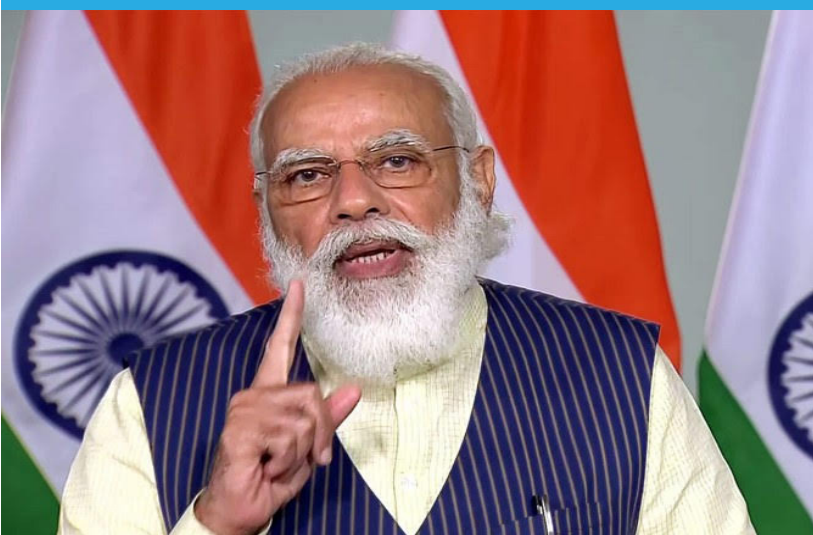




Association of  
Indian Organic Industry

# NEWS LETTER



*“The country has 80 crore youth. They are below 35 years of age. If youth have the skill, they can change the destiny of this country and we are laying stress on this.” - PM Modi in an interview to Network 18*

## INSIDE THIS EDITION

- Meeting Regulatory Challenges for Accessing Global Markets *Page 2*
- Ethylene Oxide - A New Threat in the Food Products *Page 5*

### FROM THE CEO'S DESK



Dear Friends,

**Greetings from AIOI,**

You are aware that the market for organic products in India is rising exponentially with a growth rate at 15%. The market analysis reports anticipate that Indian organic market will touch Rs. 75,000 crores in the next five years. The Government is supporting organic industry and consumer expenditure on health and wellness products have increased. Hence there is a great potential for organic products with profitability for advanced business goals. With better management systems, enhancement in infrastructure and capacity building will also provide a competitive edge in the international market. To harness this potential, the organic industry needs skilled manpower in various areas specific to organic operations.

To address this need of the organic industry and certification bodies, The Association of Indian Organic Industry (AIOI) along with **Professor Jayashankar Telangana State Agricultural University (PJTSAU)** has initiated an online certificate course starting in June 2021. This course will be career and market oriented for graduates / post graduates in agriculture, food engineering, and environment sciences and applied sciences. This initiative will also help in promoting our Prime Minister's idea of an *Atmanirbhar Bharat* (entrepreneurship) and empowerment for employment in organic Industry.

This will be an excellent means to enhance skills in the organic sector for making progress in the job market. The information, guidance, practical training and course completion certificate will provide the participants with several opportunities in the organic industry like auditors for assessment of organic production and certification, as quality assurance executives / quality managers / food managers, positions in new product development, as consultants and many more.

This edition of the e-newsletter highlights the regulatory challenges for market access and the residues of ethylene oxide in organic products.

I hope you enjoy reading this newsletter and we look forward to your feedback so we can continuously add value to it.

With best wishes

**AIOI family**

# Meeting Regulatory Challenges for Accessing Global Markets



*\* Mr. Anil Jauhari*

Indian products, especially in agri-food sector, typically face stringent regulations of the importing countries, especially developed economies, in their quest for access to global markets.

Depending on the sub sector within agri-food sector, the challenges can vary and even India's strategy for overcoming such challenges has to vary.

Any regulation usually has two components – one, the standards to be implemented by the agri-food operators – these could be product standards and/or process standards – like HACCP in high risk sectors in food or organic production and two, the manner of demonstrating compliance to these standards – be it self declaration of conformity in low risk products which European Commission (EC) uses quite extensively for industrial products or direct evaluation by the overseas regulator as USFDA does for pharma industry or the use of third party agencies as EC and US Department of Agriculture adopt in case of organic production.

All countries, who have prescribed regulations for any product, also specify the procedure for demonstrating compliance to these regulations. Any individual producer, therefore, can approach the overseas regulator, fulfil its prescribed requirements and get its products accepted. Pharma sector is a good example to cite of Indian industry's success using this approach. Therefore, any agri-food producer is free to follow the prescribed route to compliance and seek approval of the overseas regulator on his own. This, in a way, means each producer fend for himself.

The challenge here would be access to right information (imagine regulations in Japanese or Chinese languages), capability to understand and meet the requirements laid down (including testing capability which has often been a constraint) and the cost that may be incurred in the entire exercise which can be prohibitive – the fee in USD or Euros or expenses of auditors flying in from USA or Europe can push up prices of commodities and even make them uncompetitive or prevent smaller operators from even trying to access such markets.

Therefore its necessary to think of ways to make the access easier for our industry.

One of the ways is to pitch our regulations on par with international standards so that our products become more easily acceptable and we can aim for acceptance of our regulated products. Agri-food sector is governed by the SPS Agreement and the international standards setting bodies have been listed in it for human, animal and plant health as Codex, OIE and IPPC, respectively.

This itself is a challenge in India given the fact we have scores of tiny and small operators producers who may find it difficult to implement international standards. Implementing HACCP for food safety is one such example; implementing WHO GMP in pharma or AYUSH another.

Sometimes India does not even have regulations while importing countries have as was faced in organic production for years till FSSAI came up with domestic regulations.

## **IFOAM releases new study on Boosting Organic Trade in Africa.**

IFOAM - Organics International together coordinated a study about boosting organic trade in Africa. It is a market analysis and has recommended interventions to boost organic trade in Africa and was conducted by ProFound and Organics & Development.

*Source: <https://www.ifoam.bio/news/new-study-boosting-organic-trade-africa>*

Even if we upgrade our regulations to international standards, with the provision for stricter standards allowed in WTO regime, an issue would remain if importing countries adopt stricter standards which may not be appropriate for India and, therefore, may not be needed to be adopted in our regulations.

All the above situations would call for an institutional mechanism to test and certify our products to stricter regulations in the global market which, for example, is available through the Export Inspection Council (EIC) for seafood or APEDA for organic production or the Quality Council of India (QCI) in the form of AYUSH Premium Mark or ICMED schemes based on international standards like WHO GMP or ISO 13485 for medical devices respectively. The last named has an advantage that its schemes can be operated both for the domestic and overseas markets while the first two are mandated only to deal with exports but have the advantage of being able regulate exports, if needed.

Such an institutional mechanism, whether by regulation by EIC or APEDA or voluntary like by QCI can then be presented to overseas regulators for acceptance by the government. Indeed, India has been successful in securing acceptance of EIC's seafood certification system by EC and some other countries as also organic certification of APEDA, again by EC and some other countries

The WTO TBT and SPS Agreements provide for acceptance of exporting country's conformity assessment procedures or even regulations by importing countries and India needs to pursue this option assiduously to promote acceptance of its products. Ideally, if our regulations are entirely based on international standards, we could negotiate for acceptance of our products as regulated.

However, in many cases as highlighted above, our regulations are less stringent or different from those of the importing countries and, therefore, the option of having a voluntary or even regulatory system for certifying to importing countries' regulations is a viable option. It would also be appropriate to underscore the importance of conformity assessment meaning inspection, testing and/or certification procedures in meeting overseas regulations. A study by the WTO of the specific trade concerns raised by the member countries has shown that only 30% of them related to standards; 70% trade concerns related to conformity assessment. This study did not cover agri-food sector but is a good pointer.

The most commonly used method for acceptance of inspection, testing or certification across borders is **accreditation** be it regulations or voluntary standards. Fortunately, India has internationally recognized accreditation bodies, the National Accreditation Board for Certification Bodies (NABCB) and the National Accreditation Board for Testing and Calibration Laboratories (NABL), which should be leveraged to promote acceptance of India's conformity assessment. Some progressive regulators like Food Safety and Standards Authority of India (FSSAI) in food sector, CDSCO for medical devices and the Bureau of Energy Efficiency for star rating scheme have embraced this system of accreditation and third-party agencies which many regulators around the world also utilize.

#### New AIOI Members

1. GreenCert Biosolutions Private Ltd is a NPOP certification body for organic products and is based in Pune, Maharashtra. They are accredited under the NPOP by the National Accreditation Body (NAB), Government of India,
2. Grow Well Organic & Eco Products Private Limited, based in Jaipur, Rajasthan, is a manufacturer and exporter of organic pulses under the brand name, 'Bytewise Organic'.





It may be appropriate to point out that harmonization of standards is not a prerequisite for such agreements as long as we display a capability to produce and demonstrate compliance to the standards/regulations of the importing countries. EIC, as a duly designated competent authority for EU in seafood, is an excellent example of one sided understanding where India has gained access to EU market.

The acceptance of our certification system can be either through bilateral trade agreements with our trading partners or better still through multilateral trade agreements and can go a long way in making exports easier rather than making individual operators struggle with overseas acceptance on their own.

The free flow of goods in EU and ASEAN markets are excellent examples and in many regional groupings like SAARC or BIMSTEC, India is ideally paced to take the leadership to push such mutual recognition agreements. Multilateral agreements obviously would be better since they provide access to a number of countries at the same time. Multilateral agreements obviously would be better since they provide access to a number of countries at the same time.

The above narration highlights that India needs to carefully consider various options suited to each sub sector within agri-food sector to create internationally acceptable systems to promote exports.



### **UN Committee on World Food Security has approved Voluntary Guidelines on Food Systems and Nutrition.**

The UN Committee on World Food Security (CFS) in its 47th Session, on 8-11 February, 2021 endorsed the Voluntary Guidelines on Food Systems and Nutrition (VGFSyN) underlining the value these guidelines will provide to the UN Food Systems Summit, 2021 and any follow-up process.

The guidelines emphasize upon the importance of sustainable and resilient food systems, through a range of sustainable innovative approaches including agroecology and organic agriculture.

*Source: <https://www.ifoam.bio/news/voluntary-guidelines-food-systems-and-nutrition>*

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\* Mr. Anil Jauhari, Former CEO, NABCB, Quality Council of India

# Ethylene Oxide - A New Threat in the Food Products



\*Dr. (Mrs) PVSM Gouri

During 2020, on top of the Covid-19 pandemic, the world is facing a threat of ethylene oxide in various food products. The recent issue of ETO/ECH residues in organic sesame and spices has cropped up in organic export consignments from India. A concern about the presence of ETO in sesame imported from India was raised by Belgium in September, 2020. Later, similar complaints started coming from France, Luxembourg, Netherlands, Italy, Czech Republic, Finland, Germany, Austria, Norway, Sweden and other EU countries. The supply chain extended to Andorra, Bulgaria, Denmark, Estonia, Greece, Hungary, Ireland, Latvia, Lithuania, Malta, Poland, Portugal, Qatar, Romania, Russia, Saudi Arabia, Singapore, Slovakia, Slovenia, Spain, Switzerland, United Arab Emirates, and the UK. Later the ETO residues were reported in several other products like pepper, cumin, amaranth etc.

Ethylene oxide or ETO is a flammable colorless gas with a sweet odour which is commonly used as a fumigant and antimicrobial agent in food industries. It can also be used as a pesticide or a sterilizing agent due to its ability to damage DNA. This is known as a chemical fumigant used as insecticide (*storage pest management*) – disinfestation input and for reducing microbial load – disinfectant / sterilization input. However, ETO cannot be and should not be used for direct household activities due to its harmful effects.

## Organic textile sector initiative for testing genetically modified (GM) cotton has been finalized.

The global ISO IWA 32:2019 GMO has standardized the proficiency test protocol for GMO testing in cotton. This milestone has been achieved with the collaboration of GOTS, OCA and Textile Exchange with technical support from Wageningen Food Safety Research.

Fourteen laboratories from China, Germany, India, The Netherlands and Portugal have, currently, been recognized for conducting GMO testing as per the ISO IWA 32:2019 method.

The list of laboratories is jointly published by GOTS, OCA and Textile Exchange.

Source: <https://ioas.org/latest-news/organic-textile-sector-reaches-a-significant-milestone-in-testing-for-genetically-modified-gmo-cotton/genetically-modified-gmo-cotton/>

At industrial level, ETO is used widely during the production of detergents, thickeners, solvents, plastics, and various organic chemicals such as ethylene glycol, ethanolamines, simple and complex glycols, polyglycol ethers, and other compounds.

Disinfectant usage of ETO is generally practiced in critical items sensitive for wet sterilization / dry sterilization methods (e.g., rubber, plastics, electronic items / spares, health care protectives, health care facility etc.).

The current Maximum Residue Limit (MRL) in respect of conventional food items is 0.05 ppm (general); MRLs in respect of dried garlic, dried onion, dried paprika, dried ginger is 0.02 ppm. The maximum permissible level for Ethylene Oxide prescribed by EU for spices, as per the EU Pesticide Database website, is 0.1 mg/kg. The product wise updated details can be accessed at <http://www.inchem.org/documents/jmpr/jmpmono/v071pr15.htm>

In late 2019, Health Canada's Pest Management Regulatory Agency proposed to establish maximum residue limits (MRLs) for ethylene oxide on dried vegetables and sesame seeds to permit the sale of foods containing such residues. It is an insecticide registered in Canada for use on whole or ground spices and processed natural seasonings.

The MRLs proposed for ethylene oxide of 7 ppm are the same as American tolerances. There are no Codex MRLs listed for ethylene oxide in or on any commodity. Ethylene oxide is used by the US spice industry to prevent microbial contaminants such as Salmonella and E. coli to reduce bacterial loads, yeast and mould, coliforms and other pathogens.

This led to initiation of investigations at various level by different certification bodies and authorities. Especially, the organic certification bodies in India started their investigation at various levels such as farming units, processing industries and trading premises to find the source and extent of this contamination. Several investigations were done which resulted in various results but finding the actual source of ETO was the biggest challenge of whole investigation.

Let me highlight the impossibilities and possibilities of ETO contamination

## 1. Impossibilities

ETO is available in cylinders in pure form but commonly available as 9:1 ratio blend with CO<sub>2</sub> (9-parts ETO: 1 part CO<sub>2</sub>). There is no possibility of cross contamination through CO<sub>2</sub> / N<sub>2</sub> gas cylinders (used as approved methods of fumigation in organic foods).

In some plants, ethylene is present naturally which further degrades to form ethylene oxide. The expected output of ETO from natural sources is negligible. There is no possibility of natural conversion of Ethylene to ETO by oxidation, as this reaction requires high energy and presence of catalysts. Gas oxidation is also not a possibility for cross contamination.

Ethrel is a plant hormone, and is used to emit Ethylene gas (used for fruit ripening) with the help of 0.1% Etrex solution (or) Ethrel (10 ml) + Sodium hydroxide (2 g) in 5 liters of water solution. For example, red chilli during ripening can emit natural ethylene gas. But this will not get oxidized naturally to form ETO. Therefore, ethylene bio-synthesis in red chilli cannot contribute to ETO residues.

Minor level of ETO is formed in beans but the level is too low to detect. Minor level of 2-chloroethanol (2CE) may be formed by chlorination of Ethylene (Ethylene + Hypochlorite → 2CE). This is also too low to detect.

## 2. Impossibilities

### Disparity in testing ETO Presence in organic products

Disparity is reported in different EU lab reports of the same sample. This might be due to the difference in analytical methods applied by the labs.

- Free ETO is screened by using headspace GC and this method is not appropriate as it will not give any residual indication of 2-chloroethanol (2CE).
- Some labs are testing the raw material (whole spices like ginger rhizome, turmeric dry rhizomes) material by mechanical grinding which might reduce ETO residue due to its volatile nature.
- It is reported that some labs are collecting only 25gms sample and the test reports do not specify the sampling method, maximum lot size and nature of the product (ground form or whole form). Such short coming inadequate sample size can lead to missing of hot spot area in a lot.

## 3. Cross Contamination Possibilities

Some of the cross-contamination sources are:

- (a) Shared warehouse for conventional and certified organic commodities.
- (b) Containers previously loaded with ETO treated materials.
- (c) Different raw materials lots without proper traceability records used to produce finished goods
- (d) ETO fumigated / treated bag inner liners, container liners / bulk liners, sample packing pouches.
- (d) ETO treated rubber gloves, Personal Protection (PP) kits, band aids etc.
- It would be better to screen all raw materials before processing. If any low-level detection (0.01–0.05 ppm) is noticed in raw material or finished goods, the cross-contamination possibilities through the items mentioned above are strong hot spots. Rather it would be idle to screen all items expected to have direct contact with food items.

## MRLs and LOQs for certified organic food products

No MRLs for ETO residues in certified organic products should be below LOQ (current LOQ is 0.01 ppm). The LOQ of ETO residue is the sum of free ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide. Estimation of free ethylene oxide (headspace GC) is not the correct method; it will not give any residual indication of 2-chloroethanol which is a fixed residue in food items. There is no point in screening any sample for ETO residue in a laboratory facility having LOQ 2CE. This is also too low to detect at 0.05 ppm.

In conclusion, I would say that the Indian authorities and the organic certification bodies are working hard and are still investigating these cases to find out different sources and extent of this contamination.



We hope that this crisis will soon come to an end. As a precautionary measure, after testing, a health certificate should be introduced by the concerned authorities for additionally confirming that ETO is not present in the lot to be exported.

In nutshell, there is a requirement for preventive measures to be taken for cross contamination possibilities during handling in a factory, which has separate processing lines (parallel production) for organic and conventional products as there might be possibilities of intentional or unintentional treatment with ETO when the operations are taking place.

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*\* I thank Mr. Gulshan John, Managing Director, Nedspice Processing India Pvt Ltd Kochi and Mr. N.V. Baby Raphael, General Manager (Agriculture) and Quality Head, Suminter India Organics and Certification bodies in sharing their views and experiences in organic products.*

### **Commencement of Online Short-term course for Skill and Entrepreneurship Development in Organic Products by AIOI from June 2021**

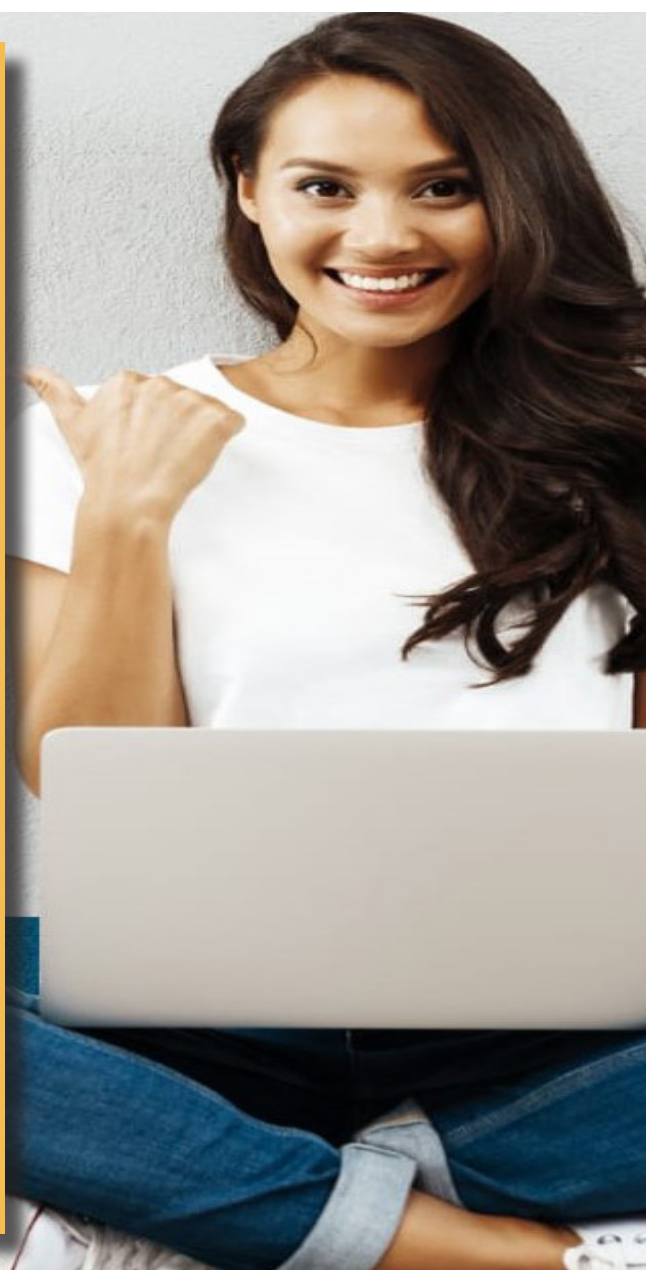
Association of Indian Organic Industry (AIOI) and The Professor Jayashankar Telangana State Agricultural University (PJTSAU), Hyderabad have jointly initiated a short-term course on Skill and Entrepreneurship Development in organic products with effect from 2021.

This digital Certificate Course is a professional course targeted to cater to the needs of organic industry. The information, guidance, practical training and course completion certificate will provide the participant with several opportunities in the industry like auditing for assessment of organic programmes, opportunities for organic certification to take up positions as quality assurance executives and quality managers organic food managers, positions in new product development, consultancy assignments as well as to establish business in organic products and many more.

Duration: 4 months

Eligibility: Graduate students, 2nd and 3rd year undergraduate students in Life Sciences and Applied Sciences. Candidates appearing for the final year exam. Bachelor's degree/equivalent qualification exam or awaiting their results are also eligible to apply.

1st batch registration commences: 1st May 2021 For more details visit [www.aioi.org.in](http://www.aioi.org.in)



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*\* Dr. P.V.S.M. Gouri, CEO & Executive Director of AIOI and Former Advisor (Organic Products), APEDA*

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