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Evaluation of 5 laboratories operated by Directorate of Marketing and Inspection (DMI) with reference to the testing of Organic Food Produce

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Acronyms and definitions

Acronyms	Definitions
AAS	Atomic Absorption Spectrometer
AGMARK	Agriculture Mark
AMD	Indo-German Cooperation on Agricultural Market Development
APEDA	Agricultural and Processed Food Products Export Development Authority
APGM Act	Agricultural Produce Grading and Marking Act
CAB	Conformity Assessment Body
CAL	Central Agmark Laboratory
DG SANTE	The Commission's Directorate-General for Health and Food Safety
DMI	Directorate of Marketing and Inspection
EFSA	European Food Safety Authority
EC	European Commission
EU	European Union
FCM	Food Contact Material
FSS Act	Food Safety Standard Act
FSSAI	Food Safety Standard Authority of India
FTDR Act	Foreign Trade & Development and Regulation Act
GC MS	Gas Chromatograph Mass Spectrometer
HPLC MS/MS	High Performance Liquid Chromatograph double Mass Spectrometer
ICP AES	Inductively Coupled Plasma Atomic Emission Spectrometer
ICP OES	Inductively Coupled Plasma Optical Emission Spectrometer
ICP MS	Inductively Coupled Plasma Mass Spectroscopy
IFOAM	International Federation of Organic Agriculture Movements
IS	India Standard
ISO	International Organisation for Standardization
ISTE	International Short-term Expert
ITC	International Trade Centre
LC IRMS	Liquid Chromatograph Intelligent Magnetic Resonance Stimulation
LC MS	Liquid Chromatograph Mass Spectrometer
LC MS/MS	Liquid Chromatograph Double Mass Spectrometer
MCI	Ministry of Commerce and Industry
MCPB	Methyl-4-Chlorophenoxy) Butyric Acid (herbicide)

NABCB	National Accreditation Board for Certification bodies
NABL	National Accreditation Board for Testing and Calibration Laboratories
NA	Not Applicable
NC	Non-Conformity
NGMO	Non-Genetically Modified Organisms
NPOP	National Program of Organic production
NSOP	National Standards for Organic Production
OCIL	Organizer of Comparisons Inter-Laboratories
PCB	Polychlorobiphenyls
QI	Quality Infrastructure
RAL	Regional Agmark Laboratory
RASFF	EU Rapid Alert System for Food and Feed
SAGL	State Agmark Grading Laboratory
SGL	State Grading Laboratories
STE	Short term Expert
SWOT	Strengths, Weaknesses, Opportunities & Threats
ToR	Terms of Reference
UV	Ultraviolet

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1 Executive Summary

The objective of this study conducted by an International short-term expert was to evaluate the scope of 5 Agmark laboratories operated by Directorate of Marketing and Inspection (DMI) upgrading these laboratories to the level of European reference laboratories.

The study endeavor identifying the required infrastructure, equipment, and technical skills required for DMI to upgrade its current testing facilities to further test organic food commodities and facilitate exports of India commodities to the EU market by a better mastery and control of their quality and safety.

The Expert evaluated, from 10 to 14 June 2024, 5 Agmark laboratories¹, for their current capabilities using questionnaires, onsite interviews of the laboratories staff and visiting the laboratory premises.

During the mission, the expert conducted a SWOT analysis of the laboratories, identifying their strengths, weaknesses and their relevance to current Indian food safety standards. The study determined the opportunities and threats regarding the Agmark mark possible developments and proposed required equipment, and technical skills so that the Agmark laboratories can test Indian organic food produce to the level of European reference laboratories, facilitating their export to the EU market.

Based on the findings of this assessment, the expert recommends:

- Actions to facilitate exports to the EU: (i) from FSSAI to better harmonize the India food regulation system to that of the EU and if not possible, (ii) to upgrade, the DMI labs to the level of European reference laboratories for food commodities testing;
- DMI to accredit its certification and inspection activities to ISO standards 17065 and 17020 respectively, allowing the international markets and particularly the EU one, to recognise the Agmark certification marks and facilitate the access to these markets.
- DMI to update the rules of the Agmark certification scheme for both traditional and organic commodities to introduce the Indian food safety provisions and if possible, to better harmonize them with the EU ones;
- DMI to upgrade the capabilities (recruitment, trainings and equipment) of the Agmark laboratories to control both the quality and safety of the food commodities certified under the Agmark mark;
- DMI to promote the Agmark mark and increase the number of licensees, which will benefit the DMI certification and inspection activities, for the Agmark laboratories, producers and consumers;
- The first step can be to improve the capabilities of CAL Nagpur, which is the most advanced laboratory that already possesses most of the required analytic equipment to test safety of food. Subsequently, according to the level of development of the updated Agmark mark, CAL Nagpur can participate by technical support and training to the improvement of the capabilities of the other RALs.

¹ Central Agmark Laboratory (CAL) at Nagpur and 4 Regional Agmark Laboratories (RAL) namely Mumbai, Delhi, Kanpur and Kolkata

2 Objectives

The tasks of the expert as described in the ToR of his assignment (See ToRs in **Annex 1**) were “to evaluate the scope of laboratories operated by Directorate of Marketing and Inspection (DMI)² so that they can test organic food produce”. The study had to identify the required infrastructure, equipment, and technical skills required for DMI to upgrade its current testing facilities to further test India organic food product (upgrading DMI laboratories to the level of European reference laboratories).

The objectives of the study were to:

- 1 - Conduct a SWOT analysis to review the current scope of 5 laboratories³ of DMI and their relevance to current Indian food safety standards.;
- 2 - Visit the above-mentioned laboratories to assess their current capabilities and propose upgradation of their scopes to test, and report on "Organic food testing". The assessment had specifically to look at the following aspects - Existing available infrastructure facilities of the laboratories and the needs for their upgradation to test safety aspects of food commodities - Existing equipment facilities and the needs for upgradation to test organic food - Existing technical skills and the needs for capacity building/ training of DMI officials;
- 3 – Evaluate the cost calculations for upgradation of the scope of the 5 DMI laboratories to test organic food product. (recommend evaluating the upgradation for CAL first for the Indian internal market and for the EU market);
- 4 - Compile a comprehensive report with recommendations for improving organic testing facilities of the Agmark laboratories.

² Directorate of Marketing and Inspection has a set up for quality certification of agricultural produce, food, and allied commodities, through the network of 11 Regional Agmark Laboratories (RAL) at different places in the country with Central Agmark Laboratory (CAL), at Nagpur as the apex laboratory. 61 technical persons are working in these laboratories against the sanctioned strength of 146 as on date. These laboratories were established to formulate standards and conduct physical and chemical analysis of agricultural and allied commodities in accordance with APGM Act 1937.

³ Central Agmark Laboratory (CAL) at Nagpur and 4 Regional Agmark Laboratories (RAL) namely Mumbai, Delhi, Kanpur and Kolkata

3 Description of activities and results

3.1 Preliminary remarks and disclaimer

As the mission of the expert was concerning exclusively to the visits and evaluation of the 5 DMI Agmark laboratories, which are not involved in sampling activities. Sampling is dedicated to DMI Marketing Officers, and as the expert had no opportunity to discuss the sampling issues they may have, he focused his activities on the testing capabilities of the 5 above mentioned laboratories and has given only some general recommendations for the DMI officers in charge of the Agmark certification scheme.

As indicated in the objectives of the study, the expert has to propose recommendations for the upgrade of the Agmark laboratories for the test of organic commodities, first for the Indian market and then, for facilitating the organic commodities to enter the EU market.

Consequently, the expert had to analyse the gap existing between the current capabilities of the Agmark laboratories and the requirements of both, the India and EU regulations relating to standard and organic commodities.

This is why, the expert proposed a reminder of the main legal provisions of the India regulations for food commodities (including the organic ones) and of those of the EU.

3.2 Reminder: The India food regulation and the Agmark certification

3.2.1 The India acts for food and the role played by the Agmark certification scheme.

The Directorate of Marketing and Inspection (DMI), an attached Office of the Department of Agriculture, Cooperation and Farmers Welfare under Ministry of Agriculture & Farmers Welfare, was setup in the year 1935, to implement the agricultural marketing policies and



programmes for the integrated development of marketing of agricultural and other allied products in the country, with a view to safeguard the interests of the farmers as well as the consumers.

The first Indian Agricultural Produce (Grading and Marking) Act, 1937 (Act No. 1 of 1937), as amended in 1986, was to provide rules for grading and marking of agricultural and other produce (see **Annex 2**).

DMI had to implement the provisions of this Act.

The standards notified in this Act are popularly called AGMARK Standards. They differentiate 2 to 3 quality grades as prescribed for each commodity.

Grades help farmers to get prices for agricultural commodities as per the quality produced by them and for consumers to get the desired quality.

Till now, A central APEX

Samples of agricultural commodities under Agmark certification, are drawn from all parts of the country - from the producing area, wholesale markets, etc. and are analyzed in the Central Apex Agmark Laboratory at Nagpur and 11 regional laboratories spread all over the country for the identified grading parameters.

DMI, since the beginning, is implementing the scheme of certification of agricultural commodities for domestic trade and export.

The AGMARK certification scheme is voluntary except for blended edible vegetable oils and fat spread for which it is mandatory as per provisions of the India regulation.

Out of the twelve above mentioned laboratories, 8 laboratories (at Nagpur, Mumbai, Chennai, Kochi, Kolkata, Delhi, Jaipur and Kanpur) are accredited by the National Accreditation Board for testing and Calibration Laboratories (NABL) as per the International Standard ISO 17025:2017. The CAL is also accredited by NABL according to ISO 17043:2012 as organizer of laboratories inter-comparisons (OCIL), this activity supports the Agmark laboratories for maintaining their ISO 17025 accreditation year after year.

Producers desirous of grading and certifying a notified commodity under Agmark should have necessary infrastructure to process the commodity and should have access to an approved laboratory or can have their own laboratory.

They can apply to the concerned office of DMI, who will deliver a Certificate of Authorization after verification of the necessary infrastructure of the applicant.

The approved Chemist laboratories test the raw material or the processed commodity before getting it packed in a suitable packing material / container.

The field officers of DMI keep regular check on the commodity graded and certified under Agmark by drawing check samples from packers' premises and market.

These checked samples are analyzed in the Agmark Laboratories and action deemed fit is taken if the graded commodity is found not conforming to the prescribed India Standards (IS).

The licensees of Agmark certificates affix the following marking on the container of the commodity to ascertain whether a commodity is certified under Agmark or not:



NAME OF COMMODITY

GRADE.....

The Agmark certification rules have been amended in 2009 (See **annex 3**) and in 2012 (See **Annex 4**) with a notification concerning rules to be applied to spices commodities.

3.2.2 A tightening of India food regulations, the Food Safety and Standards Act, 2006

More recently, the Govt. of India has enacted a very important Act known as "The Food Safety and Standards Act, 2006", abbreviated as "FSS Act 2006" (See **Annex 5**)

The FSS Act 2006 defines the rules and regulations applicable to food safety, consolidates the laws relating to food and establishes the Food Safety and Standards Authority of India (FSSAI) for laying down science-based standards for articles of food and regulating their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.

By this Act, India introduces safety notions for food, a basic concept missing in the former India and particularly in the former "Grading and Marking Act, 1937".

The duties of FSSAI are to regulate and monitor the manufacture, processing, distribution, sale and import of food so as to ensure safe and wholesome food.

FSSAI accomplished its duties by publishing various rules and regulations on the limits for use of food additives, crop contaminants, pesticide residues, residues of veterinary drugs, heavy metals, processing aids, myco-toxins, antibiotics and pharmacological active substances and irradiation of food, for accreditation of laboratories and notification of the accredited laboratories and provisions for food labelling standards including claims on health, nutrition, special dietary uses and food category systems for food.

Amongst others, FSSAI published in:

- 2011 "Food Safety and Standards Rules" organizing the Food safety control system in India (See **Annex 6**), "Food Safety and Standards (Contaminants, Toxins and Residues) Regulation giving the admitted limits for the before mentioned hazards on food commodities (See **Annex 7**), and "Food Safety and Standards (additives) as amended in 2022 (See **Annex 8**);
- 2016, "Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food" as amended in 2022, giving the nature and admitted limits for these substances (See **Annex 9**);
- 2017, "Food Safety and Standards on approval for Non-Specific Food and Food Ingredients" and "Food Safety and Standards on Organic Food" (See **Annex 10**). This regulation states that all organic food should comply with both the Food safety and Standards regulation of 2011 as well as this Food Safety and Standards on organic food of 2017;
- 2018, 2020 and 2022, "Food Safety and Standards related to Alcoholic Beverages, Fortification of Food, Foods for Infant Nutrition and Vegan Foods".

As per its duties FSSAI conducted regular surveillance, monitoring, inspection and random sampling of food products to check compliance to India standards, on milk

in 2016, 2018, 2020 and 2022, on edible oil in 2020, on trans-fat & Acrylamide Content on food, on jaggery in 2022.

FSSAI published the results of his market surveillance: during the period 2018-2022 on a total of 650 095 samples analyzed, 165 706 were found non-conforming representing 25% of the analyzed samples, that presume an insufficient implementation of the India food safety rules and regulation system.

3.2.3 The National Programme for Organic Production (NPOP),

Focusing on development of organic agriculture and quality products, India Ministry of Commerce and Industry, under the Agricultural and Processed food products Export development Authority (APEDA) launched the National Programme on Organic Production (NPOP), formally notified in October 2001 by reference to the Foreign Trade & Development Regulation Act (FTDR Act of 1992) (See **Annex 11**).

The NPOP was documented by APEDA on standards for organic production, systems criteria & procedures for accreditation of inspection and certification bodies, the national organic logo and the regulations governing its use. The standards and procedures have been formulated in harmony with international standards such as those of Codex and IFOAM and keeping Indian requirements in mind.

The updated seventh edition of NPOP (See **Annex 12**) covers the more recent issues of group certification for small / marginal farmers and mandatory checks required to be carried out by the certification bodies during their inspections.

A number of other improvements have also been made in the NPOP documents to meet the latest international requirements. All this has been possible with the continued inputs provided by different Govt. departments and commodity boards. A trademark “India Organic” was granted on the basis of compliance to the National Standards for Organic Production (NSOP).

Communicating the genuineness as well as the origin of the product, this trademark is owned by the Government of India.

Only such exporters, manufacturers and processors whose products are duly certified by the accredited inspection and certification agencies, will be granted the license to use the logo given hereafter.



The India certification mark for organic commodities under NPOP

Besides, in 2009, was published the rules for Organic Agricultural Produce Grading and Marking equivalent for organic commodities to the rules based on Grading & Marking) Act, 1937 for non-organic commodities.

The licensees under the DMI Agmark certification for grading and marking of Organic commodities shall use the logo given hereafter.



AGMARK
C.A. NO.:

The India certification mark for organic commodities under DMI Agmark certification.

The comprehensive training manual published in 2018 by APEDA, for trainings and capacity building programmes is a simplified and explanatory version of the National Programme for Organic Production (See **Annex 13**).



Market gardening scene in India.

3.3 Reminder : The EU rules and regulation on food safety

3.3.1 Common EU legislation on food safety

India wants to improve exports of food commodities including organics, to the demanding EU market, the objective being for the Agmark laboratories to be India references laboratories for organic food controls.

In the EU the basic regulation for food commodities is the [Regulation \(EC\) No 178/2002](#) which lays down the general

principles and requirements of food law, and [Regulation \(EC\) No 1331/2008](#) which establishes the common authorisation procedure for food additives, food enzymes and food flavorings.

Both regulations were amended by [Regulation \(EU\) 2019/1381](#) on the transparency and sustainability of the EU risk assessment in the food chain amended with effect from 27 March 2021. Further information on the implementation of that Regulation can be found on [DG SANTE's website](#).

The [Regulation \(EU\) No 234/2011](#) implements the common authorisation procedure and applies from 11 September 2011. That Regulation has been amended by Commission Implementing [Regulation \(EU\) No 562/2012](#) which lays down derogation from submitting toxicological data in some specific cases and the possibility of grouping food enzymes under one application under certain conditions. It has also been adjusted by [Commission Implementing Regulation \(EU\) 2020/1823](#) to accommodate the changes linked to [Regulation \(EU\) 2019/1381](#) on the transparency and sustainability of the EU risk assessment in the food chain.

The UE food safety legislation concerns:

- **Chemical safety** which includes:

- Food additives

All additives in the EU authorised and listed with conditions of use in the EU's positive list. These additives concern food enzymes, food flavorings and food colorings and nutrients.

[Regulation EC 1333/2008](#) sets the rules on food additives: definitions, conditions of use, labelling and procedures.

The list of authorised food additives approved for use in food additives, enzymes and flavorings can be found in the Annex of [Commission Regulation \(EU\) No 1130/2011](#) which amends Annex III to Regulation (EC) No 1333/2008. The additives approved for use in flavorings can be found in part 4 of this Annex.

- PCBs,



The basic principles of EU legislation on contaminants in food are laid down in [Council Regulation 315/93/EEC](#).

The maximum levels for certain contaminants in food are set in [Commission Regulation \(EU\) 2023/915](#). These maximum levels concern the following contaminants:

- **mycotoxins** (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, citrinin, ergot sclerotia and ergot alkaloids);
- **plant toxins** (erucic acid, tropane alkaloids, hydrocyanic acid, pyrrolizidine alkaloids, opium alkaloids, Δ^9 -THC);
- **metals** (lead, cadmium, mercury, arsenic, inorganic tin);
- **halogenated persistent organic pollutants** (dioxins, dioxin-like PCBs, non-dioxin-like PCBs; perfluoroalkyl substances: PFOS, PFOA, PFNA, PFHxS);
- **processing contaminants** (polycyclic aromatic hydrocarbons (PAH): benzo(a)pyrene, sum of 4 PAHs; 3-monochloropropane-1,2-diol (3-MCPD), glycidyl fatty acid esters);
- **other contaminants** (nitrates, melamine, perchlorate).

- Residues of veterinary medicinal products

The main EU regulations are the following:

- [Directive 96/22/EC](#): Bans the use of certain substances in food producing animals;
- [Regulation \(EC\) No 396/2005](#): Establishes Maximum Residue Levels for pesticides in food;
- [Regulation \(EC\) No 124/2009](#): Established Maximum Levels for the presence of coccidiostats or histaminases in food resulting from the unavoidable carry-over of these substances in non-target feed.

- Food contact materials

The framework Regulation

[Regulation \(EC\) No 1935/2004](#) provides a harmonised legal EU framework. It sets out the general principles of safety and inertness for all Food Contact Materials (FCMs).

This regulation was amended by [Regulation \(EU\) 2019/1381](#) on the transparency and sustainability of the EU risk assessment in the food chain amended with effect from 27 March 2021.

The resulting and latest consolidated version is available: [Regulation \(EC\) No 1935/2004 \(Consolidated\)](#).

[Regulation \(EC\) No 1935/2004](#) was amended by [Regulation \(EU\) 2019/1381](#) on the transparency and sustainability of the EU risk assessment in the food chain amended with effect from 27 March 2021.

Further information on the implementation of that Regulation can be found on [DG SANTE's website](#).

Commission Regulation on Good Manufacturing Practices

[Commission Regulation \(EC\) No 2023/2006](#) ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation:

- premises fit for purpose and staff awareness of critical production stages;
- documented quality assurance and quality control systems maintained at the premises and;
- selection of suitable starting materials for the manufacturing process with a view to the safety and inertness of the final articles.

Good manufacturing rules apply to all stages in the manufacturing chain of food contact materials, although the production of starting materials is covered by other legislation.

EU legislation on specific FCMs

In addition to the general legislation, certain FCMs — ceramic materials, regenerated cellulose film, plastics (including recycled plastic), as well as active and intelligent materials — are covered by specific EU measures.

There are also specific rules on some starting substances used to produce FCMs:

- Plastic Materials (See [Commission Regulation \(EU\) No 10/2011 as amended](#));
- Active and Intelligent Materials (See in [Commission Regulation \(EC\) No 450/2009 as amended](#));
- Recycled Plastic Materials (See [Commission Regulation \(EU\) No 10/2011 as amended](#));
- Ceramics (See [Commission Directive 84/500/EEC as amended](#));
- Regenerated Cellulose Film (See [Commission Directive 2007/42/EC as amended](#)).

Legislation on Specific FCMs Substances

- [Commission Regulation \(EU\) 2018/213](#) - on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials;
- [Commission Regulation 1895/2005/EC](#) - restricting use of certain epoxy derivatives in materials and articles intended to come into contact with food;
- [Commission Directive 93/11/EEC](#) - release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers.



This EU pictogram guaranty that the food packaging or kitchen accessories (plastic dishes, glasses, forks, knives or spoons) on which it is affixed are conforming the safety provisions of the EU FCM regulation.

- Hormones in meat

In 1981, with [Directive 81/602/EEC](#), the EU prohibited the use of substances having a hormonal action for growth promotion in farm animals. Examples for these kind of growth promoters are estradiol 17 β , testosterone, progesterone, zeranol, trenbolone acetate and melengestrol acetate (MGA).

This prohibition applies to Member States and imports from third countries alike. The legal instrument in force is [Directive 96/22/EC](#) as amended by [Directive 2003/74/EC](#).

Directive 96/22/EC was further amended to prohibit all uses of estradiol 17 β and its ester-like derivatives in food-producing animals ([Directive \(2008/97/EC\)](#)).

- **Biological safety**

Biological hazards include **bacteria, viruses, parasites, prions, biotoxins**. Some of these hazards have posed serious risks to public health, such as [Salmonella](#), *Listeria monocytogenes*, biotoxins in live mollusks or [BSE](#). Exposure of consumers to those through food should thus be prevented.

A comprehensive legal framework has been established by the European Commission to increase the level of food safety in Europe, building over time European consumers confidence while preventing **food crises**. It is based on scientific advice delivered by the **European Food Safety Authority (EFSA)**.

It includes:

- A [coordinated and holistic approach towards food hygiene](#), covering all levels of the food chain, applying a transparent hygiene policy to all food operators and ensuring an efficient, risk-based and independent control;
- Increasing knowledge of sources and trends of pathogens by **monitoring zoonotic agents** throughout the food and animal feed chain;
- Establishing **control programmes for Salmonella and other food-borne zoonotic diseases** to reduce the public health risk and to provide the basis for adopting measures to manage these risks;

- An assessment of the safety and quality of all types of foodstuffs by **setting out [microbiological criteria](#)**, applicable at the site of food production as well as products on the market;
- **The effective control of Transmissible Spongiform Encephalopathies ([TSE](#), [BSE](#), [scrapie](#), etc.)**, with harmonised measures in Member States to avoid contagion of other animals or exposure of the consumers. Harmonisation of TSE measures in Member States and the TSE import rules applicable to third countries.

○ **Novel food**

Novel Food is defined as food that had not been consumed to a significant degree by humans in the EU before 15 May 1997, when the first Regulation on novel food came into force.

'Novel Food' can be newly developed, innovative food, food produced using new technologies and production processes, as well as food which is or has been traditionally eaten outside of the EU.

Examples of Novel Food include new sources of vitamin K (menaquinone) or extracts from existing food (Antarctic Krill oil rich in phospholipids from *Euphausia superba*), agricultural products from third countries (chia seeds, noni fruit juice), or food derived from new production processes (UV-treated food (milk, bread, mushrooms and yeast).

The underlying principles underpinning Novel Food in the European Union are that Novel Foods must be:

- Safe for consumers;
- Properly labelled, so as not to mislead consumers;
- If novel food is intended to replace another food, it must not differ in a way that the consumption of the Novel Food would be nutritionally disadvantageous for the consumer.

For more information, the expert recommend to consult the [Novel Food status Catalogue](#).

3.3.2 Additional EU legislation on food safety for organic commodities and organic farming

Legal acts

Since January 1, 2022, the [regulation \(EU\) 2018/848](#) of the European Parliament and of the Council of 30 May 2018 is the applicable legislative act — the basic act — establishing the rules relating to organic production and the labeling of organic products, and repealing and replacing the [Regulation \(EC\) No 834/2007](#) of the Council of June 28, 2007. The new regulation provides for transitional periods for the implementation of certain new provisions, in particular with regard to trade. Please refer to Section 2 of Chapter IX of Regulation (EU) 2018/848, to the extent that the provisions of the preceding

[Regulation \(EC\) No 834/2007](#) of the Council and [Regulation \(EC\) No 889/2008](#) of the Commission may apply for a limited period.

[Regulation \(EC\) No 834/2007](#) states the following principles on organic production which should:

- respect natural systems and cycles;
- maintain and improve the condition of soil, water and air, the health of plants and animals, as well as the balance between them;
- preserve natural landscape elements;
- use it responsibly [energy](#) and natural resources;
- produce a wide variety of high-quality products that meet consumer demand;
- ensure the integrity of organic production at all stages of production, processing and distribution of food and feed;
- exclude the use of [genetically modified organism \(GMO\)](#) and products obtained from or by GMOs*, or other veterinary drugs;
- restrict the use of external inputs;
- design and manage biological processes using methods based on risk assessment and the use of precautionary measures and preventative measures;
- exclude animal cloning;
- guarantee a high level of [animal wellbeing](#).

Production and labeling

The following derivative acts to the [regulation \(EU\) 2018/848](#) also called “delegated regulations” concern organic production and labeling of organic products:

- [Delegated Regulation \(EU\) 2020/427](#) of 13 January 2020 amending Annex II to Regulation (EU) 2018/848 as regards certain detailed production rules applicable to organic products (OJ L 87, 23.3.2020);
- [Delegated Regulation \(EU\) 2020/1794](#) of 16 September 2020 amending Annex II, Part I, to Regulation (EU) 2018/848 as regards the use of in-conversion and non-organic plant reproduction material (OJ L 402, 1.12.2020);
- [Delegated Regulation \(EU\) 2021/642](#) of 30 October 2020 amending Annex III to Regulation (EU) 2018/848 as regards certain information to be communicated on the labeling of organic products (OJ L 133, 20.4.2021);
- [Delegated Regulation \(EU\) 2021/716](#) of 9 February 2021 amending Annex II to Regulation (EU) 2018/848 as regards the organic production rules applicable to sprouted seeds and endives, to the feed of certain aquaculture animals and to antiparasitic treatments intended for aquaculture animals (OJ L 151 of 3.5.2021);

- [Delegated Regulation \(EU\) 2022/474](#) of 17 January 2022 amending Annex II to Regulation (EU) 2018/848 as regards specific requirements applicable to the production and use of non-organic, in-conversion and organic seedlings and other reproductive material Plant;
- [Delegated Regulation \(EU\) 2020/2146](#) of 24 September 2020 supplementing Regulation (EU) 2018/848 regarding the exceptional production rules applicable to organic production (OJ L 428 of 18.12.2020);
- [Delegated Regulation \(EU\) 2021/1189](#) of 7 May 2021 supplementing Regulation (EU) 2018/848 as regards the production and marketing of plant reproductive material of heterogeneous biological material of particular genera or species (OJ L 258 of 20.7.2021);
- [Delegated Regulation \(EU\) 2022/1450](#) of 27 June 2022 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the use of non-organic protein feed for organic animal production due to Russia's invasion of Ukraine (OJ L 228 of 2.9.2022).

Implementing regulations

Implementing regulations to [regulation \(EU\) 2018/848](#), are laying down certain detailed rules for its implementation. Amongst them the expert caught the following ones:

- [Implementing Regulation \(EU\) 2021/279](#) of 22 February 2021 laying down detailed rules for the application of Regulation (EU) 2018/848 as regards controls and other measures aimed at ensuring traceability and conformity in organic production, as well as the labeling of organic products (OJ L 62 of 23.2.2021);
- [Implementing Regulation \(EU\) 2021/2325](#) of 16 December 2021 establishing, in accordance with Regulation (EU) 2018/848, the list of third countries and the list of authorities and control bodies recognized pursuant to Article 33(2) and (3) of Regulation (EC) No ° 834/2007 for the purposes of importing organic products into the Union (OJ L 465, 29.12.2021);
- [Implementing Regulation \(EU\) 2023/121](#) of 17 January 2023 amending and rectifying [Implementing Regulation \(EU\) 2021/1165](#) authorizing the use of certain products and substances in organic production and establishing the list of such products and substances (OJ L 16, 18.1.2023).

Trade

The following acts of secondary law relate to trade in the organic sector:

- [Delegated Regulation \(EU\) 2021/1697](#) of 13 July 2021 amending Regulation (EU) 2018/848 as regards the criteria for the recognition of control authorities and control bodies which are competent to carry out

controls on organic products in third countries, and for the withdrawal of recognition of these authorities and bodies (OJ L 336 of 23.9.2021);

- [Delegated Regulation \(EU\) 2021/1698](#) of July 13, 2021, supplementing Regulation (EU) 2018/848 with procedural rules concerning the recognition of authorities and control bodies which are competent to carry out controls on certified organic operators and groups of operators and on organic products in third countries, and by rules concerning their supervision and the controls and other tasks to be carried out by those authorities and control bodies (OJ L 336, 23.9.2021);
- [Delegated Regulation \(EU\) 2021/1342](#) of 27 May 2021 supplementing Regulation (EU) 2018/848 with rules relating to the information to be transmitted by third countries and by control authorities and bodies for the purposes of supervising their recognition under Article 33, paragraphs 2 and 3, of Regulation (EC) No 834/2007 of 28 June 2007 with regard to imported organic products as well as the measures to be taken within the framework of this supervision (OJ L 292 of 16.8.2021);
- [Delegated Regulation \(EU\) 2021/2306](#) of 21 October 2021 supplementing Regulation (EU) 2018/848 with rules relating to official controls of shipments of organic products and products in conversion intended for import into the EU and the certificate of inspection (OJ L 461 of 27.12.2021).

Certification

- Operators (i.e., producers, processors and distributors) must notify their activities to the competent authorities to obtain the official certificate attesting that they comply with the rules of labeling and organic production;
- The regulation introduces a new group certification system* for small farmers to facilitate their transition to organic farming.

For further information on EU legislation applicable to the organic farming sector, please consult:

[Legislation applicable to the organic farming sector](#) (European Commission).

The logos used on the EU market for organic food production



This is the mandatory logo to be used for organic production put on the EU market



Some voluntary quality labels such as red label, on the origin of the products labels such as AOP, VSOP... are currently used by the food producers to guaranty some specific qualities and prevent counterfeit. These voluntary labels do not replace the mandatory markings for safety. They are complementary markings.



Concerning organic food commodities, in France, an official quality label is the "Agriculture Biologique label", also called the AB Label. This voluntary label should, as shown on the picture, be associated to the mandatory EU logo for organic production indicating that all the provisions of EU legislations are considered.



The organic logo used in Germany

3.4 The similitudes and differences between the India and EU food safety regulations

We remark that the two food regulations systems of India and EU are very similar in their scope as they address the same categories of risks for human and domestic animal health.

A more detailed comparison based on the list of the declared hazardous substances and their admitted toxicity limits would certainly show some differences but it's not the purpose of the expert mission.

The comparisons of the level of implementation of the respective regulations in India and EU and the level of implementation of their market surveillance systems should also show significant differences.

From the point of view of the expert, the EU food safety regulation is currently fully implemented by the EU member states and the market surveillance authorities of the member states possess adapted capabilities for a survey the food commodities at the borders and on the EU market.

It seems that the situation is not comparable in India as FSSAI, responsible of the market surveillance and quality and food safety controls, was only recently starting, surveys of some commodities collected in all India states (milk in 2018, 2020 and 2022, edible oil in 2022, and jaggery in 2022). For more details, consult the FSSAI portal website: <https://fssai.gov.in/cms/national-surveys.php>. The results of these surveys show that the non-compliance to the FFAI standards can be as high as 40% for milk products. To be noted that on another hand, the compliance reaches 97% for trans-fat on processed food.

A good indicator of the level of compliance of the India food commodities exported to the EU market, regarding the food safety aspects, is given by the level of rejected commodities as given by the EU Rapid Alert System for Food and Feed (RASFF).

The quantities and details of the rejections of the food commodities imported from India, can be consulted at the following address:

<https://webgate.ec.europa.eu/rasff-window>, by clicking on Search and selecting the logo XLS for downloading the data.

The system allows the download of the 5000 latest notifications covering the period from 12 July 2023 to 28 June 2024, around one year survey period. (See the excel table in **Annex 14**).

The number of India rejections, during this period, reaches 319, whereas the average number of rejections for the EU countries food commodities is around 70. This poor result for India, may be due to the fact that its limits for prohibited substance are less severe than those of EU, that the list of prohibited substances in India are less than in the EU, or that India commodities are not enough controlled before their exported to the EU.

3.5 The current capabilities of the Agmark laboratories and the SWOT analysis

3.5.1 The methodology used for this analysis

The expert prepared first a succinct questionnaire to get a general overview of the existing capabilities of the laboratory. This first questionnaire is given in **Annex 15**). Prior to the field visit, questionnaire was filled by the respective DMI officials.

Based on the information collected, the expert prepared a second and more detailed questionnaire including the 4 tables of the SWOT analysis.

This questionnaire was sent to the laboratories a few days before the visit to the laboratories. The response of the questionnaires was used as common thread for the assessment of the laboratories. This second questionnaire is given in **Annex 16**). The visits to the laboratories were conducted from June 10 to 14, 2024. The Itinerary of the visit is given in **Annex 17**

3.5.2 The current capabilities of the Agmark laboratories and the SWOT analysis

Findings on the capabilities of the 5 Agmark laboratories

The objective of the SWOT analysis consist in a review the current scope of the 5 DMI Agmark laboratories, their relevance to current Indian food safety standards, and for the expert, to recommend improvements of their quality



performances and develop the testing activities in organic food commodities under Agmark marking.

The contact details of the 44 persons met during the visit of the expert are given in **Annex 18**.

Some pictures illustrating the visits of the expert to the 5 laboratories are given in **Annex 19**.

A summary of the current capabilities of the 5 visited laboratories after discussions with the technical staffs of the laboratories and analysis of the existing equipment, is given in a table given in **Annex 20**).

Annexure 20

Current capabilities of CAL Nagpur and 4 RAL (Mumbai, Kolkata, Delhi and Kanpur)

Agmark labs	Activity for Agmark Labs.	Accreditation ISO 17025							Accreditation ISO 17043 (OCIL)		Nbr of test reports issued (2023-2024)	Main chemical analysis equipment	Staff					Nbr of reports issued per technical staff
		Nbr. of analysis in the scope	Group	Commodities concerned (Accreditation scope)	Standards concerned	Uncertainty budget performed	NC major	NC minor	Nbr of OCIL in the scope	Nbr of PT organized			Head Office	Technical Staff	Other staff (UDC & MTS)	total staff		
RAL Mumbai	Sampling Testing --> Inspection Certification OCIL	104	Chemical analysis	Cereals, pulses and allied products spices, condiments , edible vegetable oils, ghee, butter, fat spread, honey, tapioca sago, rice.	India Standards (IS) AOAC 987.07 SOP/CAL FSSAI methods FSSAI methods	x	2	5	NA	NA	in total 835 Under accred. 724	* Refractometer * GC Gas chromatograph * UV- Visible spectrophotometer	Present 0 Missing 0	Present 4 Missing 17	Present 3 Missing 1	7 18 Total expected 25	209	
CAL Nagpur	Sampling Testing --> Inspection Certification OCIL -->	109	Chemical analysis	Cereals, pulses including rice , Spice and condiments (Whole and ground , aamchur and mango powder, Asafoetida, black pepper whole and ground, Blended edible vegetal oil, groundnut oil, sesame oil, butter, fat spread, cardamon, cereals and cereals and pulse products including rice, chilly (whole and ground), cloves whole, coconut oil, compounded asafoetida, coriander whole, curry powder and all mix masala, dry chillies, dry ginger, ghees, ghee butter, honey, mango powder, mustard oil, sunflower oil, sojabeen oil, Ricebran oil, castor oil, rice, tapioca sago, tumeric, food grains	India Standards (IS) AOAC 987.07 SOP/CAL FSSAI methods FSSAI methods	x			49	Chemical analysis 6	in total 861 Under accred. 500	* Refractometer * LC Liquid Chromatograph * GC Gas chromatograph * UV double beam spectrophotometer * GC MS/MS Triple quadrupole mass spectrometry * AAS Double beam (atomic absorption spectrophotometer)	Present 1 Missing 1	Present 15 Missing 7	Present 12 Missing 11	28 19 Total expected 47	57	

RAL Kolkata	Sampling	56	Chemical analysis	Atta, besan, butter,edible vegetable oil, food grains, ghee (butter, fat), honey, spices and condiments, tumeric powder	India Standards (IS)	x	2	1	NA	NA	in total 563	* Refractometer * GC Gas chromatograph * UV- Visible spectrophotometer	Present	1	Present	6	Present	0	7	94										
	Testing -->				AOAC 987.07								Missing	1	Missing	13	Missing	12	26											
	Inspection				SOP/CAL								Total expected								33									
	Certification				FSSAI methods																									
	OCIL -->				FSSAI methods																									
RAL Delhi	Sampling	102	Chemical analysis	Butter, edible vegetable oil, food grains-cereals, pulses : wheat atta, maida, suji, besan sattu, rice, ghee, honney, spices and condiments	India Standards (IS)	?	8	4	NA	NA	in total 822	* Refractometer * UV double beam spectrophotometer	Present	1	Present	6	Present	3	10	137										
	Testing -->				AOAC 987.07								Missing	0	Missing	6	Missing	0	6											
	Inspection				SOP/CAL								Total expected								16									
	Certification				FSSAI methods																									
	OCIL																													
RAL Kanpur	Sampling	87	Chemical analysis	Besan, maida, suji, ajowan whole, asafoetida, atta,black pepper, butter, caraway, cardamon, cinnamon, cassia, cumin, fennel, fenugteek, ginger, mace, mustard, nutmeg, poppy, aniseed, ajowan, chollies powder and whole, tumeric, curry powder, black pepper, cloves, coconut oil, coriander whole, ghee, ginger-garlic-bhunamasala-tamarind pastes, honey, maida, rye, sorghum, barley, oats, corn, maize, jawar, bajra, millet, suji, tumeric, vegetable oil,	India Standards (IS)	x	2	6	NA	NA	in total 971	* Gas chromatograph * UV- Visible double beam spectrophotometer	Present	1	Present	6	Present	5	12	162										
	Testing -->				AOAC 987.07								Missing	0	Missing	7	Missing	6	13											
	Inspection				SOP/CAL								Total expected								25									
	Certification				FSSAI methods																									
	OCIL -->				FSSAI methods																									

NA : Not Applicable

NC : Non Conformity

OCIL: Organizer of Comparisons Inter Laboratories

PT: Proficiency Testing

When examining this document, the expert remark that:

- The 5 laboratories are accredited according to ISO 17025 in chemical analysis proving their analysis capabilities for the commodities declared on their respective scopes.
- Their accreditation scopes are very large (from 56 commodities for RAL Kolkata to 109 items for CAL Nagpur), with some overlapping allowing them to cover similar domains in each of their respective regions;
- The expensive equipment for chemical analysis as chromatographs is in sufficient quantity to cover the current needs of the laboratories;
- The sustained activity of the laboratories with around 900 samples analyzed /per year and per laboratory, which guarantees a maintained quality level and capability of the laboratories;
- CAL laboratory of Nagpur is also accredited according to ISO 17043 for organization of proficiency testing by inter-laboratories comparisons, precious activity allowing to maintain ISO 17025 accreditation of the Agmark laboratories.

On another hand, the following remarks deserve corrective actions:

- The India NABL who accredit the laboratories to ISO 17025 doesn't control properly all the provisions of the accreditation standard, and consequently, the accreditation level of the Agmark laboratories don't reach the current International one (Some general requirements of ISO 17025 are not followed, notably regarding the civil responsibility, the financial autonomy of the laboratories). These major non-conformities may affect the credibility of the Agmark laboratories compared to that of similar EU laboratories;
- The ratio of the number of reports issued per present technical staff is very scattered starting from 57 for CA Nagpur to reach 209 for RAL Mumbai. More accurate analysis should be conducted to find answers to this large gap;
- The large difference between the number of present staff representing only 48% of the total expected staff. Understaff technical and support staff may affect the relevance of the overall efficiency of the laboratories.

The SWOT analysis of the performances of the Agmark laboratories

Based on the findings of the assessment of the Agmark laboratories, analysis of Indian and EU legislation for food commodities, information accessed from the filled in questionnaires, and discussions with the laboratories staff, SWOT analysis was conducted. As the status and the functioning rules are similar for the 5 laboratories, the expert proposes to establish a common SWOT analysis applicable to the 5 laboratories, the

specific capabilities of a particular laboratory being mentioned in the SWOT tables.

The two columns in the table below highlights the **strengths** and **weakness** of the Agmark laboratories and are considered as «internal factors” for which the Agmark laboratories and DMI have capability to change and improve.

Strengths	Weaknesses
<p>The Agmark laboratories are the oldest public laboratories of DMI working under the 1st grading and marking Act of 1937. They have a in deep experience due to their long history.</p> <p>The Agmark laboratories are official public laboratories. They are the armed arm of DMI for assessment of the commodities they certify according to grading Agmark for food commodities. In fact, they are working for <u>a captive market</u> and have no direct competitors, which can be considered as a strength. Moreover, DMI Agmark certification scheme is <u>mandatory</u> for blended edible vegetable oils and fat spread as per provisions in The Food Safety and Standards Act and regulations, 2006.</p> <p>Despite the low fees attached to the Agmark certification (10 000 INR for 5 years usage), only 1 to 3% of the commodities produced by India farmers are under Agmark grading and marking process. So, <u>development opportunities are high</u> for this mark.</p> <p>The Agmark laboratories are working according to a <u>quality management system complying with SO 17025 requirements under a wide accreditation scope</u>, for chemical analysis, as proven by the accreditation certificates issued by the India NABL. The numbers of Categories of commodities in the accreditation scope are high (See Annex 20). Some overlapping exist as each Agmark laboratory should be able to analyse theoretically the 222 notified commodities to be graded under Agmark standards. The Agmark laboratories have capability to analyse around half of the notified 222 commodities which is a plus.</p> <p>Accreditation of the Agmark laboratories according to ISO 17025 prove the <u>competences of the technical staff</u> and that they are using <u>adequate equipment</u> correctly calibrated with <u>analytical methods correctly validated</u></p> <p>CAL Nagpur is also <u>accredited by the India NABL according to ISO 17043</u> allowing it to organize up to 49 different laboratory inter-comparisons categories in chemical analysis. Up to now, CAL Nagpur organized 6 laboratories inter-comparisons (LIC). These LIC are very important for the Agmark laboratories as they allow them to maintain their</p>	<p>The captive market of the Agmark laboratories and the absence of direct competitors are not a factor of emulation to push them to improve their performances.</p> <p>The advertisement actions by DMI for the Agmark certification scheme and an active policy of seeking new customers must be developed in order to increase significantly the low market share of the Agmark certification regarding the number of food producers.</p> <p>The assessment of the expert showed that the accreditation level of the Agmark laboratories by the India NABL doesn't reach the current international level, as some important requirements of ISO 17025:2017 are not properly assessed:</p> <ul style="list-style-type: none"> - The provisions of Paragraph 5.1 of the above-mentioned ISO standard indicating that "The laboratories <u>shall be a legal entity</u>, or a defined part of a legal entity, that they should be legally <u>responsible</u> for their laboratory activities", these provisions are not demonstrated in the quality system (the legal entity should have a civil liability insurance covering the risks inherent in its activity. It should be noted that a governmental laboratory like the Agmark laboratories is deemed to be a legal entity on the basis of its governmental status. This provision should be documented in the quality management system; - The provisions of § 6.1 of the above-mentioned standard « General - The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities" is not assured as the heads of the laboratories have insufficient financial autonomy to replace in time the missing staff (see in table of Annex 20 , the missing staff of the laboratories (18/25 for RAL Mumbai, 19/47 for CAL Nagpur, 26/33 for RAL Kolkata and 6/16 for RAL Kanpur). This situation doesn't allow the laboratories to maintain a constant quality level of its chemical analysis. DMI should consider this situation and find solutions to avoid this lack of autonomy of the laboratories management. <p>DMI is <u>not accredited according to ISO 17065</u> for its Agmark certification activity and not accredited according to <u>ISO 17020</u> for its Agmark inspection</p>

accreditation ISO 17025, by proving that the test methods used, equipment and staff skills are adequate.

The Agmark laboratories are competent in chemical testing (volatile oil, piperine content (ODB), hexabromide content, free fatty acid, acidity, polybromide contents...) and physical testing (density, size, moisture, broken grains, admixture, fragments, organic or inorganic foreign matter, size...)

The Agmark laboratories have a continuous activity with around 900 test report issued/year by each of them (except for RAL Kolkata who issue around 500 test reports/year. This is a plus as the quality management system is continuously practiced and improved.

The Agmark laboratories provide training sessions for their technical staff, and induction training programs for students at colleges in analysis of agricultural commodities.

The Agmark laboratories participate to standardizations as member of the technical committees of the India Standardization body and via research and development and formulation of standards for new agricultural commodities.

The Agmark laboratories have premises surfaces allowing a possible increase in the volume of activity.

DMI is in process of carrying out the publicity of Agmark laboratories through brochures, extension activities in schools regarding the awareness of Agmark and quality assurance for food commodities

activity. This is not complying with the provisions of the India regulation asking for ISO 17065 accreditation for certification bodies (See regulations given in Annexes 6 and 10 to this report.

This situation can be source of Lack of confidence in the quality of the commodities under Agmark by some international markets as the inspection and certification processes are not accredited under the above internationally mentioned international standards.

The Agmark certification concerns grading of the commodities focusing essentially on the physical and chemical organoleptic properties of the commodities and not considering the food safety aspects as developed in § 3.2 and 3.3 of this report for both the India and EU food regulations including organic food commodities.

The Agmark certification scheme for both traditional food commodities and organic commodities should be revised to consider not only their physical and chemical organoleptic properties for their grading but also all the food safety provisions as mentioned in the previous paragraphs. The Agmark certification marking, should comply with the India food safety legislation as mentioned in FSSAI regulation provisions.

In practice, in EU, it's not permitted to put on the market, food commodities not complying with the provisions of the food safety regulations. The food commodities regarding their safety aspects shall be marked accordingly.

In addition, the commodities can be marked with any other voluntary quality marking addressing properties other than the safety ones. These complementary marking can constitute a commercial advantage for the commodities but in no case, they can replace the mandatory safety markings.

The two following columns of the tables highlights Opportunities and Threat respectively to improve or limit the Agmark laboratories capabilities. They are “external factors” meaning that DMI has very few or no influence on these factors to change significantly the situation to their advantage.

Opportunities	Threats
<p><i>The DMI can increase significantly the Agmark business activity. Currently, only 1 to 3% of food commodities put on the India market are concerned by the Agmark grading and marking certification. The strategy should be more testing of sample by the Agmark laboratories and improvement of their capability in term of human resources and equipment.</i></p> <p><i>The will of DMI to conform the Agmark marking to international practices in term of food quality marks/labels. by completing the Agmark certification scheme with the fundamental food safety aspects, upgrading the Agmark laboratories with new test/analysis capabilities including chemical safety, biological safety, food contaminants, food improvement agents..., as it's the case in the EU for food. The current grading Agmark marking can no longer allow food commodities certified under this mark to be not safe (as the safety aspects are not considered) and risking compromising health of the consumers.</i></p> <p><i>The will of FSSAI to recognise the Agmark laboratories as competent and asking them to participate to the India surveillance system regarding food safety and food quality, which is actually not sufficiently implemented to guaranty safe food for the India consumers (See results of the India market survey in § 3.4 and limit the exports particularly to the EU market, the number of food commodities rejected these last years by the EU customs and EU market surveillance authorities being abnormally high as mentioned in the EU RASFF data analysis also given in § 3.4.</i></p> <p><i>The will of the Indian authority to recognise the Agmark laboratories as Indian certification bodies for the control of organic commodities to be exported to the EU.</i></p> <p><i>The will of the India authorities to align the food safety system to that of the EU, by</i></p>	<p><i>FSSAI doesn't consider as important to change the current situation, and to harmonize the India legislation on food safety to the EU.</i></p> <p><i>Absence of will and financial capacities of the India authorities to sept-up an efficient market surveillance system assuming that the legislation is correctly applied by all the economic actors and assuming a correct safety level for the India consumers.</i></p> <p><i>Absence of financial effort of the India authorities and of DMI to upgrade the capability of its inspection and certification system by accrediting these activities according to international standards respectively ISO 17020 for inspection and ISO 17065 for certification, this upgrade facilitating the recognition by the international economic actors and improving exports of India commodities notably to the EU market.</i></p> <p><i>Absence will and financial efforts of the India authorities and of DMI to upgrade the capabilities of the Agmark laboratories for their participation to the control of safety characteristic of food commodities according to FSSAI provisions in addition to the actual control of some physico-chemical organoleptic properties of the current Agmark certification scheme.</i></p> <p><i>The long existing list of private Indian certification bodies (more than 30) already recognised by the Indian Authorities for the control of organic commodities prior to their export to the EU, and their declaration to the EU commission.</i></p>

completing its legislation and harmonizing the acceptable limits of hazardous substances to those of the EU market, this market being of importance for the India food producers as well as for the India commercial balance.

The main findings of the SWOT analysis:

- The expert considers that the current capabilities of the Agmark laboratories, as shown by the SWOT analysis, are not relevant to the current Indian food safety standards.
- The Agmark laboratories are analyzing almost exclusively appearance and organoleptic properties of the commodities under Agmark certification, (one exception is the CAL Nagpur which is able to analyse Aflatoxins B1 in spices). This certification is oriented to grading, allowing the licensees to optimize their selling prices.
- The safety aspects are absent in the Agmark certification scheme and the technical staff of the Agmark laboratories are essentially chemists, and currently do not have the capabilities to perform the requested by the India food safety legislation on various contaminants (toxic substance, heavy metals, etc.), pesticides, veterinary drugs residues, antibiotic residues and microbiological counts, genetically modified foods and also on Packaging and labelling used for food. These competences are not in the current scope of the Agmark laboratories.

2.1 Assessment of the current facilities of the Agmark laboratories

As mentioned in the previous paragraph the Agmark grading and marking scheme should at minima guarantee the safety of the commodities as required by the India regulation, the complementary aspects and organoleptic quality as covered by the Agmark certification should only be considered as a commercial advantage for licensees and consumers.

The Agmark laboratories should have the complementary capabilities to analyse also the safety aspects of the commodities under the Agmark scheme, which include:

2.1.1 The chemical safety with the analysis of:

Food additives, including food enzymes, food flavoring and nutrients, a positive list of these substances given in the regulation with their acceptable concentration level;

Food contaminants such as:

- mycotoxins (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, citrinin, ergot sclerotia and ergot alkaloids);
- plant toxins (erucic acid, tropane alkaloids, hydrocyanic acid, pyrrolizidine alkaloids, opium alkaloids, Δ^9 -THC);
- metals (lead, cadmium, mercury, arsenic, inorganic tin);
- halogenated persistent organic pollutants (dioxins, dioxin-like PCBs, non-dioxin-like PCBs; perfluoroalkyl substances: PFOS, PFOA, PFNA, PFHxS);
- processing contaminants (polycyclic aromatic hydrocarbons (PAH): benzo(a)pyrene, sum of 4 PAHs; 3-monochloropropane-1,2-diol (3-MCPD), glycidyl fatty acid esters);
- other contaminants (nitrates, melamine, perchlorate).

Residues of veterinary medicinal products, the regulation should ban the use of certain substances in food producing animals, analyse residues of pharmacologically active substances, analyse of pesticides residues, analyse the presence of non-allowed pharmacologically active substances present in food of animal origin

Food contact materials (FCM), the principles being that that materials in contact with food do not:

- Release their constituents into food at levels harmful to human health;
- Change food composition, taste and odor in an unacceptable way.

Certain FCMs: ceramic materials, regenerated cellulose film, plastics (including recycled plastic), as well as active and intelligent materials should, be covered by specific measures to ensure chemical safety of food.

Hormones in meat

As some hormones used for facilitating the growing up of animals such as estradiol 17 β , may be present in meat or in processed food containing meat, and may have hormonal effects on human health, their usage should be controlled and residues on food verified.

3.6.2 The biological safety which includes the analysis of:

Biological hazards like bacteria, viruses, parasites, prions, biotoxins, some of these hazards having caused serious risks to public health, such Salmonella, Listeria monocytogenes, biotoxins in live mollusks. Exposure of consumers to those through food should thus be prevented.

Based on the assessment of current equipment availability and the need for the increased scope of the analysis, the study recommends the installation of the equipment in the table below which is also given in annex 20.

ANALYSIS OF CURRENT EQUIPMENT OF THE 5 AGMARK LABORATORIES AND NEW NEEDS FOR TESTING FOOD SAFETY AND ORGANIC COMMODITIES

Current equipment / Brand name -Model					New needs for analysis		
CAL Nagpur	RAL Mumbai	RAL Kolkata	RAL Delhi	RAL Kanpur	Food hazardous substances to be analysed	Analytical equipment needed / Cost	Agmark labo already equiped
Refractometer /Antoon Paar Abbemat 200	Refractometer /Antoon Paar Abbemat 200	Refractometer /Antoon Paar Abbemat 200	Refractometer /Antoon Paar Abbemat 200	Refractometer /Antoon Paar Abbemat 200	Food additives, enzimies, flavorings, nutrients,	LC MS or GC MS : (@70 000\$)	CAL Nagpur (GC MS)
LC Liquid chromatograph with UV, RI, PDA nd FLD detectors / SHIMADZU					Food contaminants: mycotoxins, heavy metals, halogenated persistent organic pollutants, PAH, 3-MCPD, nitrate, melamine, perchlorate	LC MS/MS or GC MS/MS / (# 300 000\$) For Heavy metals : AAS	CAL Nagpur (GC MS/MS) CAL Nagpur RAL Delhi
GC Gas chromatograph with ECD, FID, NPD detectors / AGILENT 7890B	GC Gas chromatograph / Thermofisher Trace GC 1110	GC Gas chromatograph / Agilent		GC Gas chromatograph with ECD, FID, NPD detectors / Thermo scientific Trace 1110	Pesticides, fertilizers, herbicides	LC MS / (# 70 000\$)	
UV double beam spectrophotometer / IGENE LABSERVE IG_28DS	UV- Visible spectrophotometer / DYNAMIC Halo DB_20	UV double beam spectrophotometer / IGENE LABSERVE IG_28DS	UV double beam spectrophotometer / IGENE LABSERVE IG_28DS	UV double beam spectrophotometer / IGENE LABSERVE IG_28DS	Food contact materials	LC or GC / (# 10 000 to 20 000\$)	CAL Nagpur RAL Mumbai RAL Kolkata RAL Kanpur
GC MS/MS Triple quadripole mass spectrometry / AGILENT 7000E					Hormones, testosterone, progesterone, zeranol, trenbolone acetate and melengestrol acetate (MGA)	LC MS/MS / (# 250 000\$)	
AAS Double beam (atomic absorption spectrophotometer) / Perkin Elmer PinAAcle 900H			AAS (atomic absorption spectrophotometer) with graphite furnace / LABINDIA AA 8000		DNA analysis	Absorption chromatographie ; chemical method to separate substances	

Expressed needs for new analysis equipment

LC MS/MS, ICP MS, IC-OES, LC-IRMS	GC MS, HPLC, LC MS/MS, ICP MS, IC OES	LC MS/MS, ICP MS, IC OES, LC IRMS	HPLC, LC MS/MS, ICP MS, IC OES	HPLC, AAS, LC MS-MS, ICP-MS, IC-OES,
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3.7 The capabilities of the Agmark laboratories to further test organic food at the level of European reference laboratories

The previous provisions should be guaranteed under the Agmark laboratories but complementary provisions specific to organic aspects should be added.

The India regulation for organic food states that the commodities should be produced without the use of conventional pesticides, petroleum-based fertilizers, sewage-sludge-based fertilizers, herbicides, genetic engineering (biotechnology), antibiotics, growth hormones, or irradiation. Animals raised on an organic operation must meet animal health welfare standards, not be fed antibiotics or growth hormones, be fed 100% organic feed.

Even if the majority of the provisions should be assessed by the DMI inspectors, the Agmark laboratories should be able to verify that the commodities are not containing residues of the following elements under certain admissible limits given in the standards:

- synthetic pesticides;
- petroleum-based and sewage-sludge-based fertilizers;
- herbicides;
- genetic engineering (biotechnology) antibiotics;
- growth hormones.

The upgrade of the Agmark laboratories to test Indian organic food to the level of European reference laboratories, will demand serious improvements of the capabilities of these laboratories:

- Increasing quantitatively and qualitatively the human resources for facing the new provisions in chemical and biological analysis to cover the new food safety and organic aspects not yet covered under the current Agmark certification scheme;
- Training the current as well as new technical staff on the new test methods allowing them to perform chemical analysis on contaminants, residue from the soil, organic products and organic inputs naturally occurring toxic substances, heavy metals, pesticides, preservatives, other prohibited substances, synthetic fertilizers, Non Genetically Modified Organisms (NGMO), food additives and carriers, flavoring agents, vitamins, fatty acids, amino acid, and other nitrogenous compounds where their use is legally required or where severe dietary or nutritional deficiency can be demonstrated.

The budget for such trainings on analytical methods and their validation represent **around 20 working days of technical assistance of an international expert;**

- training the staff on analytic methods to analyse biological hazards including bacteria, viruses, parasites, prions, biotoxins. Some of these hazards have responsible of serious risks to public health, such as Salmonella, Listeria monocytogenes;
- Updating the quality management system by upgrading the accreditation scope of the Agmark laboratories with the newly validated test methods;
- Upgrading the current Agmark laboratories equipment for the analysis of hazardous substances listed above, according to the food safety and the organic India food regulations and standards. In fact, it seems that the current equipment is almost sufficient to covers theses new needs (See in **Annex 21**, the summary of the current analytical equipment of the Agmark laboratories and the equipment to be procured). CAL Nagpur with an additional LC MS/MS should be correctly equipped to start safety analysis on both traditional and organic commodities (**Expect a budget of around 250 000€**).

4 Conclusions

The tasks as presented in the ToR have been fully implemented by the expert. The conclusions are as following:

- The SWOT analysis of the 5 Agmark laboratories, shows that they have in deep analysis/testing experience of appearance and organoleptic properties of food commodities.
- The 5 Agmark laboratories are working according to a quality management system complying to ISO 17025 requirements under a wide accreditation scope (more than 110 different commodities in their accreditation scope), as proven by the accreditation certificates issued by the Indian NABL.
- The 5 Agmark laboratories have a continuous activity of around 900 test report issued/year by each of these laboratories. This activity can be considered as a benefit, the quality management system being continuously used, the quality level being by consequence maintained at the best level.
- The Agmark mark has high development opportunities, as the number of licensees represent only a few percent of the number of India producers. This allows the possibility to increase significantly the number of Agmark licensees and, the development of the Agmark laboratories activities. This will demand the setup by DMI of aggressive advertisement actions to the Indian food producers.
- On the other hand, the assessment of the expert showed that the accreditation level of the Agmark laboratories by the Indian NABL doesn't reach the current international level, as some important requirements of ISO 17025 are not properly assessed, this situation being detrimental to international recognitions, which would be very useful to facilitate export notably to the EU market.
- The Agmark certification scheme focuses on grading and marking of the food commodities, essentially based on their appearance and sensorial properties and almost completely miss (one exception for Aflatoxins) the safety aspects yet, provisions mandatory in India and as we have seen by the EU food market regulations, even for voluntary quality marks/labels. This situation disagrees with the provisions of the two above-mentioned regulations and weakens the interest of food producers for the Agmark certification.
- The Agmark grading and marking scheme should comply with provisions of the Indian food safety regulation and guarantee the safety of the commodities put on the Indian market. The specific qualities guaranteed by the Agmark certification scheme such as

organoleptic and appearance aspects should be considered as a plus by producers and consumers

- For facing this basic issue, the assessment of the 5 Agmark laboratories analysis equipment capabilities for facing the new food safety requirements, shows that they are almost sufficient, assuming the technical staff is quantitatively and qualitatively improved by hirings and training on new test methods to be developed.
- DMI is not accredited according to ISO 17065 for its Agmark certification activity and not accredited according to ISO 17020 for its Agmark inspection activity. This is not complying with the provisions of the Indian regulation regarding certification. This situation can also be detrimental for international recognitions limiting export capabilities of Agmark certified commodities.
- More generally, the expert considers that two food regulations systems of India and EU are very similar as they address the same categories of risks for human and domestic animal health.
- A more detailed comparison, of the two systems based on the list of the declared hazardous substances and their admitted toxicity limits, would certainly show differences between the two regulations and specific actions from FSSAI to harmonize the India system to that of the EU.
- The comparisons of the level of implementation of the respective regulations in India and EU and the level of implementation of their market surveillance systems should also show significant differences.
- From the point of view of the expert, the EU food safety regulation is currently fully implemented by the EU member states and the market surveillance authorities of the member states possess adapted capabilities for a survey the food commodities at the borders and on the EU market.
- It seems that the situation is not comparable in India as FSSAI, responsible of the market surveillance and quality and food safety controls, was only recently starting, surveys of some commodities collected in all India states (milk in 2018, 2020 and 2022, edible oil in 2022, and jaggery in 2022). The results of these surveys show that the non-compliance to the FFAI standards can be as high as 40% for milk products. To be noted that on the other hand, the compliance reaches 97% for trans-fat on processed food.
- A good indicator of the level of compliance of the India food commodities exported to the EU market, regarding the food safety aspects, is given by the level of rejected commodities as given by the EU Rapid Alert System for Food and Feed (RASFF).

- The total number of rejections of food commodities produced in India and exported to the EU, by the EU market surveillance authorities, reached 319 during the last year whereas the average number of food commodities, produced in the 27 EU countries and rejected by the same EU market surveillance authority is around 70. This poor result for India, may be due to the fact that its limits for prohibited substance are less severe than those of EU, that the list of prohibited substances in India is shorter than in EU, or that India commodities are not enough controlled before their exports to the EU.

5 Recommendations

Based on the findings of his assessment, the expert recommends:

- As mentioned above, to facilitate exports to the EU, (i) FSSAI to better harmonize the India food regulation system to that of the EU and if not possible, (ii) to upgrade, the DMI labs to the level of European reference laboratories for food commodities testing;
- To strengthen the resources of FSSAI, in charge of the Indian market surveillance, to develop the survey on more commodities and more frequently and to help solving the quality issues on commodities rejected by the importing countries of Indian food commodities;
- To train the DMI staff in charge of the Agmark certification scheme to allow them to setup a quality management system complying to ISO 17065 for its certification activities and to ISO 17020 for its inspection activities and to be respectively accredited by NABCB and NABL;
- To revise the DMI rules for the Agmark certification scheme for both traditional and organic food commodities to introduce the food safety provisions as per the India regulation as well as the EU one;
- To upgrade the capabilities (recruitment, trainings and equipment of the Agmark laboratories to control also the safety of the food commodities which should be added to the scope of the Agmark mark certification scheme;
- DMI to promote the Agmark mark and increase the number of licensees, a benefit to DMI certification and inspection activities as well as to the Agmark laboratories, to the producers and finally to the consumers;
- The first step could be to improve the capabilities of CAL Nagpur, which is the most advanced laboratory that already possesses most of the required analytic equipment to test safety of food. Subsequently, according to the level of development of the updated Agmark mark, CAL Nagpur can participate by technical support and trainings to the improvement of the capabilities of the other RALs.

6 Annexes

All the files of the list of annexes can be downloaded using the following link:

<https://www.dropbox.com/scl/fo/1m51gc7fnq0f7v8pyol15/AP9TzYUz68KGFN7MOp8lwRs?rlkey=8jdof69ad07dwf67r9u6obl4l&dl=0>

list of annexes:

- Annex 1 - 20240516 ToR Jean Claude Gourdon
- Annex 2 - Agricultural Produce Grading and Marking Act of 1986 amending Act No.1 of 1937
- Annex 3 - General grading and marking rules 1988 as amended in 2009.
- Annex 4 - Spices Grading and Marking Rules 2012
- Annex 5 - The Food and Safety standard ACT 2006
- Annex 6 - FSSAI - Food Safety and Standards rules 2011
- Annex 7 - FSSAI Food safety and standards (contaminants, toxins and residues 2011
- Annex 8 - FSSAI Food safety and standards (additives ... 2011 as amended in 2022
- Annex 9 - FSSAI Food safety and standards 2016 Compendium_Nutra_29_09_2021
- Annex 10 - FSSAI Food Safety and Standards rules 2017 Compendium Organic Food 26 10 2021
- Annex 11 - The FTDR act of 1992 amended in 2010
- Annex 12 - APEDA National Programme for Organic Production (NPOP) 2014
- Annex 13 - Notification Organic Agricultural Produce Grading and Marking Rules Agmark label for organics
- Annex 14 - RASFF window results July 2023 to June 2024
- Annex 15 - preliminary questions to be answered by the 5 Agmark laboratories
- Annex 16 - Second questionnaire including the SWOT analysis
- Annex 17 - Itinerary of JCG for DMI labs assessment v3
- Annex 18 - Presence lists during the visits of the expert
- Annex 19 Some pictures during the visits of the expert to CAL Nagpur and RAL Mumbai, Kolkata, Delhi & Kanpur June 2024
- Annex 20 - Current capabilities of the 5 Agmark laboratories
- Annex 21 - The equipment of the 5 Agmark laboratories and the new needs

7 Acknowledgements

The expert would like to express his deepest appreciation to all those having organized the visits to the laboratory, helped with his safe travel in each city visited, their kind welcome when arriving to the laboratories and cooperation, perspectives and expertise during his in-site assessment of the 5 India Agmark laboratories. The list of these persons is given in Annex 18 to this report.

A purple pen with a gold nib is shown writing the word "Merci" in a cursive script. The pen is positioned at the end of the word, pointing towards the right. The background is white.