

DISCLAIMER

The opinions expressed in this presentation and on the following slides are solely those of the presenter based on food regulations and not necessarily those of Herbalife Nutrition.

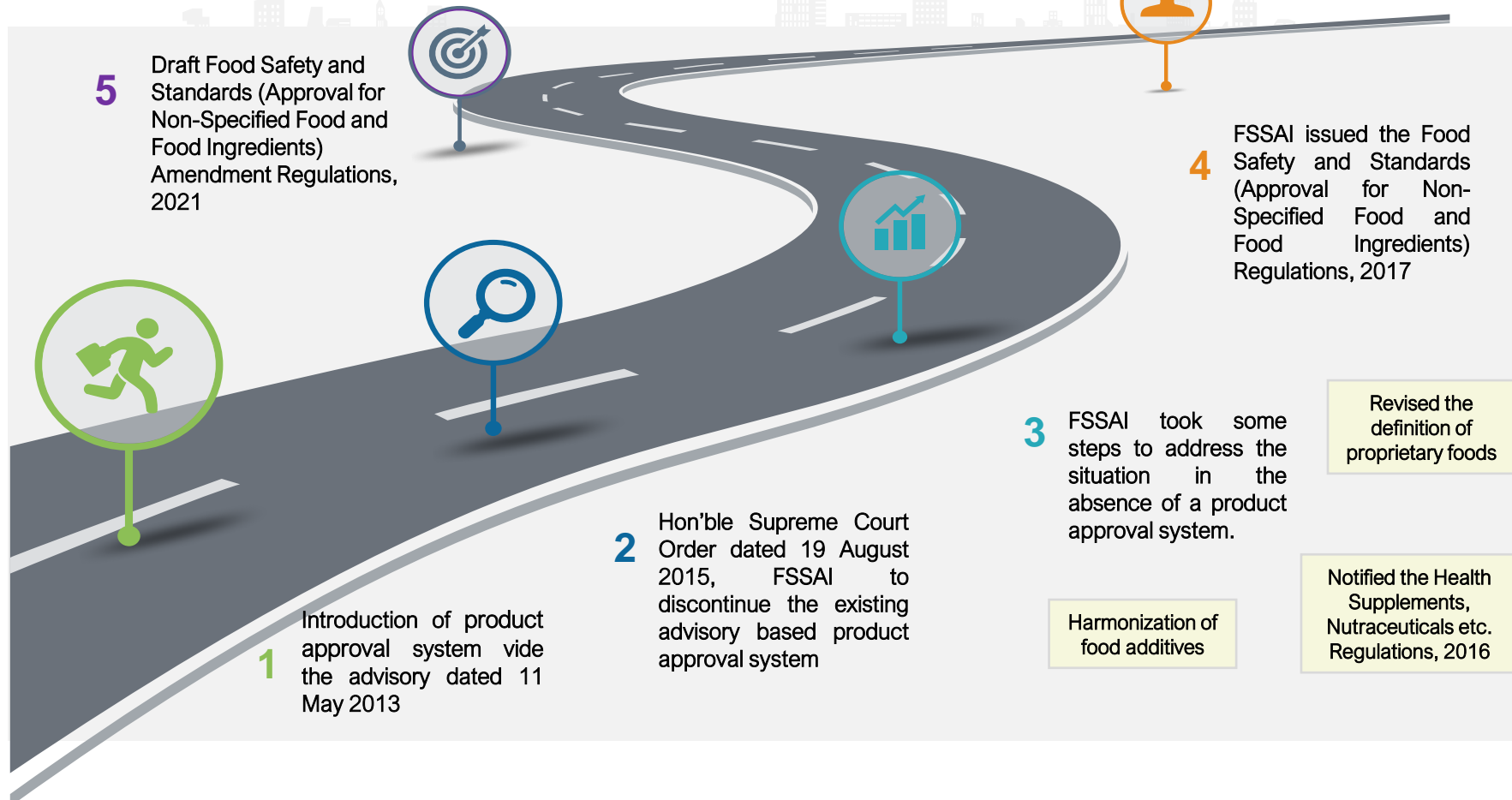
Obtaining Approval of Non-Specified Foods'

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INTRODUCTION & JOURNEY



KEY POINTS

Prior approval of non-specified food and food ingredients is a necessary before taking licensing/ registration

PRIOR
APPROVAL

FBOs must declare the top three ingredients that constitute 51 percent of the total product composition*

DECLARATION

Its product approval
not ingredient

For standardized products, i.e., food products/ingredients for which standards are prescribed in the FSS Act, Rules and Regulations, which FBOs conform to, they do not require an approval.

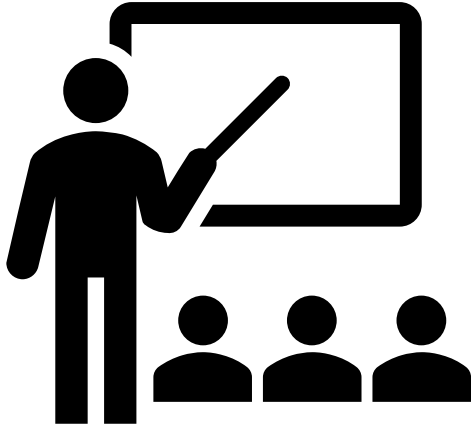
STANDARDISED
PRODUCT

In order to cover the other products/ ingredients (proprietary and novel) FSSAI has notified the various regulations.

REGULATIONS

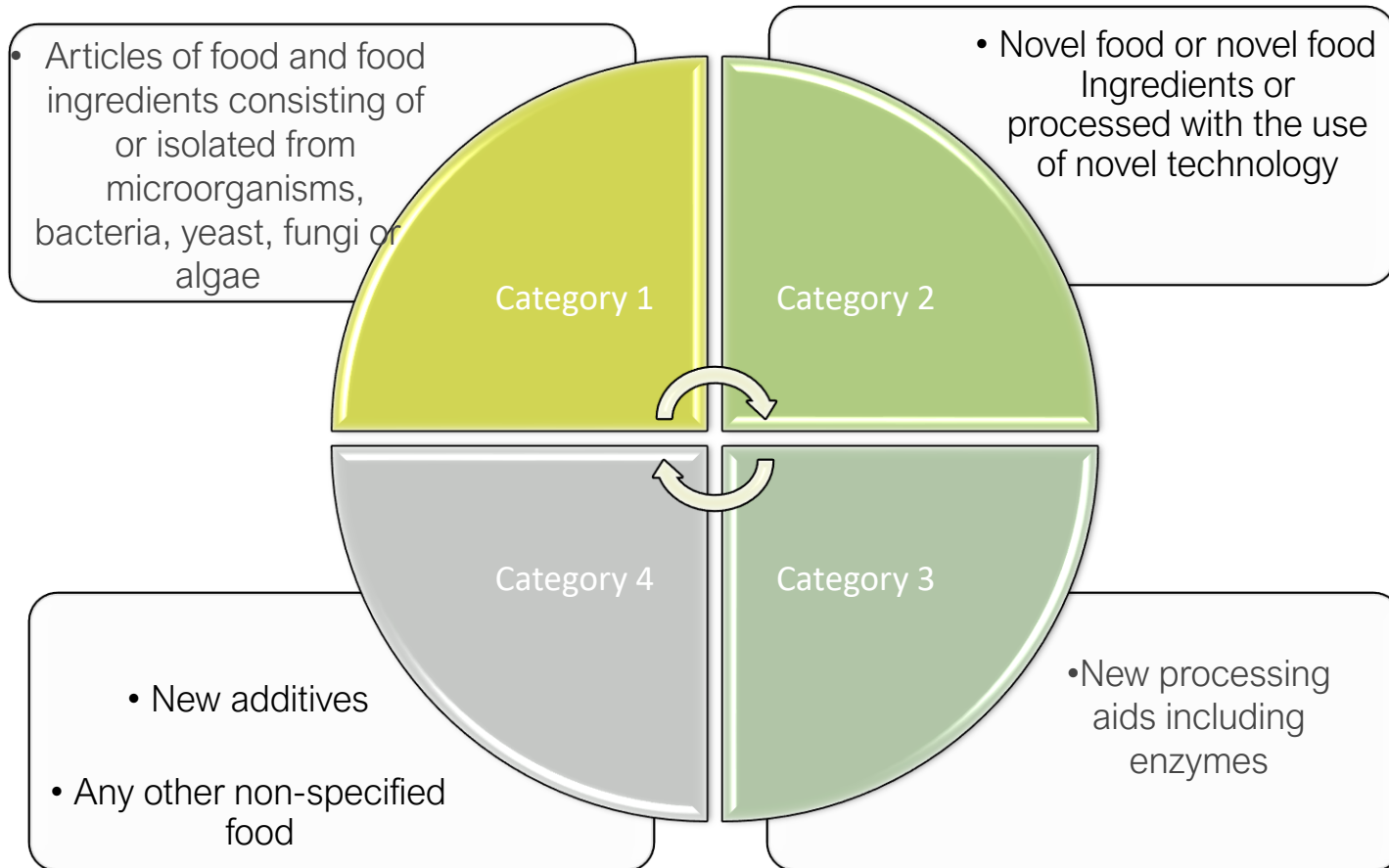


THE FOOD SAFETY AND STANDARDS (APPROVAL FOR NON-SPECIFIED FOOD AND FOOD INGREDIENTS) REGULATIONS, 2017

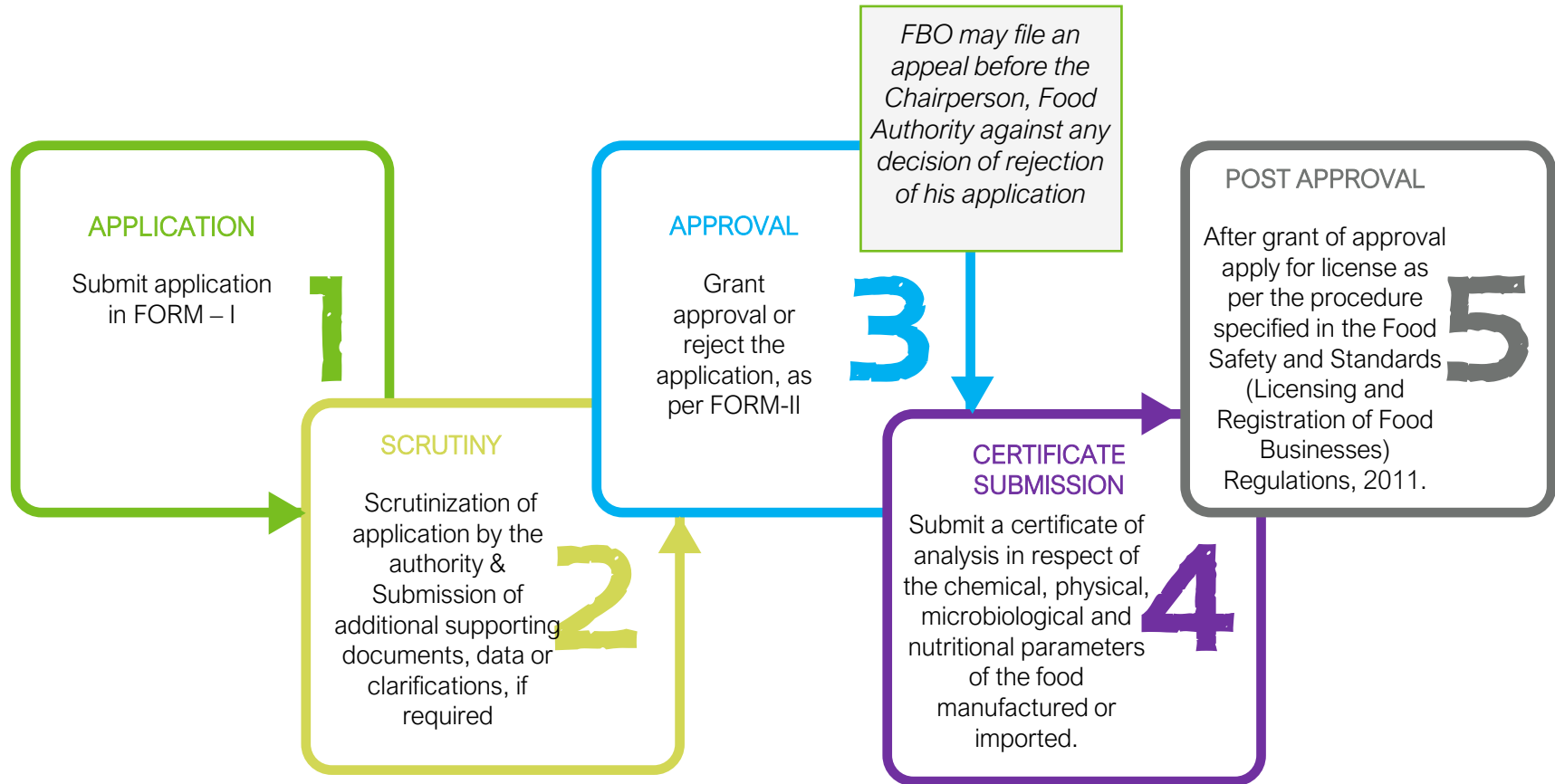


“Non-specified food” means any food other than proprietary food or food ingredients, including additives, processing aids and enzymes for which standards have not been specified in any regulation made under the Act.

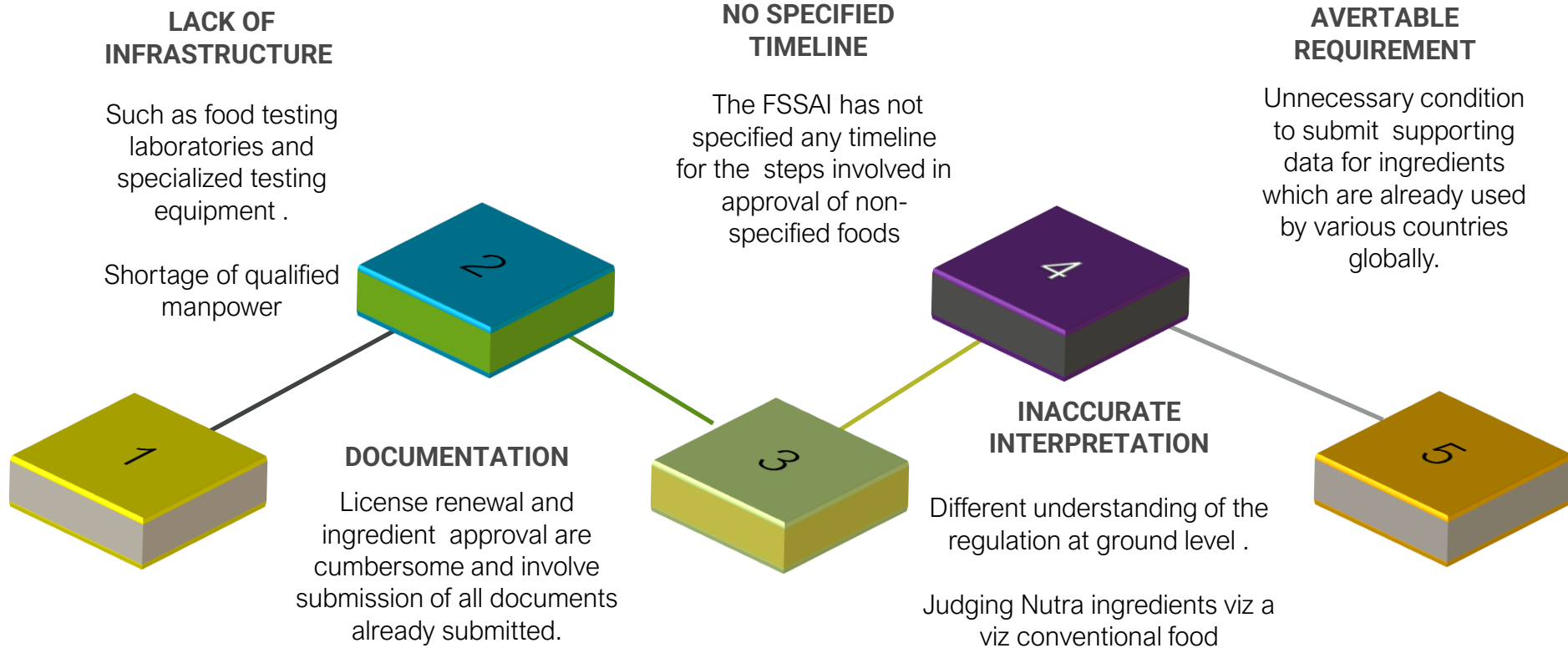
THE FOOD SAFETY AND STANDARDS (APPROVAL FOR NON-SPECIFIED FOOD AND FOOD INGREDIENTS) REGULATIONS, 2017



PROCEDURE



CHALLENGES



CHALLENGES:

INSTANCES

CAFFEINE

INGREDIENT

Caffeine is used in nutraceutical product as ingredient

VERTICAL REGUALTION LIMIT

Used as per the Additives Regulation i.e caffeinated beverages standard 300 mg/L

NOT RECONISED FOR NUTRA

Food Safety officers interprets that there is no allowance for caffeine in Nutra. Therefore, product becomes non-compliant

FSSAI APPROACH

Documents submitted to FSSAI and after detailed review Scientific panel decided that Nutra products can use upto 3 mg/kg and 300mg/ day from all sources

PERSISTANT AMBIGUITY

Keeping in mind the average weight of Indian as 60kg, it actually comes down to 180mg (approx.) which is even lower than already prescribed limits for carbonated beverages



GUARANA



ACCEPTANCE

Adopt globally acceptable safe use as reference for approval of new ingredients.



FACT

Caffeine is less in GUARANA, therefore, product failed in purity criteria available. Note: there is no purity criteria set by FSSAI



DECISION

FSSAI clarified that ingredient having food origin can be used for Caffeinated beverage, however need to maintain the purity criteria established for caffeine.



CLARITY

FBO approached FSSAI for clarity & submitted the adequate data w.r.t safety etc.



DISAPPROVAL

FSSAI prohibited use of Guarana under Nutra, which is safe ingredient and used globally 40-50 yrs

EXCLUSIVITY/ PROPRIETARY

APPLICATION

One FBO apply for approval of new ingredient after detail background exercise including R& D

01

APPROVAL

FSSAI reviews and approves the ingredient basis substantiation submitted by the FBO

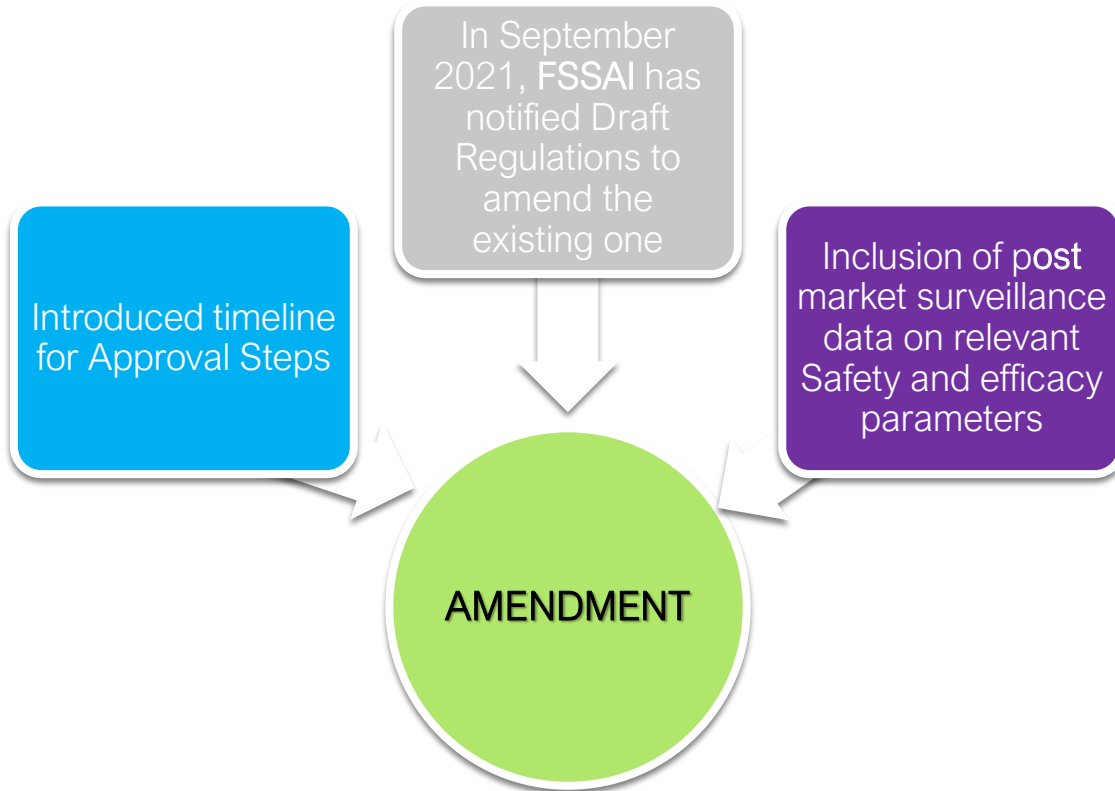
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USAGE

An exclusive right to use to be given to the applicant FBO for a specific time period before making it general

03

DRAFT: FOOD SAFETY AND STANDARDS (APPROVAL FOR NON-SPECIFIED FOOD AND FOOD INGREDIENTS) AMENDMENT REGULATIONS, 2021,



POSSIBLE CHALLENGES

INCOMPLETE TIMEFRAME

Proposed draft
doesn't not
specify time for
the authority to
respond after
submission of
additional
information by
FBO

UNREASONABLE REQUIREMENT

Unnecessary
condition to submit
post market
surveillance data
on relevant Safety
and efficacy
parameters for
ingredients which
are already
established as safe
globally.

RESOLUTION



THANK
YOU

