A dialogue on -Claim Approval Process

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Capacity Building Food regulatory Process

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Agenda Items

- Draft Food Authority (India)Approval Process
- Draft flow chart (India)
- Gaps or improvement areas if any
- Global Overview of requirements of health claims
- Principles of systemic review and approval
- Templates a snapshot
- Snapshot of health claim approval process Europe
- A possible approval process (India) To be dialogued
- References

Draft Food authority (India) Approval Process

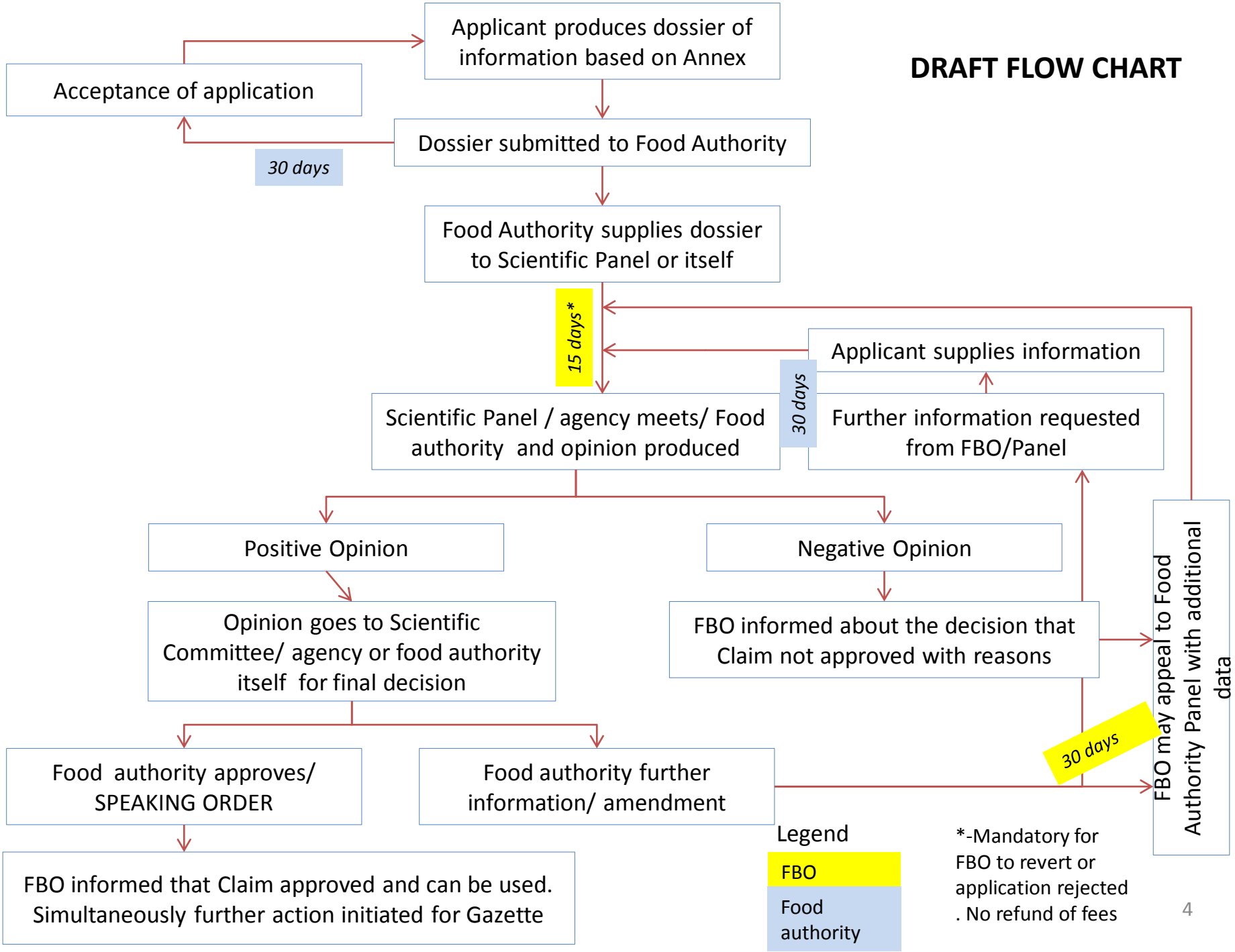
Draft Regulation outline process of getting New nutrient function and reduction of disease risk claim approved by FSSAI

Draft flow captured on subsequent slide

FBO or marketer to seek prior approval from Food authority for nutritious or health claims other than those that are defined and for which criterion are laid out under regulations or any other regulations in FSSAI

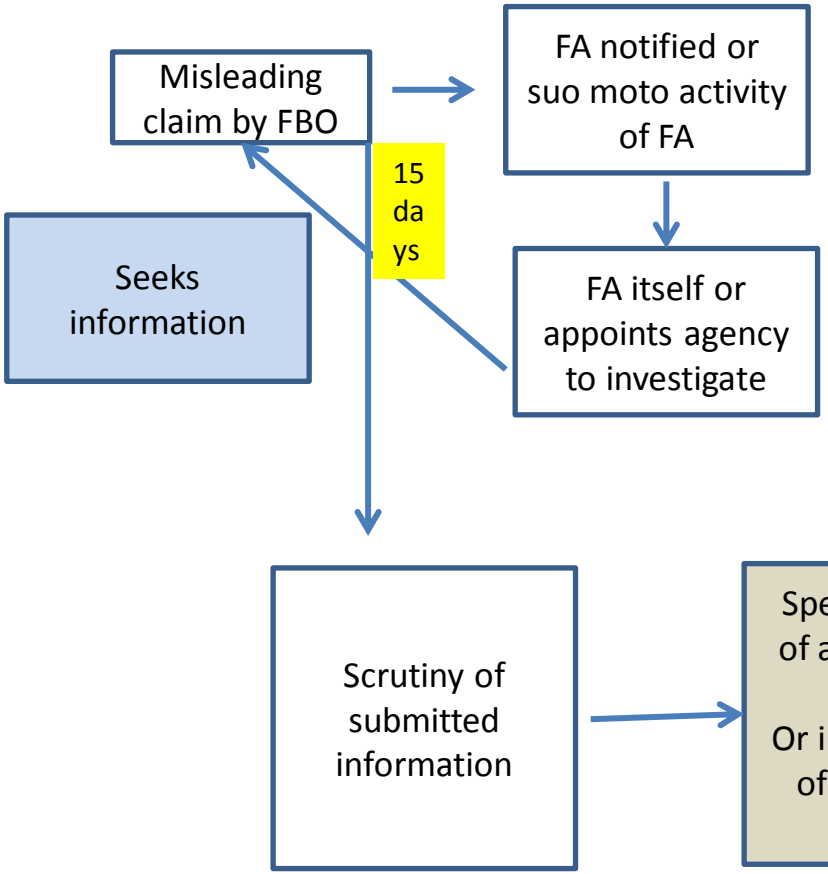
FBO to submit-
Application with applicable fees
(i)Hard/ soft copy of claim to be made
(ii)Name of ingredient, nutrient or substance on the basis of which claim is made
(iii)Validated method of analysis of ingredient or substance for which claim is made
(iv)Scientific information on which claim is made
(v)How claim is clear and meaningful and help consumers to comprehend the information provided?
(vi)Any other useful information.

DRAFT FLOW CHART



Redressal of Non compliance

- Any person who advertises or is a party to publication of any advertisement or claim not complying with regulation shall be penalised as per section 53 of FSSA 2006



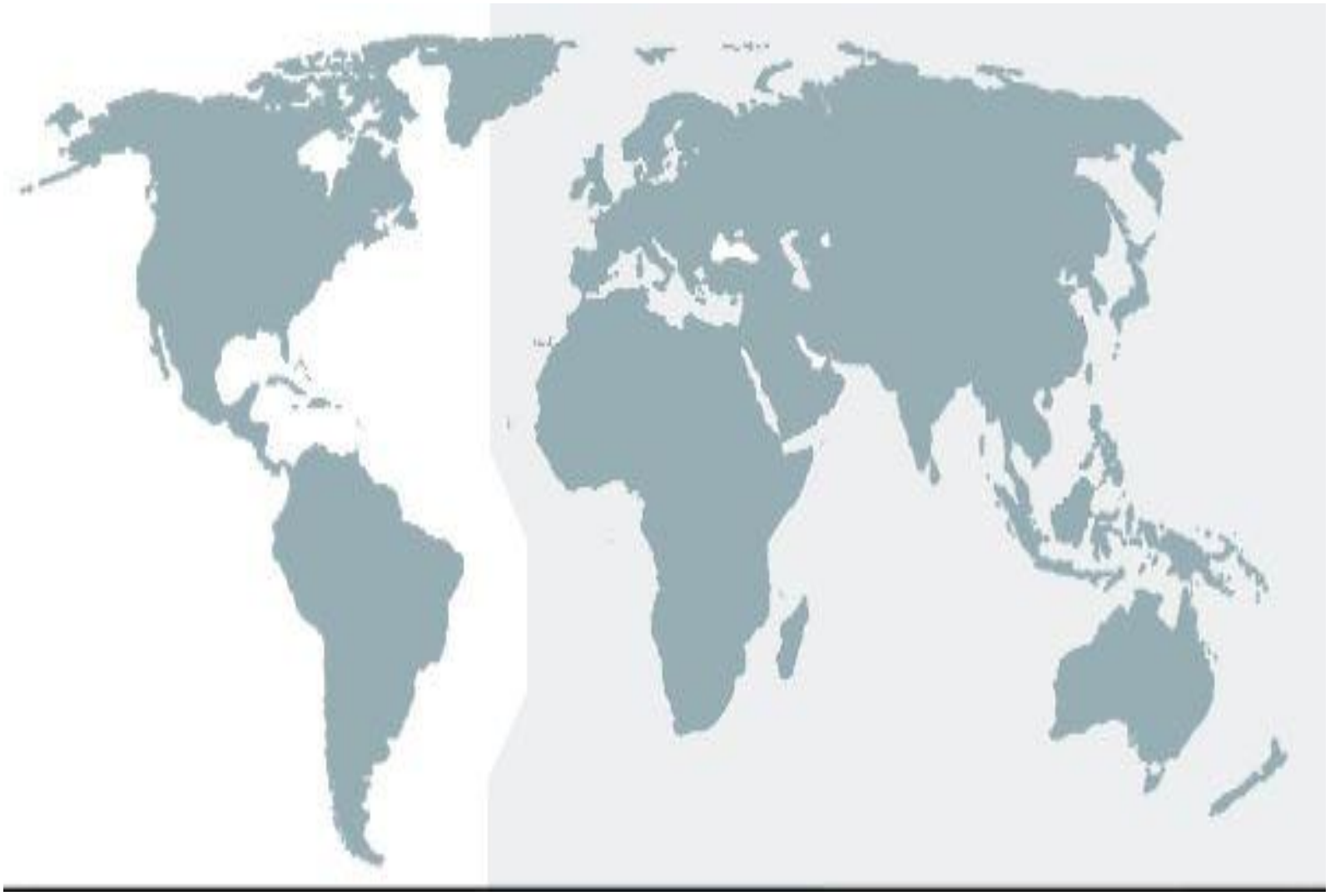
15 days intimation to FA
Packaging material change ??

Gaps or improvement areas if any for the Draft (India process)

Gap / Question Areas-

- How would the process maintain transparency?
- Can the document templates for FBO to provide information be defined and be specified ?
- What does Scientific information mean?
- Is human effectiveness to be demonstrated ?
- Are there Biological studies to be published for relevance?
- What is the feasibility of consumption of effective dose ?
- Would the steps in process and stage be updated in website?
- Can a list of Preapproved claims be adopted from other countries ?
- Can the relevance of claims in other jurisdictions that are approved be referred as evidence ?
- For risk reduction claims can the study designs be defined wrt pilot and pivot ?

Global overview



Overview of requirements for making health claims

Country	Regulatory body	Can u make a health claim(Y/N)	List of preapproved claims	Can u apply for a new health claim	Regulatory documents
Australia New Zealand	FSANZ	Y-Regulated	-200 Nutrient claims, 13 risk reduction	New claims subject to FSANZ approval	Standard 1.2.7 relevant standard of food standard code
Canada	CFIA	Y – listed in regs	3 functional claims-50 risk reduction claims	Premarket approval	Food and drugs act and regulation
Singapore	Agi food and veterinary AVA and HPB	Y- Regulated	-29 nutrient functional -5 risk red -17 other	Preapproval by AVA	Food regulations health claims listed in A guide to food labelling and advertisement
South Korea	Ministry of food and drug safety	Y-Regulated	-100 preapproved claims		Health functional food act and Health functional food Code
Indonesia	National agency of food and drug control	Y-Regulated	-11 functional -11 risk red	APPLICATION to NFDC	Control of claims on processed food labels and advertising
Japan	Ministry of Health and labour (MHLW)Consumer affairs agency (CAA)	Y-Regulated	FOSHU claims product specific. Safety of a food and effectiveness to be approved by CAA and MHLW	FOSHU regulations in practise , unlikely other countries claims to be accepted	Food labelling standard and Food for specific health use (FOSHU) Regulations
India	FSSAI	N- Draft standard permitting them to come in future	Draft reg- contain 12 risk red claims	Draft outline the process of getting new nutrient function and risk red claims approved by FSSAI	Draft regulation on labelling claims
Thailand	Thailand FDA	Y-no regulated framework	NO	APPLICATION to FDA on nutritional claims	Unofficial Notification of Ministry of public health (No 182)
USA	US FDA	Y- Reg /Nutrient functional claims	12 authorised risk reduction Claims must be truthful no preapproval	Petition to FDA	Nutrional Labelling Education Act NLEA

Systematic Review Process and principles….Canada, Europe ANZ and New Zealand

- Systematic approach
- Transparency
- Comprehensiveness
- Human evidence
- High level of certainty
- Demonstration of causality
- Biological relevance of claimed effect
- Feasibility of consumption of effective dose
- **Health Claim Wording:** The health claim wording communicates the health outcome that is substantiated in the submission, *i.e.*, it is specific to the substantiated health outcome. If, for example, the submission supports a reduced risk of infectious diarrhoea, this does not mean that the product "supports healthy immune function". The correct claim wording would more directly make a statement to the effect that the product "reduces risk of infectious diarrhoea".

- **Substantiation of one food-health relationship in a submission:** One food/health relationship is to be addressed per submission. Multiple formulations/matrices of a food can be proposed by the petitioner, provided the scientific evidence is valid for all proposed formulations/matrices, but only a single health effect can be the object of a submission. However, more than one biomarker of a single health effect may be used - *e.g.*, using total cholesterol and LDL cholesterol as biomarkers of one health effect - heart disease.

Approach common to countries like Australia and New Zealand, Canada, Europe, and other countries that follow a systemic review

https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/health-claims/guidance-documents-preparing-submission-food.htmlng and existing systemic review

Template a snippet to enable a systematic review

Template a snippet to enable a systematic review

Snapshot on Application procedure for Europe

EFSA assesses the scientific basis of nutrition and health claims submitted for authorisation in the EU. Work in the area of nutrition related to applications also includes the evaluation of novel foods, infant formulae and food allergens. The European Commission and Member States then decide whether to grant authorisation.

In the case of health claims and novel foods, applications are submitted to the national competent authority of a Member State. This includes applications for authorisation of a new health claim or for the modification of an existing authorisation. The European Commission (EC) receives applications for infant formulae and food allergens.

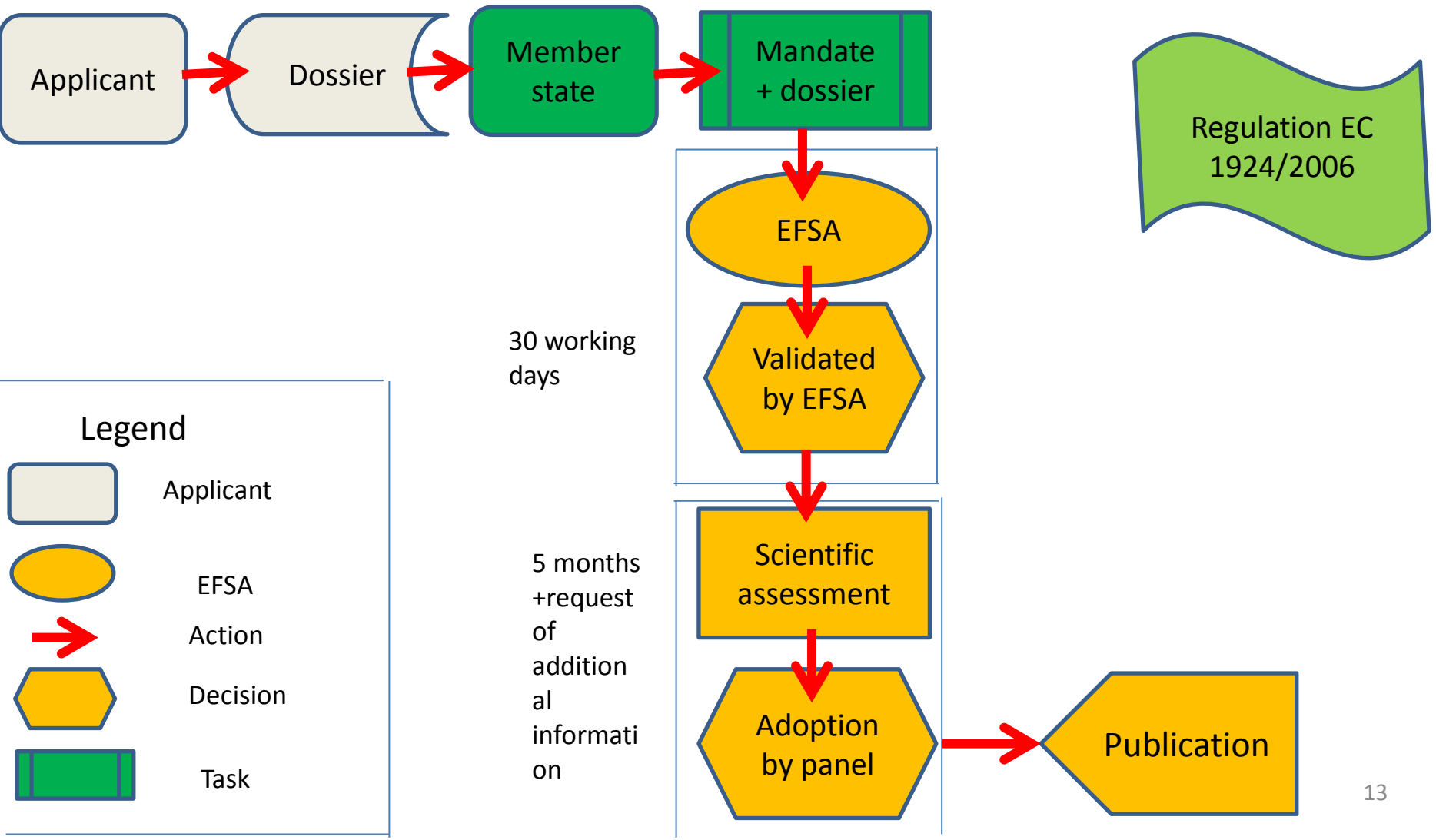
The competent authority or the EC pass on the application and any supplementary information to EFSA, which carries out the scientific evaluation.

1. Health claim application procedure
2. Novel food application procedure
3. Traditional food application procedure
4. Infant food application procedure
5. Food allergen application procedure

Health claim approval process

Health claim application and approval procedure- Europe

Applicants who wish to submit an application for authorisation of a health claim under Articles 13.5 or 14 of Regulation EC 1924/2006 or for modification of an existing authorisation should consult the guidance documents and complete the relevant application forms. Applications should be submitted to the national competent authority of a Member State. The competent authority passes the application and any supplementary information supplied by the applicant to EFSA, which carries out the scientific evaluation



European Union contd..

- EFSA responsible for evaluating claims
- EC with member states decides authorisation, restrictions and final wording
- Member states of EU responsible for enforcing health and nutritional claims

- EFSA Assists applicants by providing

- General guidance document for stakeholders and also
- Guidance on the substantiation of health claim in specific areas
- Application for Health claim should follow the format and content as provided by EFSA on Scientific and technical guidance for preparation and presentation of an application for authorisation (Commission regulation (EC) No 353/2008

- Preapproved Health claims can be used
- New claims subject to afore listed process
- Approved claims published on Website
- Unapproved claims published on website

A possible Approval process for India – (TBD…a la Systematic review)

Transparency

- Simple and clear
- Visibility of status online
- Public access to approved or in process claims and unapproved claims like EFSA
- Trainings led by FBO and FSSAI on the “claim process “
- Timely publication

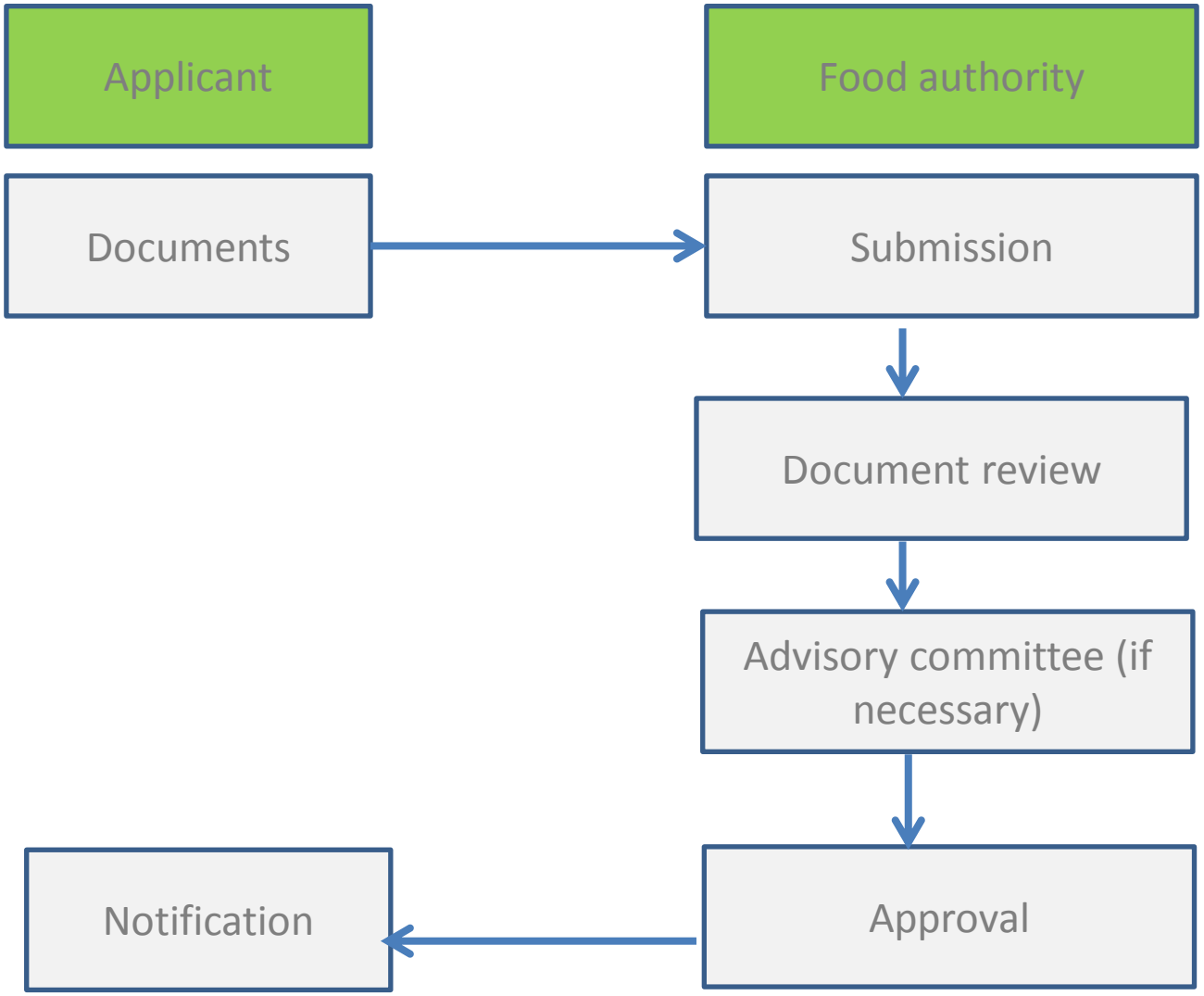
Templates(Ref CFIA)

- Human evidence
- High level of certainty
- Demonstration of causality
- Biological relevance of claimed effect
- Stepwise Directions to prepare a clear Dossier by FBO
- Pre-screening committee before accepting an application
- Define and regulate other substantiation modes if any

Measure of Effectiveness

- Comprehensive process
- Governance structure
- Defined and agreed timelines
- Mechanism for Monitoring the performance and improvements if any

Ideal process….Time ?????(By when)



References

- https://www.efsa.europa.eu/en/applications/nutrition
- Global regulatory environment on health claims MPI Technical Paper No 2016/61 New Zealand Government
- General comparison of health claims with regards to food and supplement legislation framework Europe USA and Canada by Nigel Baldwin
- Guidance document for preparing a submission for Health claims
- https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/health-claims/guidance-documents-preparing-submission-food.htmlng and existing systemic review
- http://www.mpi.govt.nz
- http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/health-claims/eng/1392834838383/1392834887794
- http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/nutrient-content/eng/1389905941652/1389905991605
- Notice calling for suggestions , views , comments etc from stakeholders on the draft food safety and standards (Advertisements and claims) Regulation 2017

I AM CURRENTLY UNDER CONSTRUCTION SO THANKYOU FOR YOUR PATIENCE……