

The global economy has witnessed a serious slowdown in 2019, with growth recorded at 3 percent which is relatively low from 3.8 percent in 2017. Such growth is a consequence of rising trade barriers, elevated & uncertain trade and geopolitics, peculiar factors causing macroeconomic damage in several emerging market economies; and other factors, such as low productivity growth and aging demographics in advanced economies.

Most mainstream forecasters expect that the worst of the storms are past, and they are expecting global growth to rebound in 2020. IMF predicts that, *“global growth in 2020 is projected to improve modestly to 3.4 percent. Growth for advanced economies is projected to slow to 1.7 percent in 2020, while emerging market and developing economies are projected to experience a growth pickup from 3.9 percent in 2019 to 4.6 percent in 2020”*. Majority of these estimates may be driven by recoveries in stressed emerging markets, such as Turkey, Argentina, and Iran, and the rest by recoveries in countries where growth slowed significantly in 2019 relative to 2018, such as Brazil, Mexico, India, Russia, and Saudi Arabia. Let's discuss some major factors which may influence global growth in 2020:

### Trade Disputes

Despite the preliminary agreement between the United States and China of a “phase one” trade deal that promises at least a cease-fire between the world's two biggest economies, the trade wars are far from over. Uncertainty is still looming around the “phase one” deal with China, as this is not yet converted into a done deal as yet and many of similar agreements have come undone in months past.

These trade tensions are not limited to the fight between Washington and Beijing. The ongoing trade fights between USA and Europe, which include tariffs on European steel, tariffs on European goods due to the Airbus-Boeing dispute and tariffs on French goods in response to a controversial French digital tax, may influence the global growth.

The UK will formally exit the Union at the end of January 2020; however, negotiating a free trade agreement between the UK and Europe before the end of the year is almost impossible to meet. Delay and failure to sort out two key issues, such as tariff rates between Britain and the Union and regulatory standards between the two sides, could lead to another Brexit cliff edge at the end of the year, with all that requires for new investment, business and consumer confidence, and growth.

## Influence of China

The Chinese economy clearly shows a slow trend. However, IMF expects an insignificant growth of 5.8 percent, well below that of recent years, while the World Bank expects a slightly better 6.1 percent growth. As the World Bank notes, one big tool that China has, is massive indebtedness. It might work in the short run, but it would risk making barely profitable companies less productive and would impact future growth. If China does face a big slowdown, the pain will be felt elsewhere, especially among many developing countries.

## The Debt Bomb

The World Bank, in a special report, noted that global debt levels reached an all-time high. Debt growth is particularly alarming in emerging markets, the World Bank says, which hold about \$50 trillion in debt, making them particularly vulnerable to any shock, whether a slowdown, or trade wars. The report says that, *“Developing countries have already been through three debt crises—in the 1980s, the 1990s, and the 2000s—with hugely painful consequences. A fourth might be on the way. The fourth wave looks more worrisome than the previous episodes in terms of the size, speed, and reach of debt accumulation in emerging markets”*.

Here are some performance assumptions of major economies around the globe in 2020:

- Global recession or a marked plunge in global growth unlikely
- US Economy likely to slow down further next year but consumers will shield the economy
- Chinese Economy - growth likely to drop below 6 per cent but consumption will support growth
- Eurozone - likely to lose further momentum and could grow more slowly
- UK economy - economic outlook shrouded by political and economic uncertainty
- Japan may escape the expected recession, but growth likely to decelerate markedly
- Asia (ex-Japan) - growth should pick up marginally, led by India
- Middle-East economic outlook particularly worrying
- Global Financial Markets - several downside risks

## India: 2020 At A Glance

In another sharp downgrade for the Indian economy's outlook, the Asian Development Bank (ADB) has revised the estimate for India's growth rate in the financial year 2019-2020 downwards to 5.1 per cent from the previous forecast of 6.5 per cent. It has also cut the estimate for the next fiscal, FY 2020-21 to 6.5 per cent from 7.2 per cent. In India growth has slowed substantially as a result of a credit crunch and weakening domestic demand. This is another addition to the series of downward revision of India's economic forecast for the ongoing fiscal. The Reserve Bank of India (RBI) in its monetary policy announcement in December 2019 revised its FY 2019-20 outlook to 5 per cent from 6.1 per cent.

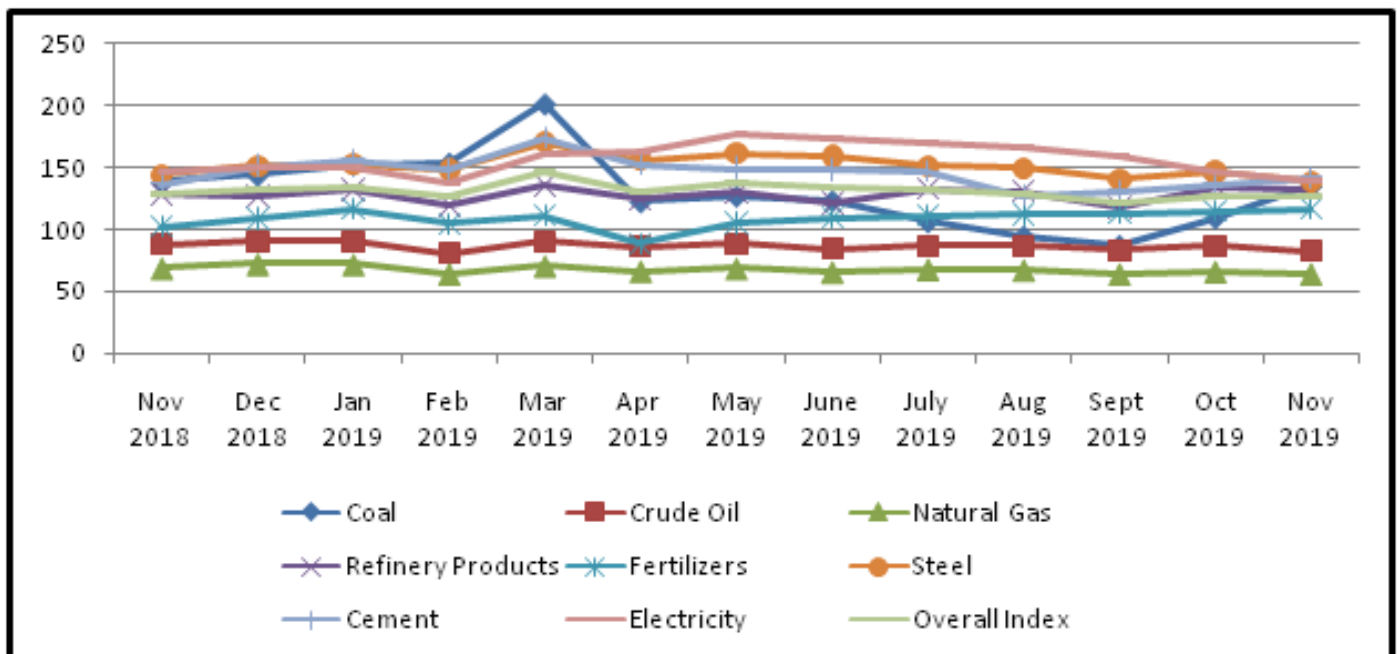
The recently issued performance index of Eight Core Industries shows 40.27 percent weight of items included in the Index of Industrial Production (IIP). The combined Index of Eight Core Industries stood at 126.3 in November, 2019, which declined by 1.5 percent as compared to the index of November, 2018. Its cumulative growth during April to November, 2019-20 was 0.0 percent.

### Sectors

- Coal production (weight: 10.33 percent) declined by 2.5 percent in November, 2019 over November, 2018. Its cumulative index declined by 5.3 percent during April to November, 2019-20 over corresponding period of the previous year.
- Crude Oil production (weight: 8.98 percent) declined by 6.0 percent in November, 2019 over November, 2018. Its cumulative index declined by 5.9 percent during April to November, 2019-20 over the corresponding period of previous year.
- The Natural Gas production (weight: 6.88 percent) declined by 6.4 per cent in November, 2019 over November, 2018. Its cumulative index declined by 3.1 percent during April to November, 2019-20 over the corresponding period of previous year.
- Petroleum Refinery production (weight: 28.04 percent) increased by 3.1 percent in November, 2019 over November, 2018. Its cumulative index declined by 1.1 percent during April to November, 2019-20 over the corresponding period of previous year.
- Fertilizers production (weight: 2.63 percent) increased by 13.6 percent in November, 2019 over November, 2018. Its cumulative index increased by 4.0 percent during April to November, 2019-20 over the corresponding period of previous year.

- Steel production (weight: 17.92 percent) declined by 3.7 percent in November, 2019 over November, 2018. Its cumulative index increased by 5.2 percent during April to November, 2019-20 over the corresponding period of previous year.
- Cement production (weight: 5.37 percent) increased by 4.1 percent in November, 2019 over November, 2018. Its cumulative index declined by 0.02 percent during April to November, 2019-20 over the corresponding period of previous year.
- Electricity generation (weight: 19.85 percent) declined by 5.7 percent in November, 2019 over November, 2018. Its cumulative index increased by 0.7 percent during April to November, 2019-20 over the corresponding period of previous year.

### Performance of Eight Core Industries Since Nov 2018



(Data Source: Ministry of Commerce and Industry, Government of India)

## PARLIAMENT WATCH 2020



The budget session of Parliament is less than a month away. The session is expected to begin at the end of January, with the Budget being presented on the 1st of February (Saturday). On ten previous occasions, the budget has been presented on a Saturday. In fact, the last time it happened, was in 2015. This was the budget presented by the then Finance Minister Arun Jaitley, which restarted the conversation about GST and set the stage for direct benefit transfer through Jan Dhan accounts etc. The Budget Session is also the longest session of Parliament. It stretches from end January to end of April. During this period Parliament meets for approximately 30 days.

While the focus of the session is on the Budget, there is more to the session. An important aspect of the session is the setting of the governments' policy agenda for the year. On the first day of the session, the President will address MPs from both Lok Sabha and Rajya Sabha in the Central Hall of Parliament. In his speech (prepared by the

government) he will outline the priorities of the government for the coming year. These priorities will be then translated into government policy or legislation that the government pilots through Parliament.

During Prime Minister Narendra Modi's first term 133 Bills were passed by Parliament. Another 46 Bills which were in the pipeline lapsed after the dissolution of Lok Sabha. In the first six months of his second term many of the lapsed Bills like consumer protection, motor vehicles amendment, code on wages, triple talaq etc. have been reintroduced and passed. This has resulted in almost a clean legislative plate before Parliament in 2020. The upcoming budget session, therefore, would be the one to watch out for. It will act as a weather pane for the legislative agenda that the government intends to roll out over the next four years. There are some indicators which can shed light on the government's intent when it comes to issues around land, labour and capital. Let's take land first. The NDA government's first attempt legislative attempt in this direction was the 2015 amendment to the



land acquisition act. The amendment was relaxing the requirements for the acquisition of land for strategic and developmental activities. The Bill faced stiff opposition in Parliament and had to be put in cold storage. The government then encouraged state governments to amend the central law in its applicability to their states. Which many of them did.

But there hasn't been a major legislative push on the subject of land in Parliament since 2015. Over the last decade, successive governments have been working towards digitisation of land records. The 2019 general election manifesto of the BJP mentions that this process will be completed on a mission mode basis. The manifesto also talks about second-generation land reforms to ensure title guarantee for the landholder and reduce land-related litigation. Studies have pointed out land dispute litigation accounts for 2/3rd of all pending cases in the country.

Another one suggests that land disputes take an average of 20 years to resolve. With a comfortable majority on its own in Lok Sabha and improved floor management in Rajya Sabha, the government could be looking towards fulfilling its electoral promises on land reforms.

On the other hand reform in the labour sector is something that the government is actively pursuing. In the last six months, three significant Bills have been introduced related to the sector.

The first Bill deals health, safety and working conditions in establishments employing more than 9 workers. The second Bill is the Industrial Relations Code Bill which deals with industrial disputes and trade unions. The third Bill is focusing on the social security of workers, like provident fund and maternity benefit. These three Bills will consolidate 25 existing laws. These bills are currently being examined by the parliamentary committee on labour, headed by Lok Sabha MP Shri Bhartruhari Mahtab. In Prime Minister Narendra Modi's first term, the legislative focus of the government was on the financial sector. Approximately 26% of the total laws passed were from this sector. Some of them being FDI in Insurance, GST, Insolvency Code, Fugitive Economic Offender law etc. The Insolvency and Bankruptcy Code continues to evolve. In the upcoming session, the government will push for the passage of an amendment to the law. This amendment will set the minimum threshold for initiating resolution by financial creditors and by allottees real estate projects. The Companies Act has also seen amendments, especially towards

decriminalising of offences. However, the major announcements for catalyzing the economy will have to wait for the budget.

The government's attention is also towards the use of personal data. The DNA Technology (Use and Application) Bill and the Personal Data Protection Bill have been introduced to provide the regulatory mechanism for the usage of data of individuals. Both of these Bills are also being scrutinized by parliamentary committees. The DNA Bill is being examined by a committee headed by Rajya Sabha MP, Jairam Ramesh. Lok Sabha MP, Smt Meenakshi Lekhi is chairing a joint committee of the two houses which is scrutinizing the government's personal data protection bill. The committee process is a structured opportunity for stakeholders to get their voice heard in the lawmaking process.

The policy initiatives of the government are not limited to the laws being made by Parliament. Over the last two years, the government has been working on policies on subjects like e-commerce, online pharmacies and the new education policy. Some of these are closer to finalization and might see movement during the year.

Parliament and politics go hand in hand. During the course of the year, 73 Rajya Sabha MPs will be retiring. The electoral outcomes in the states during the last few years will get reflected in the composition of Rajya Sabha. This will determine whether the government or the opposition control the decision making in the upper house. Another aspect of politics is the composition of the council of ministers. The current strength of the council stands at 56 ministers. Constitutionally there is space for 24 more ministers in the council. It remains to be seen whether the Prime Minister will expand or reshuffle his cabinet in the coming months. The next four months will also provide clarity in what the government intends to do over the next four years.

*(This article has been prepared by Mr. Chakshu Roy, Head of Legislative and Civic Engagement, PRS Legislative Research)*



# POLICY BRIEF

## Global Regulatory Outlook 2019



It's the year 2020. India is gearing up to become a \$5 trillion economy within the next 5 years, and as suggested by experts, a significant contribution toward this growth has to come from exports. In this scenario, regulatory compliance becomes a priority, and here's why.

With a rise in bilateral and multilateral trade agreements and establishment of cross border value chains, trade competitiveness has also increased. As a result, policy makers now rely on regulations as a tool for the agenda of trade protectionism. An analysis of India's trade with existing FTA partners also suggests that non-tariff barriers and administrative hurdles are among the key reasons for our exporters being generally unable to capitalise on the benefits of an FTA.

With this in mind, regulatory considerations must now play a bigger role in strategic decision making for businesses. This article

takes a look back at 2019, and provides a brief overview of some of the major regulatory developments which took place across selected sectors.

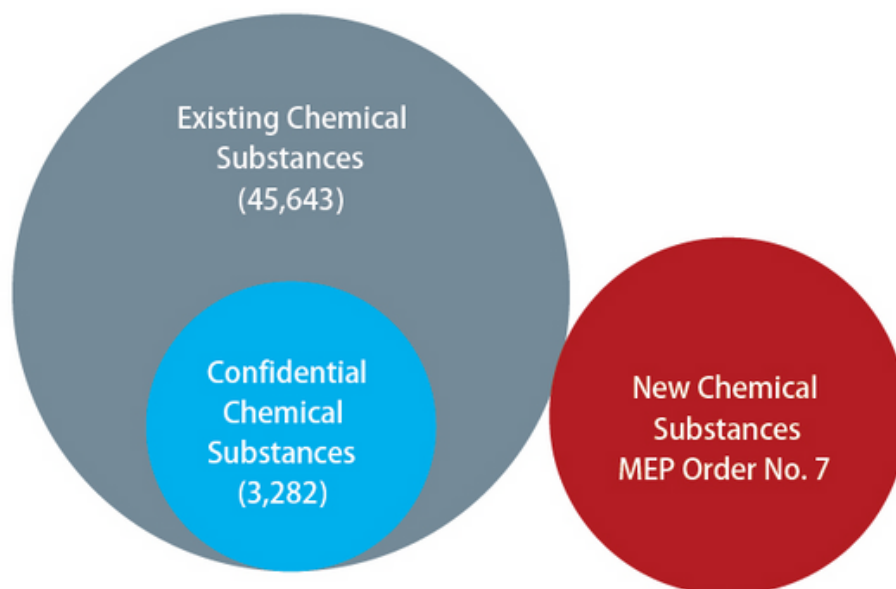
### **China- Regulation of Chemical Substances**

China's Ministry of Ecology and Environment published two Draft Regulations in 2019 (colloquially known as China REACH) which regulate chemicals: Environmental Risk Assessment and Control Regulation for Chemical Substances and the Measures on the Environmental Management of New Chemical Substances (Amendment to MEP Order 7). These are expected to become the overarching legislation governing existing and new chemical substances but with an emphasis on the control of environmental risk. Some pertinent points of these regulations are:

- It governs both existing substances and new substances that are not included in the Inventory of Existing Chemical Substances of China (IECSC).
- Any company manufacturing, processing and using, and importing a chemical substance

would need to provide the MEE with a report including basic information about the substance, including its name, quantities and uses.

- A maximum time limit of 5 years has been set for the protection of confidential business information related to substance identity.
- MEE will establish a plan for the risk assessment of chemical substances subject to prioritised assessment.
- Companies manufacturing, processing and using, and importing a substance in the plan would need to provide information, including data on emissions, physico-chemical properties, toxicology and eco-toxicology.
- New chemical substances with annual production or import volumes of less than one metric ton and polymers with less than two percent of new chemical monomer or polymers of low concern (PLC) will only require a record filing.



### **China- Amendments to Drug Administration Law**

The National People's Congress of China passed amendments to the Drug Administration Law (DAL), which took effect on December 1, 2019. The amendments include:

- Establishment of the Drug Marketing Authorization Holder (MAH) System including new evaluation and approval systems.
- Adoption of a drug traceability system and a unified quality management system for drug retail franchise operations and online drug sales.
- Overhaul of the clinical trial approval and drug review and evaluation processes.
- Efforts to reduce the price of foreign import drugs as well as speed up the import drug registration process for drugs that are urgently needed for public health

## Indonesia- Halal Assurance



Indonesia issued a draft technical regulation for mandatory implementation of Halal product assurance in particular products. This assurance will be given in the form of a Halal certificate issued by Halal Insurance Agency or other Halal Agencies registered with Halal Product Assurance Organizing Agency (BPJPH), Ministry of Religious Affairs of Indonesia. The products covered by this technical regulation include Food and beverages products, Traditional medicine and health supplements, Medicines and Prescription drugs (excluding psychotropics), Cosmetics, chemical products and genetically engineered products, Clothing, headgear and accessories, Household appliances, stationery and office equipment among others.

## Indonesia-2D barcode in Food and Drugs

The National Agency of Drug and Food Control (NADFC) of the Republic of Indonesia issued regulation on 2D Barcode Application in Drug and Food Control.

This regulation specifically regulates graphical representation of digital data in a two-dimensional format with high decoding capacity that can be read by optical devices used for identification, tracking and tracing. The application of 2D Barcodes as regulated in this decree includes medicines, traditional medicines, health supplements, cosmetic and processed food which are produced domestically and/ or imported into Indonesian territory for trading.

*Note: Although this regulation was issued in 2018, it was notified to the World Trade Organisation (WTO) in December 2019.*



**EU: REACH amendments**

The European Union issued some amendments concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). These amendments (currently a draft) lend clarity regarding the duties of registrants pertaining to updates of their registration dossiers. These amendments apply to only the updating obligations under Article 22(1)(a)-(i) of REACH. Previously, Article 22 of REACH states that updates should be undertaken 'without undue delay' in the cases provided in Article 22(1)(a)-(i). The Draft Regulation identifies two timeframes for specific situations: updates to be done within 3 months and others to be done within 6 months. Some examples are:

- Updates to be done within 3 months
- Change in a registrant's status or identity
- Change in tonnage band
- New identified uses and new uses advised against
- Updates to be done within 6 months
- Change in composition of substance
- New knowledge of risk to human health

**EU: Amendment to General Food Law**

The European Union notified amendments to the General Food Law intending to improve the transparency of the EU risk assessment process carried out by the European Food Safety Authority (EFSA). Upon enforcement, all scientific data, studies and other information supporting applications as well as other requests for a scientific output by EFSA shall be made publicly available proactively, with the exception of duly justified confidential information, early on in the EU risk assessment process.

EFSA will establish and manage a database of studies commissioned or carried out (at pre-submission phase) by business operators to support a future application or notification in relation to which Union law makes provisions for EFSA to provide a scientific output, including a scientific opinion. To this end, business operators are required to, without delay, notify EFSA of the title and the scope of the study, the laboratory or testing facility carrying out the study, and the starting and planned completion dates of any study commissioned or carried out by them to support an application or a notification. The notification obligation will also apply to laboratories and other testing facilities located in the Union carrying out those studies, and also to laboratories and other testing

facilities located in third countries insofar as set out in relevant agreements and arrangements.

This notification obligation is significant because an application or notification shall not be considered valid or admissible where it is supported by studies that have not been notified, unless the applicant or notifier provides a valid justification for non-notification of such studies.

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

## WTO Notifications In 2019

The World Trade Organisation (WTO) is a global international organization dealing with the rules of trade between nations. Its chief function is to ensure smooth and free trade flow. WTO is a forum for governments to negotiate trade agreements.

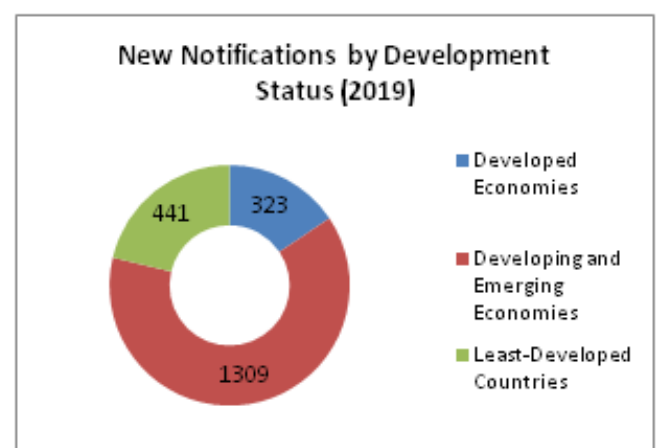
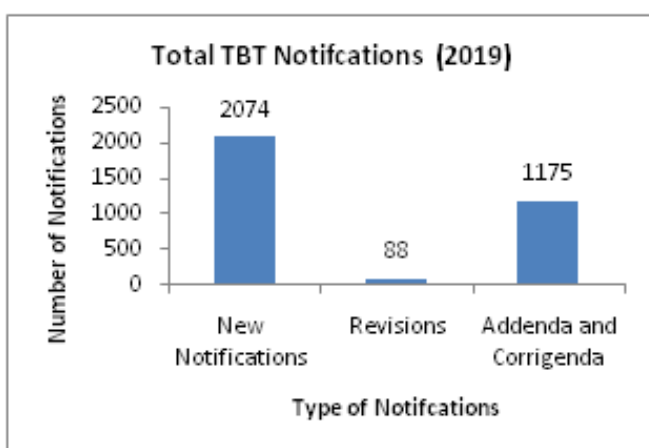
The WTO Agreements on the application of Sanitary (for protection of human and animal health) and Phytosanitary (for protection of plant health) Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT) try to strike a balance between the uses of standards in international trade.

These agreements provide a stable and transparent framework to help producers of goods and services, exporters and importers conduct their business.

The WTO has 164 members, accounting for 98% of world trade. A total of 22 countries are negotiating membership. Each member files notifications which are reviewed by the relevant bodies of the WTO. This ensures transparency in the multilateral trading system. The current article presents an analysis of the notifications issued at the WTO in 2019. The article is divided in two sections, one part giving an overview of the TBT notifications and the second part giving an overview of the SPS notifications.

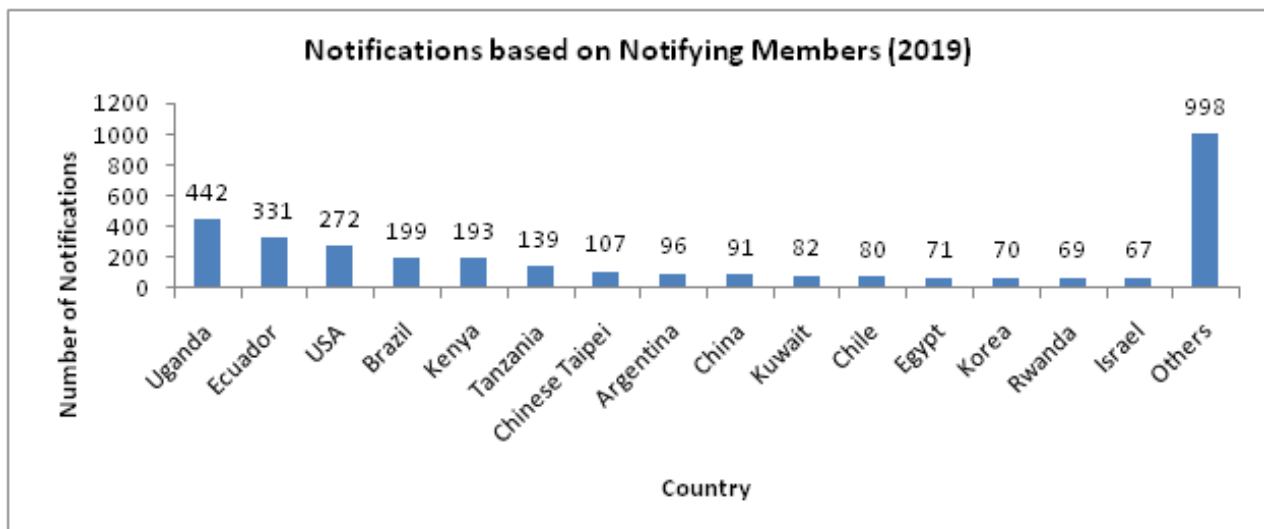
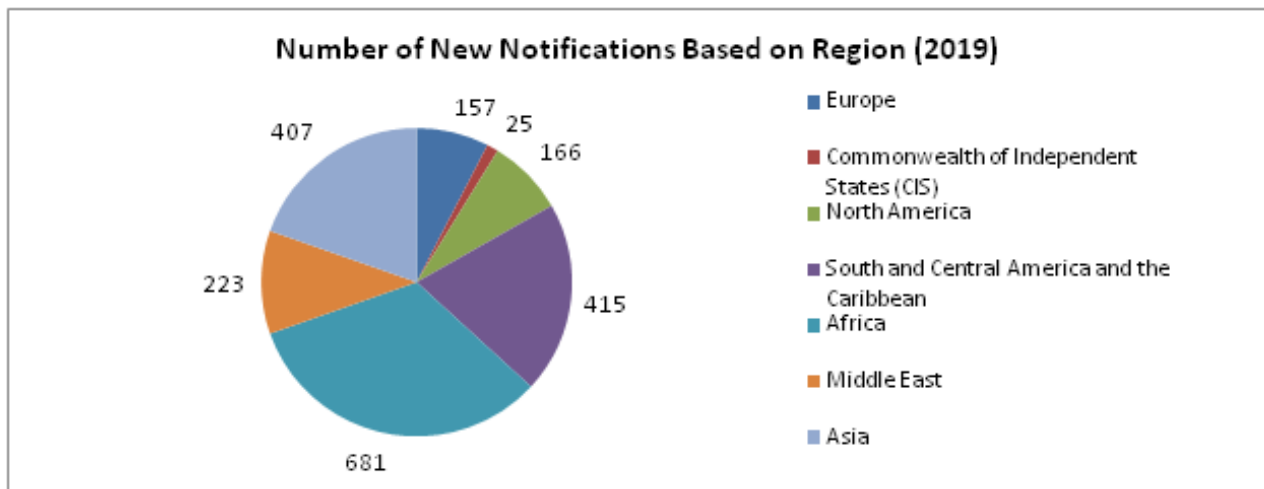
### Technical Barriers to Trade (TBT)

A total of 3337 notification were issued at the WTO in the year 2019. The notifications are issued in the formats: new/regular, revisions, addenda and corrigenda. Out of the 2704 new notifications issued, 1309 were the ones by developing and emerging economies, 441 by least developed countries and 323 were by developed economies.



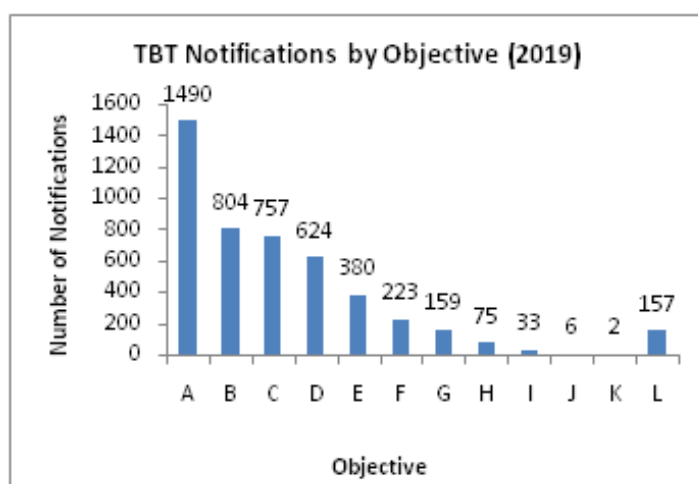
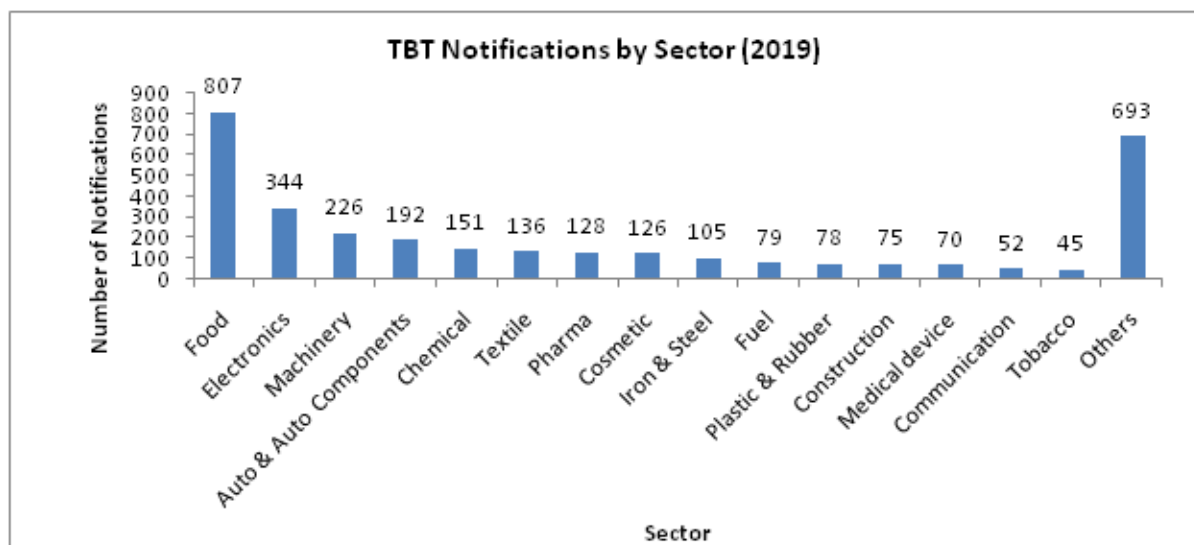


On categorising the new notifications based on the geographical regions, Africa was seen as the most active member in notifying at the WTO with 984 total notifications out of which 681 were new notifications. Uganda and Ecuador were among the top two countries from this region with 442 and 331 new notifications respectively. United States of America and Brazil were positioned next after this region with 271 and 199 new notifications respectively. United States of America and Brazil were positioned next after this region with 271 and 199 new notifications respectively.

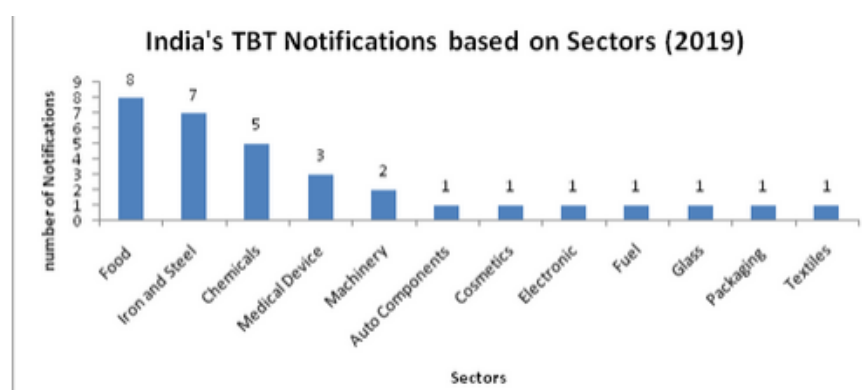


In 2019, the most regulated sector with maximum number of notifications was the food sector with 807 notifications followed by electronics, machinery, auto and auto components and chemicals with 344, 226, 192 and 151 notifications respectively. On classification of the notifications based on their objectives, subject of protection of human health and safety was regulated the most with 1490 notifications. Other important subjects of concern were quality requirements, consumer information focusing on labelling, prevention of deceptive practices and consumer protection, environment protection, harmonisation, reducing trade barriers and facilitating trade.

In 2019, the most regulated sector with maximum number of notifications was the food sector with 807 notifications followed by electronics, machinery, auto and auto components and chemicals with 344, 226, 192 and 151 notifications respectively. On classification of the notifications based on their objectives, subject of protection of human health and safety was regulated the most with 1490 notifications. Other important subjects of concern were quality requirements, consumer information focusing on labelling, prevention of deceptive practices and consumer protection, environment protection, harmonisation, reducing trade barriers and facilitating trade.



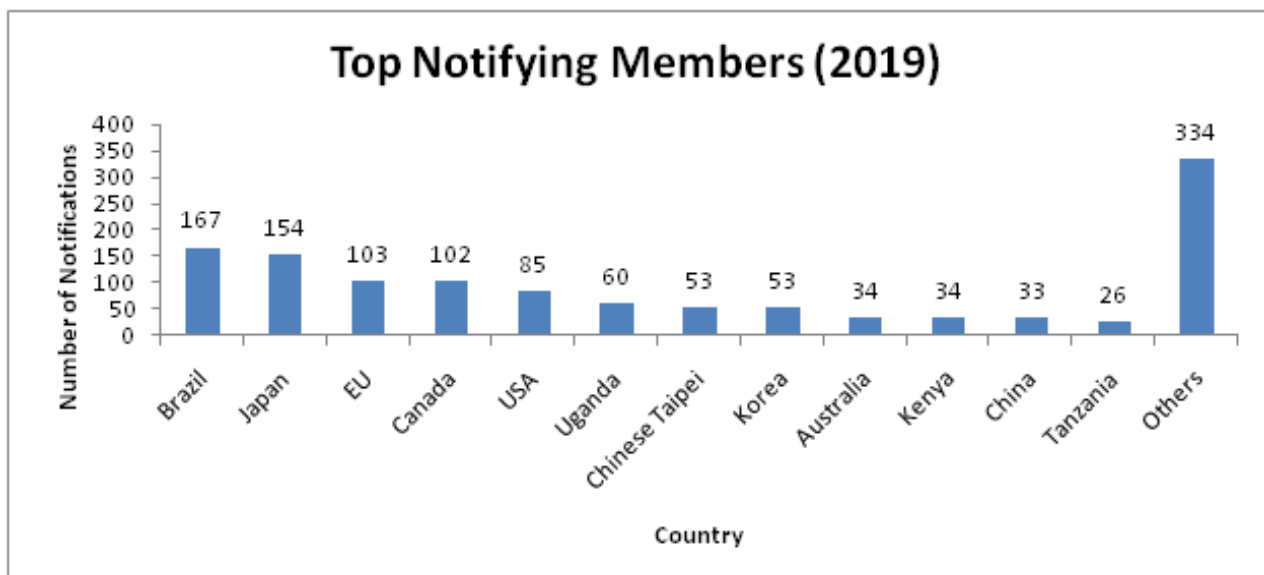
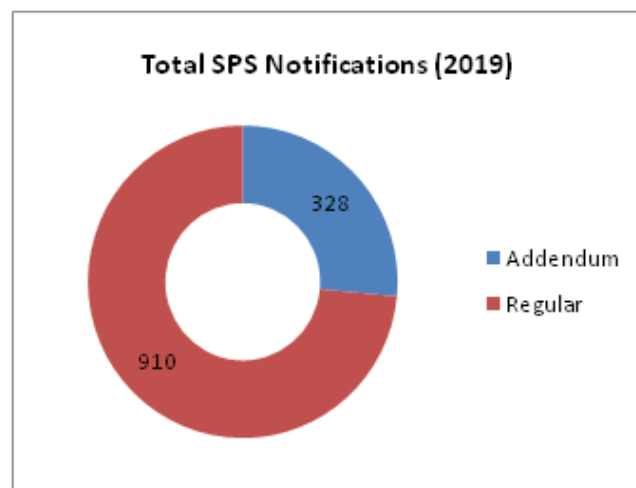
Notifications by Objective		
Code	Objective	Number of Notifications
A	Protection of human health or safety	1490
B	Quality requirements	804
C	Consumer information, labelling	757
D	Prevention of deceptive practices and consumer protection	624
E	Protection of the environment	380
F	Harmonization	223
G	Reducing trade barriers and facilitating trade	159
H	Protection of animal or plant life or health	75
I	Cost saving and productivity enhancement	33
J	National security requirements	6
K	Not specified	2
L	Other	157



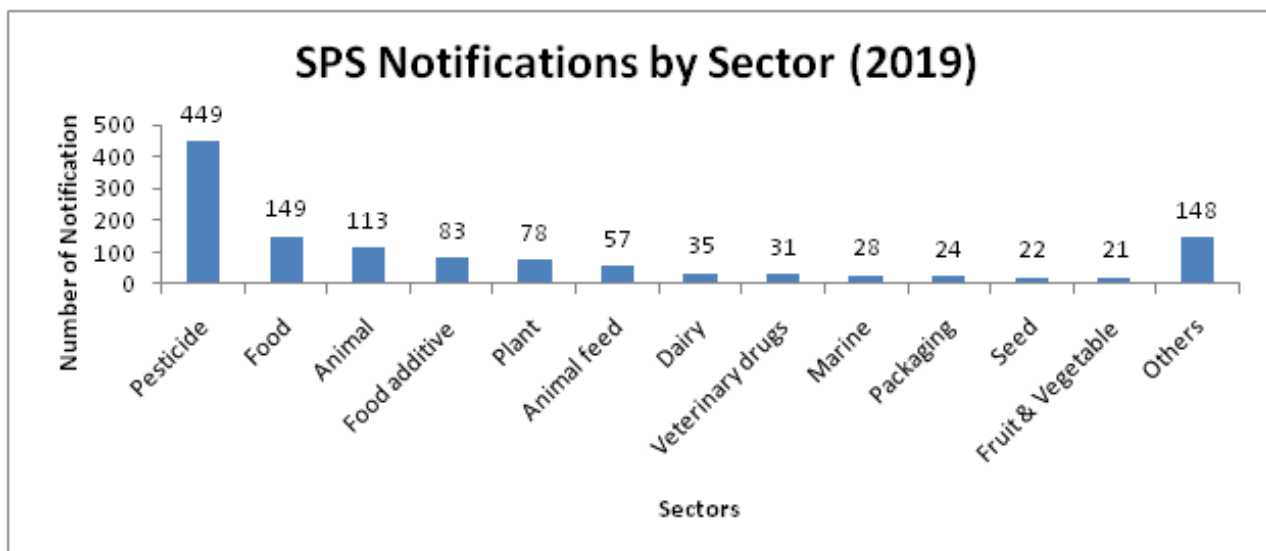
After analysing the TBT notifications notified at the WTO, it was observed that India issued 32 notifications in 2019. Major sectors covered by these notifications were Food with 8 notifications, Iron and Steel with 7, Chemicals with 5, Medical Devices with 3 and machinery with 2 among others.

### Sanitary and Phytosanitary Measures (SPS)

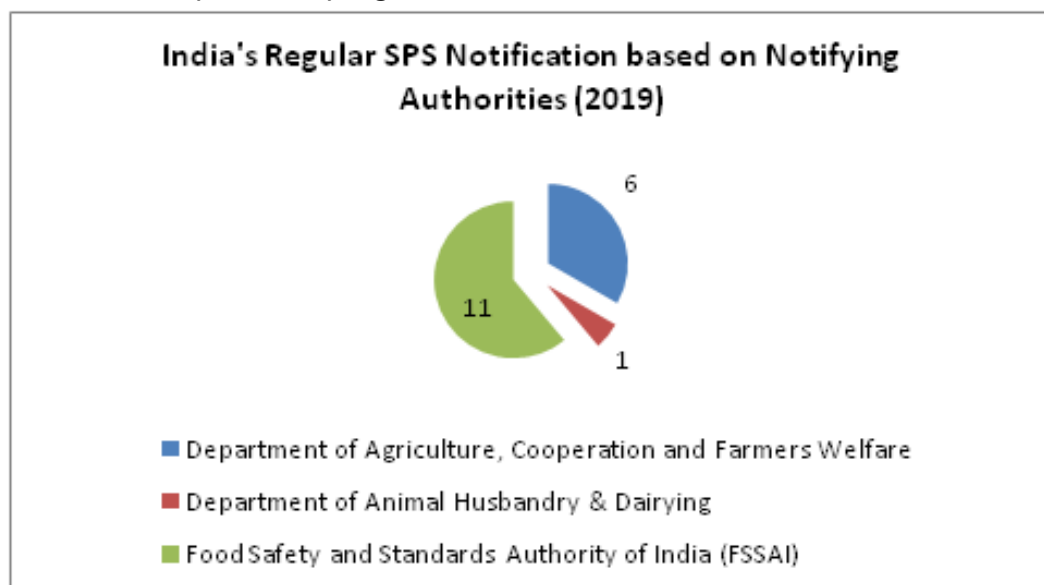
A total of 1762 notifications were issued at the WTO, out of which 1238 were relevant to India in 2019. Among these, 910 were regular notifications and other 328 were addenda. Brazil and Japan were the most active notifying members with 167 and 154 notifications respectively.



Out of the notified issues, pesticide regulations were the maximum with 449 notifications. It was followed by issues related to food with 149, animal with 113 and food additives with 83 notifications among others. This is indicative of the fact that countries are becoming more concerned about the chemicals and pesticides coming in contact with food products and keeping pesticides under strict surveillance.



On analysis notifications issued by India, it was observed that 19 notifications were issued in 2019 at the WTO. Out of these 18 notifications were regular and 1 was Corrigendum. It was noted that the maximum number of notifications were proposed by the Food Safety standards Authority of India (FSSAI) followed by Department of Agriculture, Cooperation & Farmers Welfare and Department of Animal Husbandry & Dairying.



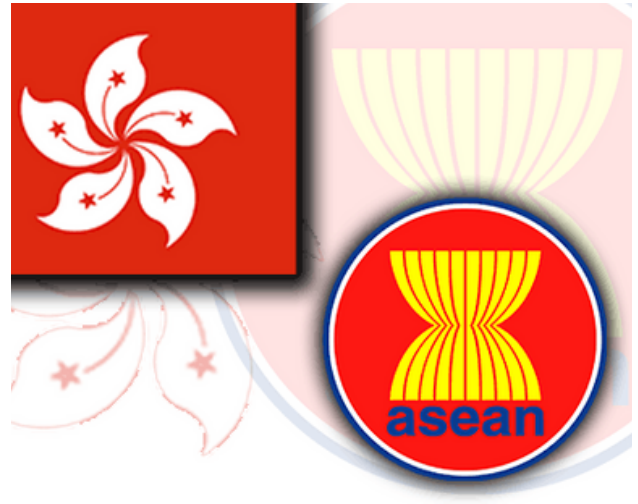
*(This article has been prepared by Ms. Aishwarya, Research Associate and Ms. Anjali Chauhan, Research Analyst, RV-VeKommunicate)*

# FTA UPDATES

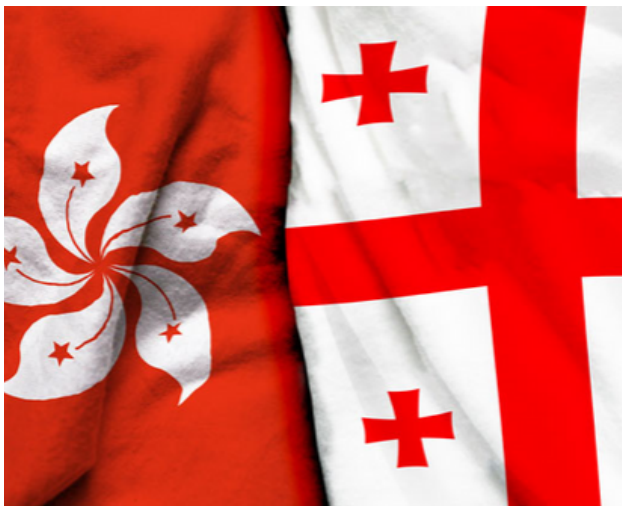
## List Of FTAs: Signed And Entered Into Force In 2019



Eurasian Economic Union-Iran Free Trade Agreement has entered into force on 27 October 2019.



ASEAN-Hong Kong Free Trade Agreement has entered into force on 11 June 2019



Hong Kong and Georgia Free Trade Arrangement has entered into force on 13 February 2019



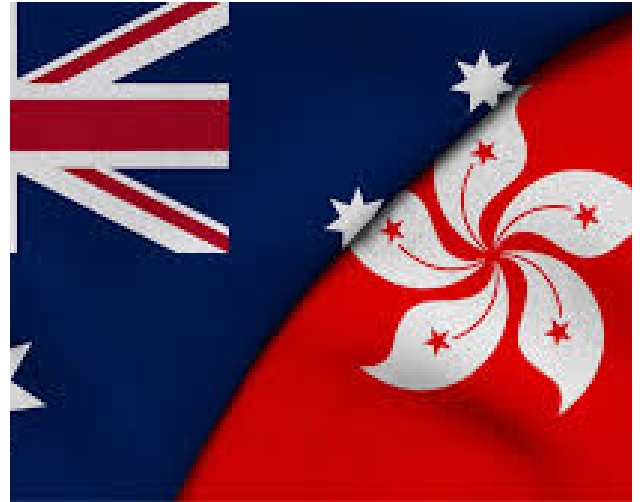
Japan- European Union Economic Partnership Agreement has entered into force on 1 February 2019



## List Of FTAs: Signed But Not Yet In Effect In 2019



Eurasian Economic Union and Serbia have signed an FTA in 2019 but it has not entered into force as yet.



Australia and Hong Kong have signed an FTA in 2019 but it has not entered into force as yet.



Australia and Indonesia have signed an FTA in 2019 but it has not entered into force as yet.



China and Mauritius have signed an FTA in 2019 but it has not entered into force as yet.



Eurasian Economic Union and Singapore have signed an FTA but it has not entered into force as yet.



## List Of FTAs: Negotiations Started In 2019



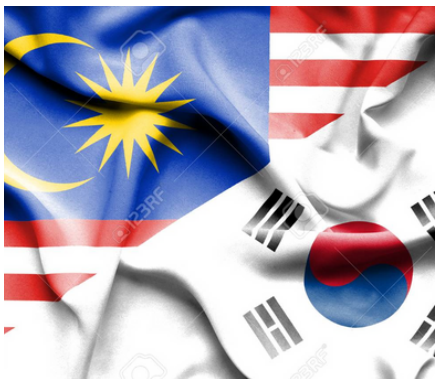
**India and Iran  
preferential trade  
agreement negotiation  
started in 2019.**



**Indonesia and Morocco  
preferential trade  
agreement negotiation  
started in 2019.**



**USA and Japan FTA  
negotiation started in  
2019.**



**South Korea and Malaysia  
FTA negotiation started  
in 2019.**



**S Korea-Russia bilateral  
economic partnership  
agreement negotiation  
started in 2019.**



**Malaysia and Iran FTA  
negotiation started in  
2019.**



**S Korea and Philippines  
FTA negotiation started  
in 2019.**



**Bangladesh and Bhutan  
FTA negotiation started  
in 2019.**

# PHARMA & MEDICAL DEVICE NEWS

## US FDA Finalizes E-submissions For Medical Devices



In 2018, the United States FDA proposed updating existing rules for various types of premarket applications, including premarket approval (PMA) submissions. Instead of requiring medical device manufacturers to submit multiple copies in both paper and electronic formats, the US EPA proposed eliminating paper submission and mandating a single electronic submission.

The FDA has now issued a final rule amending its former requirements in line with the earlier proposal. Paper and multiple copies will no longer be required, and medical device manufacturers are required to submit one electronic copy of an application. The rule further clarifies that both e-Copies (electronic files that are “created and submitted on CD, DVD, or flash drive and mailed to the FDA”) and e-Submissions (files “produce by an electronic submission template” and “transmitted over the internet”) fall under the category of electronic copies.

This rule will take effect from January 15, 2020. It will amend the regulations for the following submission types:

- Premarket Notification
- Confidentiality of Information Certifications
- Investigational Device Exemption (IDE)
- Premarket Approval (PMA)
- PMA Supplement
- Humanitarian Device Exemption (HDE)

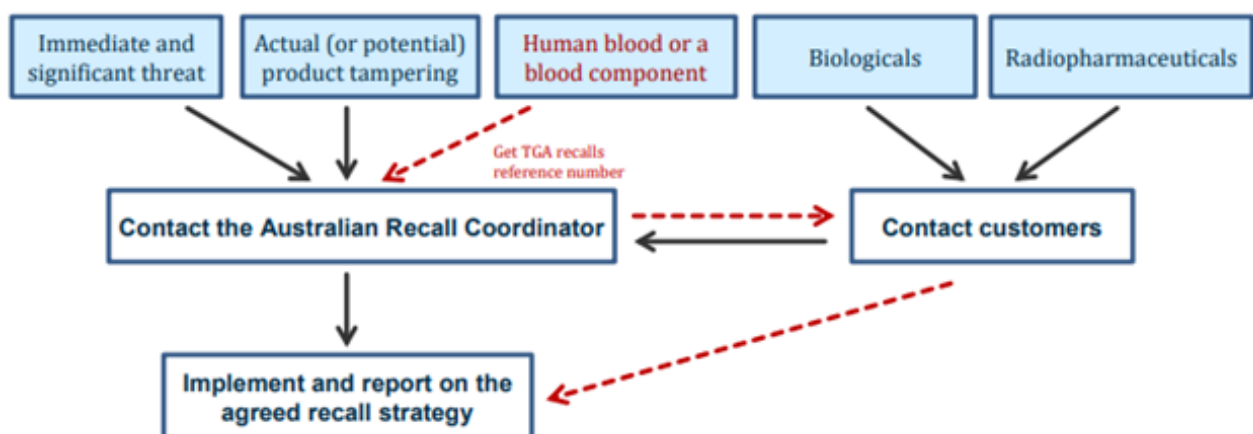
According to the rule, this action is part of FDA’s implementation of Executive Orders (EOs). Under these EOs, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction while allowing the Agency to achieve public health mission and fulfill statutory obligations. The economic impact analysis that accompanied the final rule states that the final rule will produce cost-savings for firms without imposing any additional regulatory burdens for submissions or affecting the Agency’s ability to review submissions.

## Australia Updating Uniform Recall Procedure



The Australian Therapeutic Goods Administration (TGA) has issued an updated version of the Uniform Recall Procedure for Therapeutic Goods (URPTG). It does not feature substantial revisions affecting the structure of the document, but there are several points of clarification that may be necessary for sponsors (including manufacturers and distributors) to avoid mistakes associated with the recall process.

### Recall Procedure





## EU New Guidance On Medical Device Sampling Criteria



European regulators have issued two new guidance documents, which address sampling criteria for medium-risk medical devices and in-vitro medical devices (IVDs), and clarify Medical Devices Regulation (MDR) codes for designation of Notified Bodies to the Regulation.

### MDR and IVDR sampling criteria

First, the European Medical Device Coordination Group's (MDCG) guidelines provide definitions of sampling criteria for Class IIa and IIb medical devices under the MDR, as well as for Class B and C IVD products under the In-vitro Diagnostic Medical Devices Regulation (IVDR).

Both new regulations require assessment of technical documentation of:

- At least one representative device per generic device group for MDR Class IIb and IVDR Class C devices; and
- At least one representative device for each category of devices for MDR Class IIa and IVDR Class B devices.

### MDR, IVDR codes for Notified Bodies

Second, MDCG's guidance clarifies information regarding codes used for designation of Notified Bodies under the new Regulations. These codes are designed for use by European authorities to define the scope of Notified Body designations under the MDR and/or IVDR, as well as by Notified Bodies themselves to indicate their staff qualifications as well as qualifications necessary for particular device assessments.

These codes may be very broad and, furthermore, unambiguous authorization of personnel to codes and the assignment of codes to a device are not always straightforward. However, the notified body's system needs to ensure, in all cases, that the authorization of personnel and team allocation for the conformity assessment of a device ensures adequate knowledge and expertise. The document lays out three main code types:

- MDA/MDN pertains to device design and intended purpose; to be used for allocation of staff to review device technical documentation. These codes may target either a field of

medical application or a device's physical/technological principles.

- MDS is applicable to devices with specific characteristics; used for allocation of staff for technical documentation reviews as well as for auditing special processes in some cases.
- MDT is applicable to technologies and processes related to manufacturing of devices; used for allocation of manufacturing site auditors. MDT code assignment should be based on production processes for a device itself as well as for upstream production processes.

## Saudi Arabia Easing Medical Device Registrations Through Single E-platform



Saudi Arabia's Saudi Food and Drug Authority (SFDA) have rolled out a single registration platform for all medical device market authorization, authorized representation and related applications to be submitted to the regulator. The new system provides a single platform for submitting Medical Device Marketing Authorization (MDMA), Medical Device National Registry (MDNR), Saudi Authorized

Representative and related applications to SFDA. Previously, Saudi Arabia market applicants had to utilize individual systems to submit MDMA, MDNR and other applications to Saudi regulators.

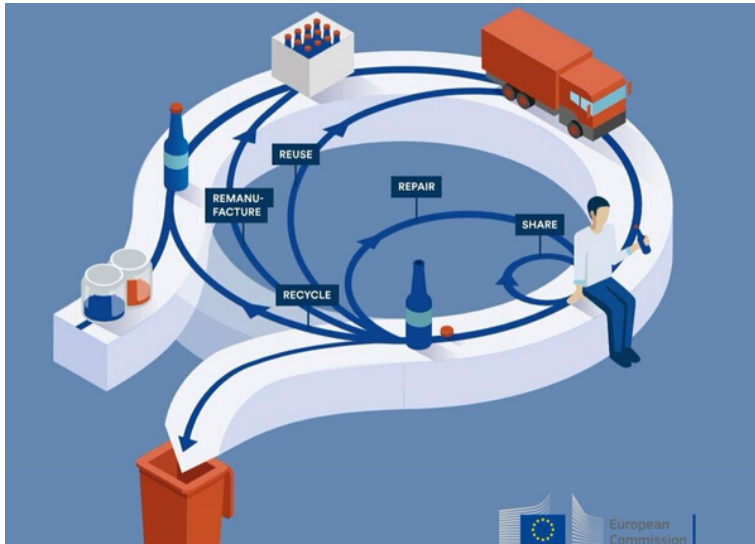
**Deadlines** for migration to the new system According to SFDA, Saudi medical device market registrants and in-country representatives face a January 26, 2020 deadline to open new accounts and transfer both existing and in-process applications over to the new system. Following that deadline, any applications not yet migrated to the new system will be cancelled.

**Implications** for SFDA medical device registration going forward The launch of new system lays more groundwork for SFDA's anticipated overhaul of Saudi Arabia's medical device regulatory system in early 2020.



# MARKET UPDATES

## EURATEX Circular Economy Action plan



European textile and clothing industry body EURATEX has completed its four year (2016-2019) circular economy action plan to ensure sustainable resource use and tackle urgent environment, social and economic challenges.

In December 2015, the European Commission established a unique comprehensive strategy, the Circular Economy Action Plan. The plan aimed to boost jobs, growth and investment while protecting environment and natural capital. It included 54 actions covering the whole cycle of materials and products – from production and consumption to waste management and the market for secondary raw materials. As of December 2019, more than 90% of actions have been delivered.

The Action Plan aimed to stimulate Europe's transition towards a circular economy to boost global competitiveness, foster sustainable economic growth and generate new jobs. It gave a clear signal to economic operators that the EU is using all the tools available to

transform its economy, opening the way to new business opportunities and boosting competitiveness.

The Plan promoted broad range of measures for changing the full product lifecycle that go beyond a narrow focus on the end-of-life stage. Innovative and more efficient ways of producing and consuming increasingly emerged as a result of the incentives that the Action Plan put in place. The circular economy has created many jobs in Europe and globally, while preserving precious and increasingly scarce resources, reducing environmental impacts of resource use and injecting new value into waste products.

The following actions are still in process contributing to the European transition towards a circular economy:

- Revised legislation on waste, which is set to reinforce EU's current role of global leader in recycling
- The first-ever European Strategy for plastics, and a follow-up legislation to reduce the negative effects

## The European Green Deal: Decoded



In December 2019, the European Commission presented the “European Green Deal” a roadmap for making the EU's economy sustainable by turning climate and environmental challenges into opportunities across all policy areas and making the transition just and inclusive for all.

European Commission President Ursula von der Leyen in her statement said that, *“The European Green Deal is our new growth strategy – for a growth that gives back more than it takes away. It shows how to transform our way of living and working, of producing and consuming so that we live healthier and make our businesses innovative. We can all be involved in the transition and we can all benefit from the opportunities. We will help our economy to be a global leader by moving first and moving fast. We are determined to succeed for the sake of this planet and life on it – for Europe's natural heritage, for biodiversity, for our forests and our seas. By showing the rest of the world how to be sustainable and competitive, we can convince other countries to move with us.”*

The European Green Deal provides a roadmap with actions to boost the efficient use of resources by moving to a clean, circular economy and stop climate change, revert biodiversity loss and cut pollution. It outlines investments needed and financing tools available, and explains how to ensure a just and inclusive transition. The European Green Deal covers all sectors of the economy, notably transport, energy, agriculture, buildings, and industries such as steel, cement, information and communication technology (ICT), textiles and chemicals.

Here are the 10 main points in the commission plan:

**1. ‘Climate neutral’ Europe:** This is the overarching objective of the European Green Deal. The EU will aim to reach net-zero greenhouse gas emissions by 2050, a goal that will be enshrined in a ‘climate law’ to be presented in March 2020. It means updating the EU’s climate ambition for 2030, with a 50-55% cut in greenhouse gas emissions to replace the current 40% objective. The 55% figure will be subject to a cost-benefit analysis.

The commission plans to review every EU law and regulation in order to align them with the new climate goals. This will start with the Renewable Energy Directive and the Energy Efficiency Directive, but also the Emissions Trading Directive and the Effort Sharing Regulation, as well as the Land Use, Land Use Change and Forestry (LULUCF) directive. These proposals will be submitted as part of a package by March 2021. A plan for “smart sector integration”, bringing together the electricity, gas and heating sectors closer together “in one system”, will be presented in 2020.

**2. Circular economy:** A new circular economy action plan will be tabled in March 2020, as part of a broader EU industrial strategy. It will include a sustainable product policy with prescriptions on how to make things in order to use fewer materials, and ensure products can be reused and recycled. Carbon-intensive industries like steel, cement and textiles, will have to focus their attention under the new circular economy plan. One key objective is to prepare for “clean steelmaking” using hydrogen by 2030. New legislation will also be presented in 2020 to make batteries reusable and recyclable.

**3. Building renovation:** This is meant to be one of the flagship programmes of the Green Deal. The key objective there is to “at least double or even triple” the renovation rate of buildings, which currently stands at around 1%.

**4. Zero-pollution:** The objective is to reach a “pollution-free environment” in air, soil or water by 2050. It includes a new chemical strategy for a “toxic-free environment”.

**5. Ecosystems & biodiversity:** A new biodiversity strategy will be presented in March 2020, in the run-up to a UN biodiversity summit that will take place in China in October 2020. Europe wants to lead by example with new measures to address the main drivers of biodiversity loss. That includes measures to tackle soil and water pollution as well as a new forest strategy. New labelling rules will be tabled to promote deforestation-free agricultural products.

**6. Farm-to-fork strategy:** To be tabled in 2020, the new strategy will aim for a “green and healthier agriculture” system. This includes plans to significantly reduce the use of chemical pesticides, fertilisers and antibiotics.

**7. Transport:** One year after the EU agreed new carbon dioxide emission standards for cars, the automotive sector is once again in the commission’s firing line. The current objective is to reach 95gCO<sub>2</sub>/km by 2021. Electric vehicles will be further encouraged with an objective of deploying one million public charging

points across Europe by 2025. “Sustainable alternative fuels” – bio-fuels and hydrogen – will be promoted in aviation, shipping and heavy duty road transport where electrification is currently not possible.

**8. Money:** The commission proposes a ‘Just Transition Mechanism’ to help regions, which are heavily dependent on fossil fuels. EU has the ambition to mobilize €100 billion precisely targeted to the most vulnerable regions and sectors.

**9. R&D and innovation:** With a proposed budget of €100 billion over the next seven years (2021-2027), the Horizon Europe research and innovation programme will also contribute to the Green Deal. 35% of the EU’s research funding will be set aside for climate-friendly technologies under an agreement struck earlier this year. And a series of EU research “moonshots” will focus chiefly on environmental objectives.

**10. External relations:** Finally, EU diplomatic efforts will be mobilised in support of the Green Deal. One measure likely to attract attention and controversy is a proposal for a carbon border tax. As Europe increases its climate ambitions, third world countries are also expected to play their roles.

# OFF BEAT

## WTO Allured With Certain Distinctive Regulations In 2019

### Good, Bad & Ugly: Plastics

The Republic of Korea amended the Act on the Promotion of Saving and Recycling of Resources. Under the amendment, Korean Ministry of Environment will classify the packaging materials into four grades and evaluate them according to their recyclability. The four grades would be 'the best', 'good', 'fair' and 'bad'. Incentives will be received for 'the best' grade and 'the bad' grade would be required to pay 30% extra along with mentioning the fact on the label that it is hard to recycle.

A ban will be imposed on Polyvinyl chloride (PVC; a synthetic polymer), and on coloured Polyethylene terephthalate (PET; a thermoplastic polymer resin) bottles. This is a result of extreme negative impact on the recycling process. According to the Korean Ministry of Environment, clear containers are always preferred over those with colours due to the difficulty in recyclability.

A grace period will be granted after the entry into force of the amended Act in consideration of industry's preparation period. Nine months will be granted for grading and evaluation and up to 15 months for labeling, which adds up to a total of 2 years for the entire grace period. One year is given to manufacturers to improve their products' recyclability.

Experts say that this is an unprecedented strong action against wastes in the world. On the other hand, foreign exporters of alcoholic

drinks, most notably wine exporters, complain about the strict new regulation which might affect the trade.

### Fit or Fad?

A shift in the product type to new, innovative and healthy food options was observed in 2019. These food items were different from the usually regulated food products.

Rwanda, an East African Country came up with requirements for sampling and test methods for pumpkin seed flour, pumpkin pulp flour and sesame flour to name a few, intended for human consumption or other uses in the industry. Many requirements of these products were in compliance with relevant international standards like International Organisation for Standardization (ISO), Association of Analytical Communities (AOAC) and (Codex Alimentarius Commission (CAC). Some of the other general food products also covered by other East African countries (Uganda, Tanzania, and Kenya) include sunflower seeds, tofu, dried mango, evaporated milks and quick frozen vegetables.



This could open up window for exporters, opening up new markets if they are in compliance with the relevant international standards.

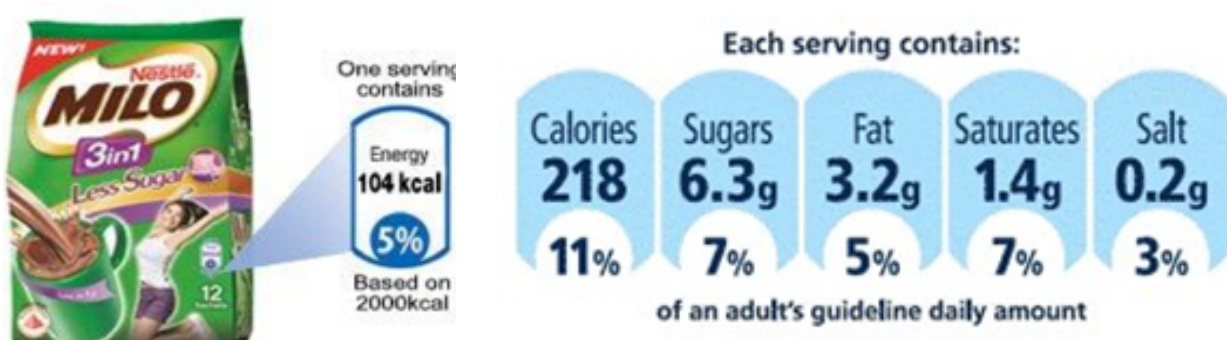
### Restyling The Modern Way: Food Labelling

National labelling laws, international norms and guidelines as well as private standards aim to protect consumers from deception and businesses from unfair competition. Food labelling is also becoming a policy tool for motivating change in consumer behaviour and shifts in food production practices.

With increase in global trade and a shift from traditional face-to-face food producer and buyer relationship, need to create food labels that are clear and can be trusted is of prime importance. Food labelling includes any written, printed or graphic matter that is present on the label.

FAO works in partnership with WHO to advise the Codex Alimentarius Commission on technical and policy matters related to food labelling. The Codex Committee on Food Labelling (CCFL) is the Codex subsidiary body responsible for setting standards and guidelines on labelling that is applicable to all foods. Innovations in food labelling have been providing information about the principles and requirements of food labelling by reviewing the latest trends in this area. Some attractive innovations adopted by countries across the worlds are noteworthy:

- **Front-of-pack (FoP) nutrition labelling (EU):** The WHO first proposed FOP nutrition labelling as a policy measure to improve diet and health. To date, the most common 'critical nutrients' that have been included in FOP nutrition labelling schemes are sodium, fats (saturated, trans) and total sugars. European Union's Regulation allows voluntary repetition on pre-packed food labels of those elements of the mandatory nutrition declaration that are of key importance for public health. The aim is to provide consumers with at-a-glance nutrition information, so that they can make informed food choices and can balance their diets and control their energy intake. FoP can be declared as energy only or energy plus fat, saturates, sugar and salt.





- Traffic lights system of food labelling (UK): Some front-of-pack nutrition labels use red, amber and green colour coding. Colour-coded nutritional information tells at a glance if the food has high, medium or low amounts of fats, saturated fat, sugars and salt. The more green on the label, the healthier the choice.

	Per 100 g	Reference intake	% of RI	Traffic lights
Energy	1610 kJ 380 kcal	8400 kJ 2000 kcal	19 %	19 %
Total fat	21 g	70 g	30 %	30 %
Saturates	11 g	20 g	55 %	55 %
Sugars	7 g	90 g	8 %	8 %
Salt	2 g	6 g	33 %	33 %

Each burger contains:



% of an adults reference intake.

Typical values per 100g: Energy 966kJ/ 230kcal

- Nutri-Score (France): The nutri-score system was developed to make the front-of-pack system of labelling simple and accessible for all. The system includes a colour coded scheme, ranging from dark green to dark orange associated with letters from A-E. Products designated with an 'A' have the 'best nutritional quality' while products designated with an 'E' have 'poorer nutritional quality'. The scheme enables the consumers to compare the nutritional quality of seemingly similar products.



- Country of Origin labelling (Australia): The Australian Government has a country of origin food labelling system. The labels will feature either a simple text statement, or a mark that includes a kangaroo logo, accompanying text and a gold chart, which will show the percentage of ingredients sourced in Australia. Under this system the food labels will fall into four categories namely, grown in Australia, produced in Australia, Made in Australia and packed in Australia.

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

## Processed Food: Demand of the Era



This section provides the overview of food processing sector in India across different areas. Further, how growing food processing sector is helping market for food processing machinery to flourish. It also talks about the shift of consumer's interest towards healthy, organic, plant-based (vegan), clean-label products resulting in the more processed product in the market.

Food processing has been the core of the food sector with 32% share of countries total food market (FICCI, 2019). The industry ranked fifth in terms of production, consumption, export and expected growth. The year 2019 has been observed with people shift of interest towards healthy, organic and plant-based (vegan) and clean label products. The 2020 will project the similar trends covering different sectors (Agro and Food Processing, 2019). According to the FICCI report, there will be hike for the market for Indian organic food market by 3 times by 2020. Also, India is the second largest fruits and vegetable producer

worldwide, with similar scenario in case of marine products and meat and poultry. Globally, India leads in terms of largest producer of milk with an estimate of 137.7 MT production.

The Indian Government wishes to boost growth of food processing sector with amendments such as 100% Foreign Direct Investment (FDI) in food products marketing together with several incentives at both central and state government level with a strong focus on supply chain infrastructure.

As per Department for Promotion of Industry and Internal Trade (DPIIT) report (2018-19), there is around 44% increase in the Industrial Entrepreneurship Memorandum (IEM) filed with an increase by more than 2 times in the investment.

With the growth of food processing sector there is growth of market of Indian food processing machinery. The areas of growth mainly includes fruit and vegetable processing, meat, poultry, dairy & seafood, packaged/convenience food, soft drinks and grain processing. The reason behind this growth is the rapid changes in food habits and

consumerist culture developing in the country.

The export and import for the food processing machinery (HS code 8438) was increased by approximately 10% and 24% respectively this year.

The Breakthrough technologies of Food Processing The sector has been introduced with new five cutting-edge technologies that operates with types of energy such as heat, electricity, pressure and vacuum, singly or in combination, in novel ways to process food better. They kill microorganisms, drive out moisture and perform other functions to preserve food, to make it safer and to make it taste better.

- Spirajoule uses an electrically heated auger plus steam to treat spices, herbs, nuts, grains and other bulk product. Spirajoule heats more reliably than steam alone. The technology is manufactured and sold by the French firm Etia SAS, under the trade name Safesteril.
- Microwave-assisted thermal sterilization (MATS) has the potential to impart shelf-stability in products where it was previously unavailable, like whole-muscle meat and seafood. “MATS packaging looks a lot like plastic retort packaging,” It was developed at Washington State University and is being commercialized by 915 Labs, a startup based in Denver.
- Radiant energy vacuum (REV) involves driving moisture from food by exposing it to microwaves while it’s under vacuum. The moisture removal is uniform and can be calibrated to each application. It can be used for any food product with a accurate way of removing water at controlled temperature. It provides better retention of nutrients, color and flavor as process is fast. EnWave Corp is the sole provider for REV.
- High-pressure processing (HPP) kills microorganisms inside a sealed package without any heat whatsoever, extending its shelf life while maintaining its freshness. HPP can only be performed on a batch basis, which gives it a disadvantage over continuous thermal processing. But that’s mitigated because increasing the capacity of an HPP system can be done without expanding its footprint.
- Pulsed electric field (PEF): It can inactivate microorganisms without heat and can improve a food’s handling and processing characteristics by driving out moisture and other components. Pulsemaster is the supplier for the equipment.

## **Veganism: The New Trend**

The new trend of veganism has been observed in the last few years, resulting in more vegan products entering Indian market. Consumers increased awareness about animal welfare, health and environmental impacts contributes to the shift of interest from meat to plant based diet. The animal industry is one of the prime sources of green house effect, increases risk of long term diseases like heart disease, cancer and stroke and animal raised for meat, dairy, eggs are treated with antibiotics and hormones, which when enters human body leads to development of antibiotic resistance. Globally, the industry is expected to grow by 2022 with CAGR of 6.7 reaching US\$ 10892 million.

In India, new companies like Green Dot, Vezlay, Unived and Ahimsa have entered market with the full range of vegan products. With this, in year 2019, Vegan India Expo, the first global B2B vegan fair was organized in the month of July. The event was organized by organized by EXHIMACT and VERIFAIR with the support of National Small-Scale Industries Corporation (NSIC), World Vegan Federation and Federation India Animal Protection Organizations (FIAPO). Expo was successful to bring brands, businesses and consumers in touch to raise awareness and promote vegan lifestyle in India and for business promotion.

## **Fortification**

Food fortification is a scientifically proven, cost- effective sustainable food processing method which addresses the issue of micronutrient deficiencies. It has been a growing sector across India to combat malnourishment. With government taking new initiative for improved access of nourish food to the population, Food Safety Authority of India in year 2016 has put in operation Food Safety and Standards (Fortification of Foods) Regulations, for fortifying staples namely Wheat Flour and Rice, Milk and Edible Oil and Double Fortified Salt. The standards are given as follows:

- Wheat Flour and Rice fortification with Iron, Vitamin B12 and Folic Acid,
- Milk and Edible Oil fortification with Vitamins A and D and
- Double Fortified Salt fortification with Iodine and Iron

The food companies producing fortified food products needs to put the '+F' logo on their product with tagline "Sampoorna Poshan Swasth Jeevan". The regulation was notified in Gazette of India as Food Safety and Standards (Fortification of Foods) Regulations, 2018.

The Government of India, this year has approved central- sponsored pilot scheme on Fortification of Rice and its Distribution under Public Distribution System. The scheme has been approved for three year beginning 2019-20. In Union budget 2019-2020, a total amount of Rs. 42.65 has been allocated. Under this scheme,

Union Ministries of Women and Child Development, Human Resource Development and Consumer Affairs, Food and Public Distribution has mandated the distribution of fortified wheat flour, rice, oil and double fortified salt in their schemes - Integrated Child Development Services (ICDS) and Mid-Day Meal (MDM) and Public Distribution System (PDS) respectively. This scheme covers only 15 districts per state preferably during initial state. The effort will help more coverage of market for the fortification of food. The companies working under government for such schemes will flourish further. As per one report, the annual market for the fortified food covering rice, wheat and milk as per demand provided by the Union Ministry of Consumer Affairs, Food and Public Distribution (MOCAFPD) and the volume of fortifying mixture required given by the Food Safety and Standards Authority of India (FSSAI), is over Rs. 3,000 crore. Further, a market of Rs 1,700 will be created alone from the fortified rice ([downtoearth.org.in](http://downtoearth.org.in)).

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



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