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POLICYPULSE



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Foreword

The Coronavirus or COVID-19 has struck hard. Across continents, countries have been forced to lockdown towns and companies and people are faced with fear and anxiety. The country where it originated, China that has practically become the factory to the world has faced unprecedented closures thereby adversely impacting global and regional value chains. The travel industry has faced the maximum brunt of the Coronavirus.

Stock markets, across the globe, have bled, and investors and stockbrokers have lost trillions of dollars in a matter of few hours. India, too, has faced a market meltdown and companies, dependent on imports from China or other markets, are taking a deep look at their inventory to plan their survival. The impact of the Virus on the



industry follows the not very rosy economic outlook that India has faced in the recent months.

This issue of Policy Pulse takes a close look at the global economy as also how the eight core sectors have performed in India in January 2020, which is the latest data available in the public domain. With the Virus in focus, this issue focusses on the medical devices industry and provides updates from China and Canada in this sector. Besides it analyses the medical devices regulations of India and Brazil.

With an eye on allowing companies to raise capital the Union Cabinet recently allowed Indian companies to list on foreign exchanges. The REACH that started from the European Union is now expanding its hold with Nigeria being the latest country to adopt similar regulations. Russia and its Eurasian partners also want to create an inventory of chemicals and details of how they will move forward is in this edition. The usual "Offbeat" column spells out the "claim game" while another article looks at how e-waste needs to be managed. Hopefully the next edition in April will provide a rosier picture of the world economy.

We are proud to announce the broadening of our service offerings by adding strategic digital social media. We have entered into a strategic partnership with a specialist media company that focuses on Developing Effective Brand & Marketing Strategies, Creating Content in All Formats, Developing Digital Applications & Platforms, Designing Unique Customer Experiences and Automating Processes with Data, Al & IoT solutions. We will integrate and leverage their expertise to connect, communicate and engage with audiences across all available digital platforms.



MACRO-ECONOMIC SNAPSHOT

Global Economy: The Coronavirus Impact

The Paris-based OECD in its report for March 2020 is of the view that the Coronavirus puts the world economy at risk. It feels that growth prospects remain highly uncertain and "annual global GDP growth is projected to drop to 2.4% in 2020 as a whole, from an already weak 2.9% in 2019, with growth possibly even being negative in the first quarter of 2020". The adverse impact on confidence, financial markets, the travel sector and disruption to supply chains contributes to the downward revisions in all G20 economies in 2020, particularly ones strongly interconnected to China, such as Japan, Korea and Australia, the OECD said.

"However, provided the effects of the virus outbreak fade as assumed, the impact on confidence and incomes of well-targeted policy actions in the most exposed economies could help global GDP growth recover to 3.25 % in 2021. A longer lasting and more intensive coronavirus outbreak, spreading widely throughout the Asia- Pacific region, Europe and North America, would weaken prospects considerably. In this event, global growth could drop to 1.5 % in 2020, half the rate projected prior to the virus outbreak," said the OECD.

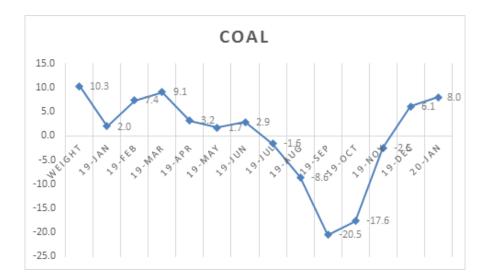
The World Bank in January had said "global economic growth is forecast to edge up to 2.5% in 2020 as investment and trade gradually recover from last year's significant weakness but downward risks persist"

Indian Economy: Performance of Eight Core Industries

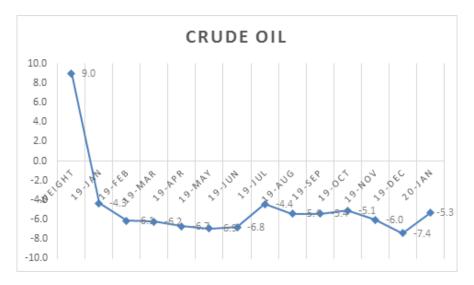
The Eight Core Industries comprise 40.27 percent of the weight of items included in the Index of Industrial Production (IIP). The combined Index of Eight Core Industries stood at 137.5 in January, 2020, which increased by 2.2 percent as compared to the index of January, 2019. Its cumulative growth during April, 2019 to January, 2020 was 0.6 percent.

1. **Coal** production (weight: 10.33 per cent) increased by 8.0 percent in January, 2020 over January, 2019. Its cumulative index declined by 2.4 percent during April to January, 2019-20 over corresponding period of the previous year.

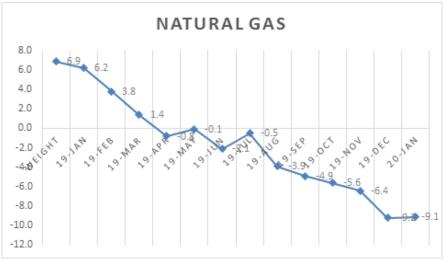




2. **Crude Oil** production (weight: 8.98 percent) declined by 5.3 percent in January, 2020 over January, 2019. Its cumulative index declined by 6.0 percent during April to January, 2019-20 over the corresponding period of previous year.

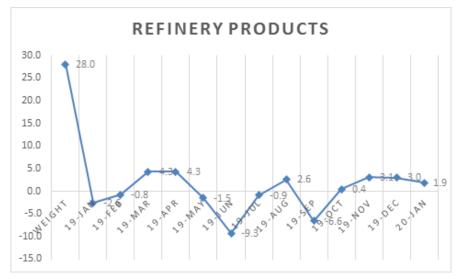


3. The **Natural Gas** production (weight: 6.88 percent) declined by 9.1 percent in January, 2020 over January, 2019. Its cumulative index declined by 4.3 percent during April to January, 2019-20 over the corresponding period of previous year.

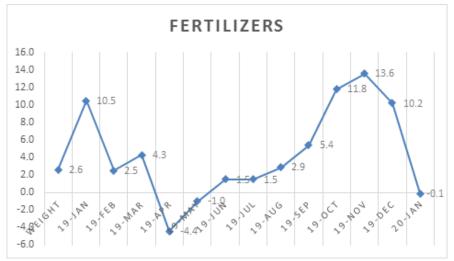




4. **Petroleum Refinery** production (weight: 28.04 percent) increased by 1.9 per cent in January, 2020 over January, 2019. Its cumulative index declined by 0.4 percent during April to January, 2019-20 over the corresponding period of previous year.



5. **Fertilizers** production (weight: 2.63 percent) declined by 0.1 percent in January, 2020 over January, 2019. Its cumulative index increased by 4.2 percent during April to January, 2019-20 over the corresponding period of previous year.

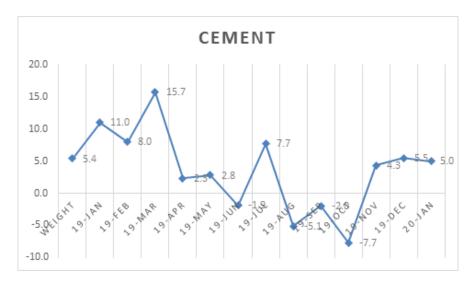


6. **Steel** production (weight: 17.92 percent) increased by 2.2 percent in January, 2020 over January, 2019. Its cumulative index increased by 5.3 percent during April to January, 2019-20 over the corresponding period of previous year.

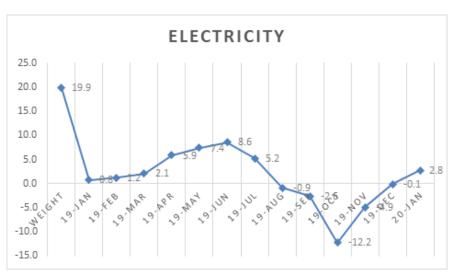




7. **Cement** production (weight: 5.37 percent) increased by 5.0 percent in January, 2020 over January, 2019. Its cumulative index increased by 1.1 percent during April to January, 2019-20 over the corresponding period of previous year.



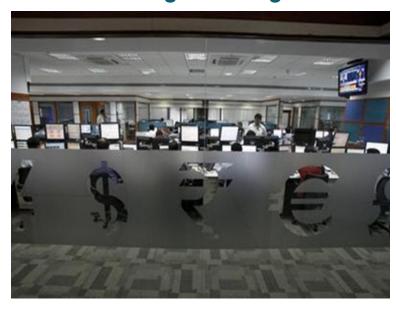
8. **Electricity** generation (weight: 19.85 percent) increased by 2.8 percent in January, 2020 over January, 2019. Its cumulative index increased by 0.9 percent during April to January, 2019-20 over the corresponding period of previous year.





POLICY BRIEF

Cabinet Approves Indian Firms To Get Listed On Foreign Exchanges



March 2020, the Union Cabinet has approved the Companies (Second Amendment) Bill, 2019 to amend the Companies Act, 2013, which will enable the listing of Indian companies on stock exchanges in foreign jurisdictions. The listing of Indian companies in foreign stock exchanges is expected to increase the competitiveness of Indian companies in terms of access to capital, broader investor base and better valuations. This move will certainly help Indian start-ups access a larger pool of investors to raise capital and at the same time allow exits by existing investors.

Union Finance Minister, Ms. Nirmala Sitharaman in her statement said that "the priority is to remove criminality under the Act and the Bill will further ease of living for law abiding corporates. The changes brought in the Bill will lead to further declogging of the criminal justice system in the country".

Currently, Indian companies go for the depository receipts route (American Depository Receipt or Global Depository Receipt) to tap investors globally but that window has become less attractive in recent years, prompting the Government India Securities of and and Exchange Board of India (SEBI) to eye a direct listing window.

The Act would have enabling provisions for listed as well as unlisted companies in India to list their shares abroad. The framework for enabling such listing under the foreign exchange and securities laws would be finalised by the Ministry of Finance in consultation with Ministry of Corporate Affairs, Reserve Bank of India and the Securities and Exchange Board of India.



MARKET UPDATES

China: Guidance On Use Of Generic Names For Medical Devices

China's Center for Medical Device Evaluation (CMDE) has published a guidance document to clarify the principles employed by the National Medical Products Administration (NMPA) for determining generic names of medical devices.

In December, 2015 the China Food and Drug Administration (CFDA) issued the 'rule of setting medical device's "generic name" to regulate the generic names of medical devices to be sold in China, so that users can easily identify the functions of the device. Earlier to this, as per CFDA requirements, product names of medical devices have to be exact/word to word match to the names listed in the classification catalogue or names listed in the clinical trial list for the product to be qualified accordingly. This practice has caused lots of confusions among manufacturers on how to choose their Chinese product names, since it is closely related to the device classification, clinical trial exemption and reimbursement, etc. In lieu of the above confusion, CMDE has published a guidance document on the principles of determining generic names for medical devices in China.

The NMPA regulation stipulates that the name of any medical device submitted for registration in the country must be the generic name, so the additional guidance should be of use to manufacturers interested in entering the Chinese market.

Canada Allows Electronic Submissions Of Medical Device Clinical Trial Data

Canadian pharmaceutical and medical device market regulator the Health Canada has started accepting some clinical trial-related information from sponsors via electronic submissions. According to a notice from Health Canada, sponsors may now utilize the regulator's recently developed electronic Common Technical Document (eCTD) format to file clinical trial regulatory activities.

Using eCTD for clinical trial regulatory activity submissions is currently optional, but once a sponsor has made a filing to Health Canada using the eCTD format, that sponsor must provide all additional data pertaining to the same protocol via eCTD.

Which clinical trial regulatory activities may be filed using eCTD?

- Health Canada identifies the following clinical trial regulatory activities as eligible for eCTD submissions:
- Pre-clinical trial application consultation meetings (PRE-CTA);



- Clinical trial applications (CTAs) using either seven-day administrative or 30-day default performance standards;
- CTA notifications (CTA-N);
- Any responses and post-clearance data pertaining to regulatory activities mentioned above.

Nigeria: Set To Develop REACH Alike Regulation



Nigerian government is looking at developing a "comprehensive REACH alike regulation national legal framework" for managing chemicals and waste by 2022. The framework will align existing legislation and will come after a legal assessment of the country's chemicals and waste-related policies and laws. The scope and structure of the legal framework will be determined by stakeholders based on the outcome of the review of existing regulations.

It will be implemented as part of a UN environment programme (UNEP) project, aimed at strengthening the legal and institutional infrastructure for managing chemicals in Nigeria. Nigeria is a major importer and consumer of chemicals, which

are extensively used in industrial processes, manufacturing, power generation, agriculture and health sectors.

Currently the country has several sectoral regulations that deal with chemicals management issues and present "jurisdictional overlaps", but lacks national legislation that is "clear, simple and enforceable". It also lacks sustainable funding to follow up on chemicals management issues infrastructure for and the regulation. The marketing and selling of chemicals "unqualified persons and nonprofessionals" is also a problem. In addition to developing the national framework, it plans to:

- develop and implement a national strategy for building capacity on chemicals and waste;
- establish a national environmental monitoring network to collect data;
- develop a national accreditation course for chemical dealers;



- review and update Nigeria's National Committee on Chemicals Management, a coordinating body on chemicals that is co-chaired by the environment and health ministries;
- "mainstream" chemicals and waste issues into other national processes; and
- conduct a pilot study to test the feasibility of different national cost-recovery measures

Russia Extends Chemical Inventory Notification Deadline

Russia's Ministry Of Industry And Trade has officially extended the deadline for companies to submit data to its national inventory of chemicals. The initial deadline for submission of data was 1st January 2020, but the Russian authorities have ministry announced a new deadline of 1st May 2020.

Each of the Eurasian Economic Union (EEU) member states – Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia – are expected to create inventories as part of national registers of substances and mixtures. These will feed into the Eurasian technical regulation on the safety of chemical products Eurasia-REACH.

The Eurasian Economic Commission, the executive arm of the EEU, will eventually merge all data collected from member states into one common inventory for the entire region. The inventories will only include substances that have been notified directly to them. So far approximately 1,000 data (excel file) submissions have been made to the Russian inventory. Each data (excel file) can contain multiple substances. The compilation of inventory data has preceded implementation of secondary legislation under the technical regulation. EEU members are yet to agree on three areas:

- a list of chemicals that are restricted and banned;
- a position on the grounds for refusing state registration of chemicals; and
- rules for completing chemical safety reports.



Regulation of Medical Devices in India & Brazil: A Comparison

Healthcare has long been established as a sector of vital importance for a country's economy and has held the interest of policy makers across the globe. In addition to pharmaceuticals, medical devices are also a key component of this sector.

The medical devices industry comprises of articles, instruments, apparatuses, and machines that are used in the prevention, diagnosis or treatment of illness or disease, by detecting, measuring, restoring, correcting, or modifying the structure or function of the body. The advent of technology, ageing populations worldwide, coupled with extended life expectancy have all been driving factors for the emergence of this industry.

Due to the dependence on technology, this industry is largely driven by developed nations. Globally, the market leaders are USA, Germany, Netherlands, China, Belgium, Ireland, Japan and Switzerland, who collectively accounted for more than 65% of total global exports of medical devices in 2018-2019 which was around USD 130 billion. The current market size of the medical devices industry in India is estimated to be USD 11 billion and expected to reach USD 50 billion by 2025.

The ever-increasing usage of these products and their associated affordability and accessibility issues has made medical devices an object of public concern and makes the case for greater regulation of this sector. Every country has its own regulatory body to maintain quality and prevent the introduction of unsafe medical devices. These regulatory bodies have developed certain guidelines for the import, manufacture, sale and distribution of these devices. Additionally, a number of countries have established cost-containment efforts. India is also set to cap trade margins for medical devices at 30%. In the recent past, a number of regulatory changes have been brought forth in the medical devices segment in India. These are indicated below.

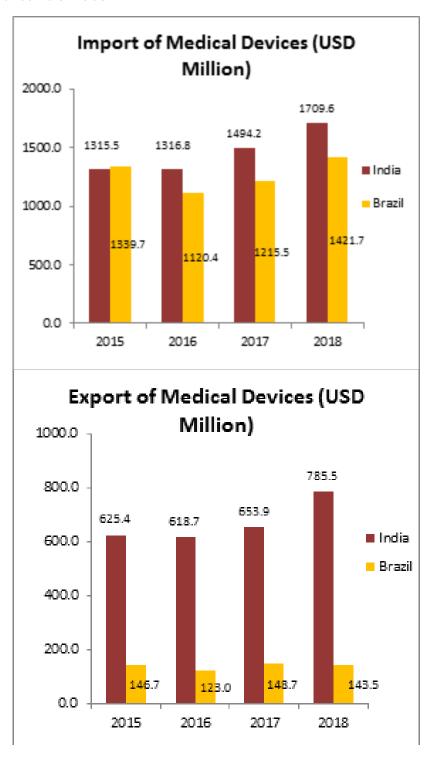


^{*}This has not yet been adopted or enforced.



However, India has not been the only country to initiate changes in the regulatory regime. Other developing nations have also been strengthening their regulations governing medical devices. One such nation has been Brazil, the largest medical equipment market in South America and a developing economy similar to India. Considering the process of getting authorisation for marketing a medical device as an indicator of the stringency of a regulatory regime, this article presents a comparison of the regulatory process followed in India and Brazil.

I. Trade in medical devices





II. Comparative Analysis

	India	Brazil
Competent Authority	CDSCO (Central Drug Standards Control Organization)	The National Health Surveillance Agency (ANVISA) or in Portuguese: Agencia Nacional de Vigilancia Sanitaria (ANVISA)
Regulated under	Medical Devices Rules, 2017 Medical Devices Amendment Rules, 2020	Law No. 6360 of 1976, decree 74.094/97 Resolution RDC-185 of October 22, 2001 Other ancillary regulations
Classification	Classifies medical devices into A, B, C and D. Class A includes- low risk devices such as thermometers. Class B includes low to moderate risk devices such as hypodermic needles. Class C includes moderate to high risk devices such as lung ventilators. Class D includes high risk devices such as heart stents.	Medical Devices are divided into Class I, Class II, Class III and Class IV. Class I devices represent the lowest risk and Class IV devices the highest risk. Lower-risk Class I and II devices follow the Cadastro registration route, which includes a simplified application. Higher-risk Class III and IV devices follow the Registro registration process.
Local contact	A manufacturer can appoint an authorized Indian agent to register with the CDSCO on their behalf. The authorized Indian agent should have a wholesale drug license as per Form 20B and 21B.	To register a medical device the manufacturer must either: • Have an office in Brazil or • outsource the registration to a licensed consulting firm, often referred to as a hosting company or a Brazil Registration Holder (BRH) or • Obtain multiple registrations for the same device, through various importers. All local distributors must be authorized by the Brazilian authorities to import and distribute medical devices.
Good Manufacturing Practice (GMP) Certificate	NO	YES; A Brazil Good Manufacturing Practice (BGMP) certificate is required.
Quality	A certificate of compliance with respect to ISO standard 13485 is required. India also adopts the regulatory standards of the Bureau of Indian Standards (BIS) and those of the International Organization for Standardization (ISO).	Active medical devices under IEC 60601-1 must be certified by a National Institute of Metrology, Standardization and Industrial Quality (INMETRO) accredited test agency (Notified Body) and display the INMETRO marking.INMETRO certification is valid for 5 years, and annual audits and fees are required.
Registered in other country	If the product is not registered in any of the countries like USA, Europe, Japan, Canada or Australia, an applicant needs to prove the efficacy and safety of it by conducting clinical trials in India to get registration certificate.	
Dossier requirements	 Form 40 TR6 Challan Power of Attorney 	All files must be submitted in Brazilian Portuguese.



	India	Brazil
	Schedule D(I) ISO 13485 Certificate Full Quality Assurance Certificate CE Design Certificate Declaration of Conformity Free Sale Certificate Certificate of Marketability from GHTF countries Other Regulatory Approvals PMS report Plant Master File Device Master File	Class I and II device manufacturers must compile a comprehensive technical dossier for their Brazilian Registration Holder (BRH) to keep on file, along with proposed labeling and IFU. This includes: • Cadastro application in both printed and electronic (CD or DVD) formats; • proof of payment of the Sanitary Surveillance Supervision Inspection Fee (TFVS), attested by the presentation of a Federal Tax Payment Form (GRU) • Authenticated copy of the Compliance Certificate issued by the Brazilian Compliance Assessment System (SBAC), • For imported medical products, a consular declaration along with its sworn translation, issued no less than two years prior by the responsible manufacturer(s) when no validity date is included in the document, duly authorizing the importer to represent and commercialize the product(s) in Brazil. • Class III and IV device manufacturers must prepare a Technical File that includes clinical data, clinical studies, and additional device information. Legal documents, IFUs, and proposed labeling are also included in the Technical File. Audits will be carried out by ANVISA for Class III and Class IV devices. Fees for these audits are due every two years.
Validity of Registration	The registration certificate is valid for 3 years.	Class I and II registrations do not expire. Class III and IV registrations expire after ten years.

III. Conclusion

In both India and Brazil, the medical devices industry is import driven. Although both countries also exports these devices, with India's exports valued substantially more, it is evident that the focus is more on regulation rather than boosting production. The registration process in the two countries is similar with some notable differences:

- The requirement to submit all documents in Brazilian Portuguese is an additional barrier which does not exist in the Indian regime.
- India follows an easier process for clinical trials for devices registered/authorised in certain specified countries. Brazilian system has no such provision.



• However, the validity term of the registration is much shorter in India necessitating renewal every few years.

Therefore, if the process of getting authorisation for marketing a medical device is considered as an indicator of the stringency of a regulatory regime, then, barring the aforementioned exceptions, India and Brazil seem to be on par.

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



OFF BEAT

The Claim Game

Evolution of technology has led to myriad of food products and preferences to consumers. On the contrary, a bigger challenge faced is in understanding the information on the food label. Food information on the food label plays an important role in helping the consumer to make an informed choice while buying a food product. Food label includes nutrient declaration, nutrition claims, health claims among others.

This article focuses on health claims which provide information on specific health benefits caused by specific functional ingredients. Health claims have attracted enormous interest from the food industry as a way towards growth with value-added products in markets.

Globally, the health claims have been defined by countries and organisations like USFDA - US Food and Drug Administration, CAC - Codex Alimentarius Commission, EU - European Union and FSSAI - Food Safety and Standards Authority of India. The different definitions as given by these organisations have been given below.

Definitions Of Health Claims

USFDA

- A health claim by definition has two essential components: a substance (whether a food, food component, or dietary ingredient) and a disease or health-related condition.
- A statement lacking either one of these components does not meet the regulatory definition of a health claim.

EU

 Health claim means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health

CAC

 Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.

FSSAI

 Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.



Classification Of Health Claims

The health claims have been classified into different categories or types in countries across the globe. The classifications have been ranging from general to specific and also based on type of authorization. Some widely known classifications from CAC, EU, and USFDA are briefly given below.

CAC/FSSA

- "Nutrient function claim" - is that which describes the physiological role of the nutrient in growth, development and normal functions of the body
- •"Other function claims" – These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body.
- "Reduction of disease risk claims" - Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

- "Reduction of Disease Risk Claims" - any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.
- "Children's development and Health claim" - health claims solely referring to the development and health of children and where the science is only valid for children, e.g. calcium is good for children's growth.
- •"General Health
 Claims" other than
 disease risk reduction
 and children's
 development and
 health. These claims
 relate to the effect of a
 substance on a body
 function.

ISFDA

- "Authorised Health Claims" - Authorized health claims in food labeling are claims that have been reviewed by FDA after a significant scientific agreement (SSA) and are allowed on food products or dietary supplements to show that a food or food component may reduce the risk of a disease or a healthrelated condition.
- "Qualified Health Claims" - Qualified health claims (QHCs) are supported by scientific evidence, but do not meet the more rigorous "significant scientific agreement" standard required for an authorized health claim. They must be accompanied by a disclaimer to accurately communicate to consumers the level of scientific evidence supporting the claim.

Although, health claims have been defined and classified differently across the globe, the rationale behind them is based on the international guidelines setup by the CAC.

CODEX gives guidance on general labelling of foods and the health or nutrient claims on food labels. The Codex Committee on Food Labelling (CCFL) sets standards and guidelines for nutrition information on food packages enabling consumers to make informed food choices.



As per the codex 'guidelines for use of nutrition and health claims', health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education.

The health claim must consist of two parts:

- Information on the physiological role of the nutrient or on an accepted diethealth relationship; followed by
- Information on the composition of the product relevant to the physiological role of the nutrient or the accepted diet-health relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food

The claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituent in the context of a healthy diet.

Process For Substantiation Of Health Claims

CODEX – The competent national authorities takes into account the general principles of substantiation for the review of scientific evidence for health claims. Such a process typically includes the following steps:

- Identify the proposed relationship between the food or food constituent and the health effect;
- Identify appropriate valid measurements for the food or food constituent and for the health effect;
- Identify and categorise all the relevant scientific data;
- Assess the quality of and interpret each relevant scientific study;
- Evaluate the totality of the available relevant scientific data, weigh the
 evidence across studies and determine if, and under what circumstances, a
 claimed relationship is substantiated.

EUROPEAN UNION – The conditions of use for health claims is governed by the nutrition and health claims regulation (Regulation (EC) No 1924/2006 – NHCR) and its implementing regulation establishing an approved community list (Regulation (EU) No 432/2012 as amended). As per the regulation:



- Nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence.
- Health claims made on foods are prohibited unless they are authorised by the
- Commission in accordance with that Regulation and included in a list of permitted claims.
- Applications for authorisations of health claims are submitted by food business operators to the national competent authority of a Member State. The national competent authority forwards valid applications to the European Food Safety Authority (EFSA) hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.
- The Authority delivers an opinion on the health claim concerned.
- The Commission decides on the authorisation of health claims, taking into account the opinion delivered by the Authority.

SOME RECENTLY REFUSED HEALTH CLAIMS (EUROPEAN UNION)

- L-Carnitine 'L-carnitine contributes to normal lipid metabolism'
- Black Tea 'Improves endothelium-dependent vasodilation, which contributes to healthy blood flow'
- NWT-02 (a fixed combination of lutein, zeaxanthin and docosahexaenoic acid in egg yolk) – 'Consumption of NWT-02 reduces loss of vision'

The refusals of health claims were based on 'no cause and effect relationship' established between the consumption of the substance and the proposed effect by the applicant.

INDIA – The Food Safety and Standards Authority of India (FSSAI) establishes fairness in claims and advertisements of food products by 'Food Safety and Standards (Advertising and Claims) Regulations'. As per the regulation:

- The food business operator or marketer shall seek prior approval from the Food Authority for reduction of disease risk claims.
- The food business operator shall submit an application along with applicable fees as prescribed by Food Safety and Standards Authority.
- The food authority itself or may appoint an agency or panel to carry out preliminary scrutiny of the application submitted by food business operators or marketers for approval of their claims.



- On scrutiny, deficiencies, if any, shall be informed to applicant within ninety days from the date of receipt of application and the applicant shall provide the information required by the food authority within thirty days of the receipt of the communication, failing which the application shall be rejected without any further reference.
- After scrutiny, the Food Authority may pass a speaking order either for approval or rejection of concerned claims and may also suggest an amendment for the concerned claim.
- The amended claim may be submitted to the Food Authority within thirty days for reconsideration.
- In case of rejection, the food business operator or marketer shall not use that claim in their advertising and marketing communication in respect of articles of food offered for sale or for promotion of sale, supply, use or consumption.

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



E-waste Management System: An approach toward Sustainable Development

E-waste has raised a serious concern for environment over the last few years. Electronic waste or E- waste describes the electronic products which are near to the end of their "useful life". This includes product categories like computers, televisions, VCRs, stereos, fax machines and mobile phones. With upcoming technologies and increased usage of electronic gadgets, the e-waste generation is increasing tremendously. It causes a threat to the environment as well as to the labors handling such waste as this exposes them to hazardous substances.

As per the report issued by The United Nations Environment Programme (UNEP) 2019, the e- waste generation worldwide will reach 120 million tonnes per year by 2050. The report further discloses that the global e- waste reaches a value of over 62.5 billion in a year, which is more than the GDP of most countries.

E- waste generation in India has been increasing exponentially. The Associated Chambers of Commerce and Industry (ASSOCHAM), India has estimated that e-waste generation would reach 5.2 MT annually by 2020. Henceforth, with such a scenario, there should be stringent rules of a waste management system that operates in India as well as globally.

With a view of the aforesaid facts, many countries are in a process to adopt a more regulated system for the waste management system. In the regard, two countries Brazil and Bangladesh with an aim of e-waste management has issued draft rule for e-waste collection at the World Trade Organization's Information Portal. Under this producers/ manufacturers are responsible for collection of ewaste from consumers. Brazil has named it as the "Reversed Logistic System" which covers household electrical and electronic products and their However Bangladesh has named it Extended Producer components. Responsibility (EPR), where producers are liable to give timely incentive to consumer fixed by the Government for returning waste products. This also involves the submission of EPR plan needs to Department of Environment (DoE). In this Direction, India has issued E- waste (Management) Rules, 2016 which was further amended in year 2017 and 2018 by The Ministry of Environment, Forest and Climate Change. This will reduce e-waste generation and increase recycling. Under these rules, the government introduced EPR which makes producers liable to collect 30-70% (over seven years) of the e-waste they produce.



The best way an e- waste management system can work effectively is the adoption of recycling process. However, still only 20% of e-waste is recycled globally. This creates demand for an addition market sector based on recycling of e- waste which can be a great source of revenue generation. The practice of recycling is globally being followed to an extent that the medals for "Tokyo Olympic 2020" will be made of the 50,000 tonnes of recycled electronic waste. The approach like this will be beneficial in a long run for the overall agenda of sustainable development.

The possible way forward for companies and the government for e -waste management can be the following:

- There can be a separate department under 'Ministry of Environment, Forest and Climate Change' for the e -waste management.
- Companies can have an entire team of e-waste management which can track the movement of their product till its end life to disposal.
- Companies can also hire a third party to manage the e- waste generated by them.
- Consumers should also be held responsible under the law for carefully disposing off the e- waste generated in their households.

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



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