Product development and the challenges of making health claims
Introduction of the Industry Guidance Paper

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PATHWAY-27

- …not only an acronym…
- **PATHWAY-27 main aim is to define "roadmaps" that can be followed while producing bioactive-enriched foods and demonstrating they are effective.**

TECHNICAL/TECHNOLOGICAL BARRIERS:

- **lack of guidelines/supporting documents**;
- lack of knowledge (how best to conduct RCTs, statistics);
- **difficulties in appropriate characterisation of food/constituent;**
- difficulties in establishing the relationship between the constituent and the claimed effect considering the target population;

ECONOMIC BARRIERS:

- **length of the process** of authorisation increasing the time and cost of product development;
- high input costs;
- **limited human** and financial **resources** of the food businesses.
- lack of specialised human resources for organizing and performing clinical tests;

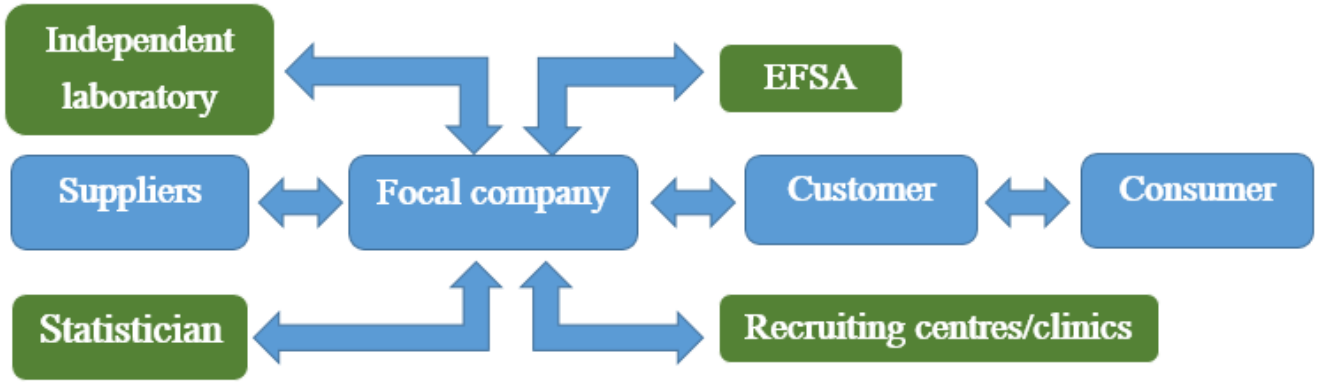
SCIENTIFIC BARRIERS:

- lack of appropriate biomarkers, to be used, accepted by EFSA;
- difficulties in establishing the relationship between the food/bioactive substance and the claimed effect;
- difficulties in setting up the experimental design and human intervention studies;
- **limited availability of information on good practices and typical pitfalls**

Why the Industry needs a Guidance Paper?

The development of products with health claim

- is **more complex process** than the development of conventional products
- Process includes **costly tests** and **analysis** for **provision of appropriate samples** for scientific substantiation
- requires high level of **collaboration** and **harmonized** interaction of several disciplines and independent partners
- More **guidance** is necessary **for SMEs**



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Objectives of the Guidance Paper (1)

This guidance offers a **structured product development approach** focusing on all aspects what users should consider when **designing products with health claims**.

The Guidance Paper targets food businesses, particularly **SME**s and their suppliers (material, knowledge and related services)

Main topics of the Guidelines (1)

- ✓ **Stages of the development of products** with health claims- highlighting the importance of high reproducibility and uniformity
- ✓ **Characterization of the bioactive constituent**
- ✓ Food safety evaluation of the product
- ✓ **Shelf-life assessment**
- ✓ Aspects for the validation and the verification of health claims to prepare scientific substantiation
- ✓ Dossier development
- ✓ Intellectual property rights
- ✓ **Market and product launch concepts**

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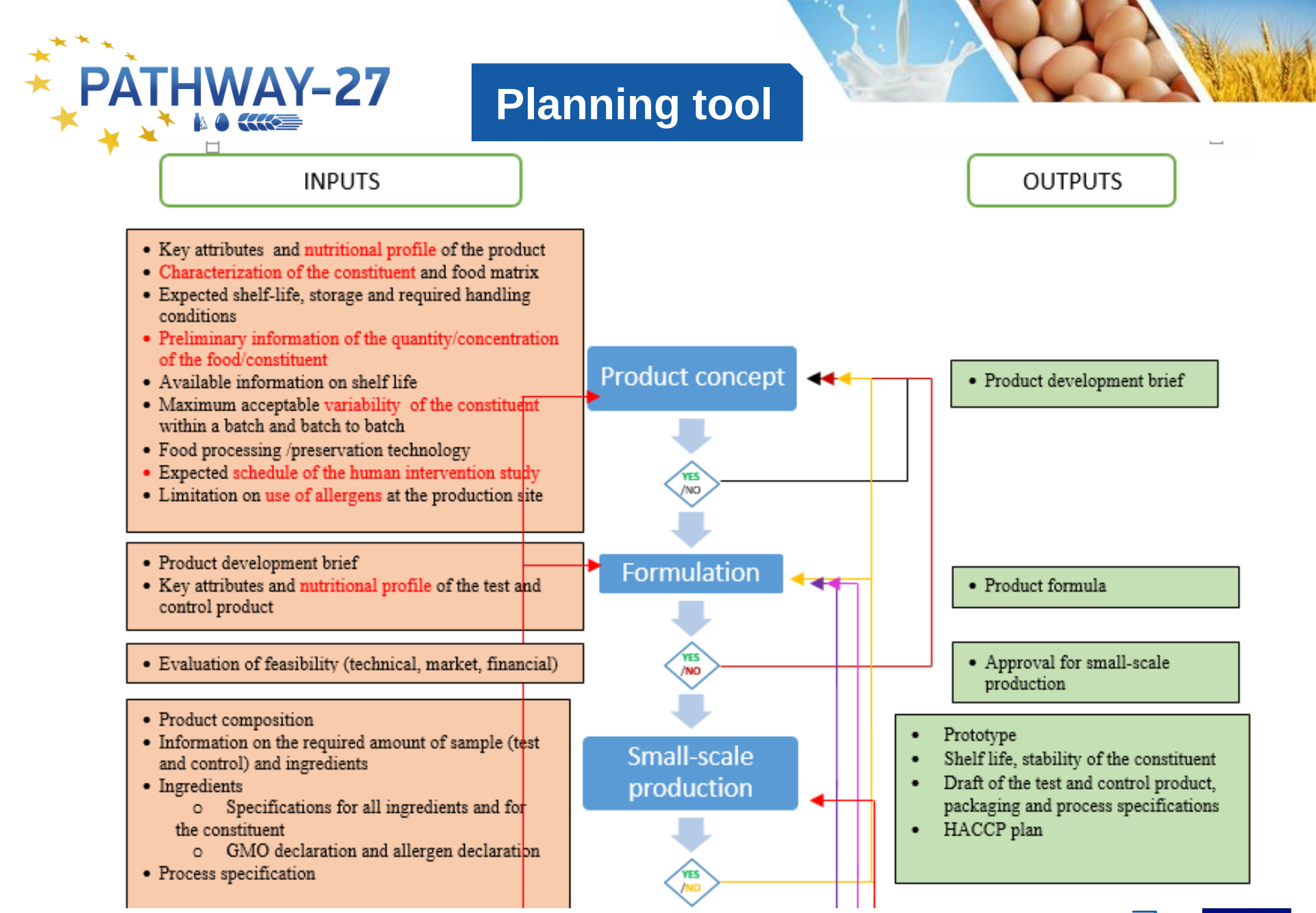
Planning tool



Planning tool

- Food safety and stability declaration on the products
- Ethical approval for consumer testing
- Specifications

Consumer acceptance test

YES /NO

- Revision of the product formulation and production process based on the feedback from the consumer test

- Product formulation
- Product specification
- Packaging specification
- Process specification

Pilot scale production

YES /NO

- Modified prototype
- Standardized/ verified final product , packaging and process specification
- Revised HACCP plan
- Variability within a batch and batch to batch
- Compliance to food safety requirements

- Required sample amount
- Verified shelf life and stability
- Compliance to reproducibility requirements
- Production and delivery plan
- Specifications (test and control product, packaging and process)

Factory scale production trials

YES/ NO

- Final product
- Verified chemical and microbiological properties
- Variability within a batch and batch to batch
- Verification of shelf life and nutritional profile
- Revised HACCP plan
- Compliance to reproducibility requirements

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Planning tool

INPUTS

OUTPUTS

Product, process, packaging approval

- Approved product, process and packaging specifications
- Approved labelling
- Approved FSMS

YES/NO

- Ethical approval for performing human intervention study
- Recruiting plan
- Design of human intervention study
- Production and delivery plan

Human intervention study

- Verified relationship between the claimed effect and the food/constituent

YES/NO

- EFSA guidance on health claim substantiation (EFSA Journal, 2011)
  - Administrative and technical data of the applicant
  - Characterization of food/constituent
  - Summaries of the performed studies
  - Scientific data which form the basis for substantiation of the claim
  - Glossary, abbreviation

Dossier development

- Approved dossier, claim and registration of the claim

YES/NO

- Approved claim
- Approved labelling
- Approved FSMS
- Compliance to specifications
- Awareness built

Market launch

- Product compliance to specifications, available for the market

SEVENTH FRAMEWORK PROGRAMME

Establishing the main attributes of the bioactive constituent and the claim

- Characterization of the bioactive constituent
  - Source and bioavailability
  - Physical, chemical and microbiological properties
  - Stability in the food matrix-considering the effect of the manufacturing process
- Definition of the claimed effect
  - —Minimum amount of bioactive constituent in one portion
  - —Variability from batch to batch and within a batch
- Establishment of the nutrient profile – if it is existing

Prerequisites for the human intervention studies

- The control product for the human intervention studies should match as closely as possible the composition and sensory properties of the product with health claim (test product) but it does not contain the bioactive constituent;
- Estimated amount of test and control products in total for each clinical centres
- Recruitment capacity of the clinical centres during the set time
- Duration of the human intervention studies
- Sample storage capacity of the clinical centres
- Sample preparation facilities at the clinical centres

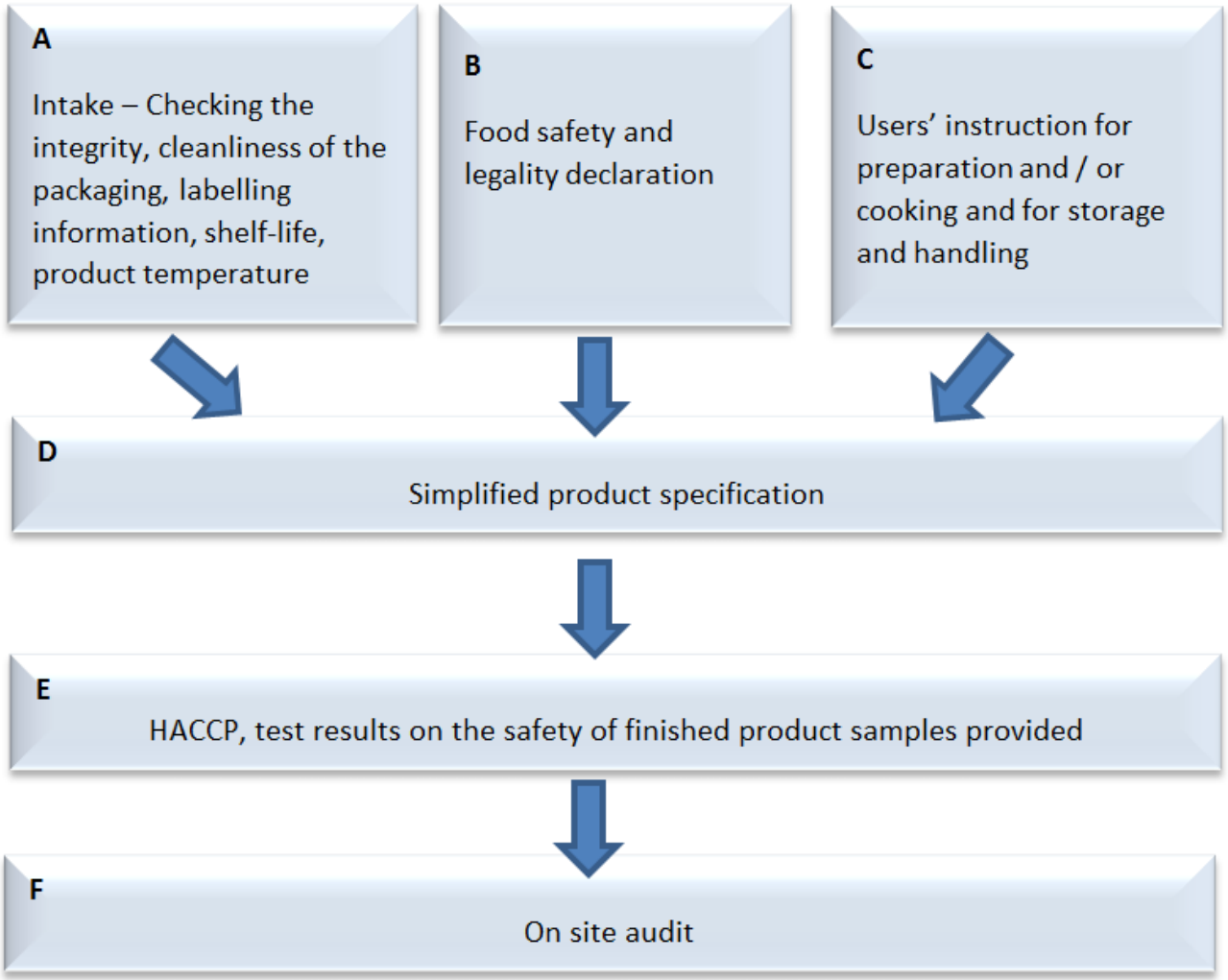
System of process control to ensure the required reproducibility

- Designing the performance criteria and the process control for each step
- Identification of the key control points
- Identification of the key process parameters
- Establishing a monitoring system at the selected key control points
- Establishing corrective actions
- Verification and validation of the process performance

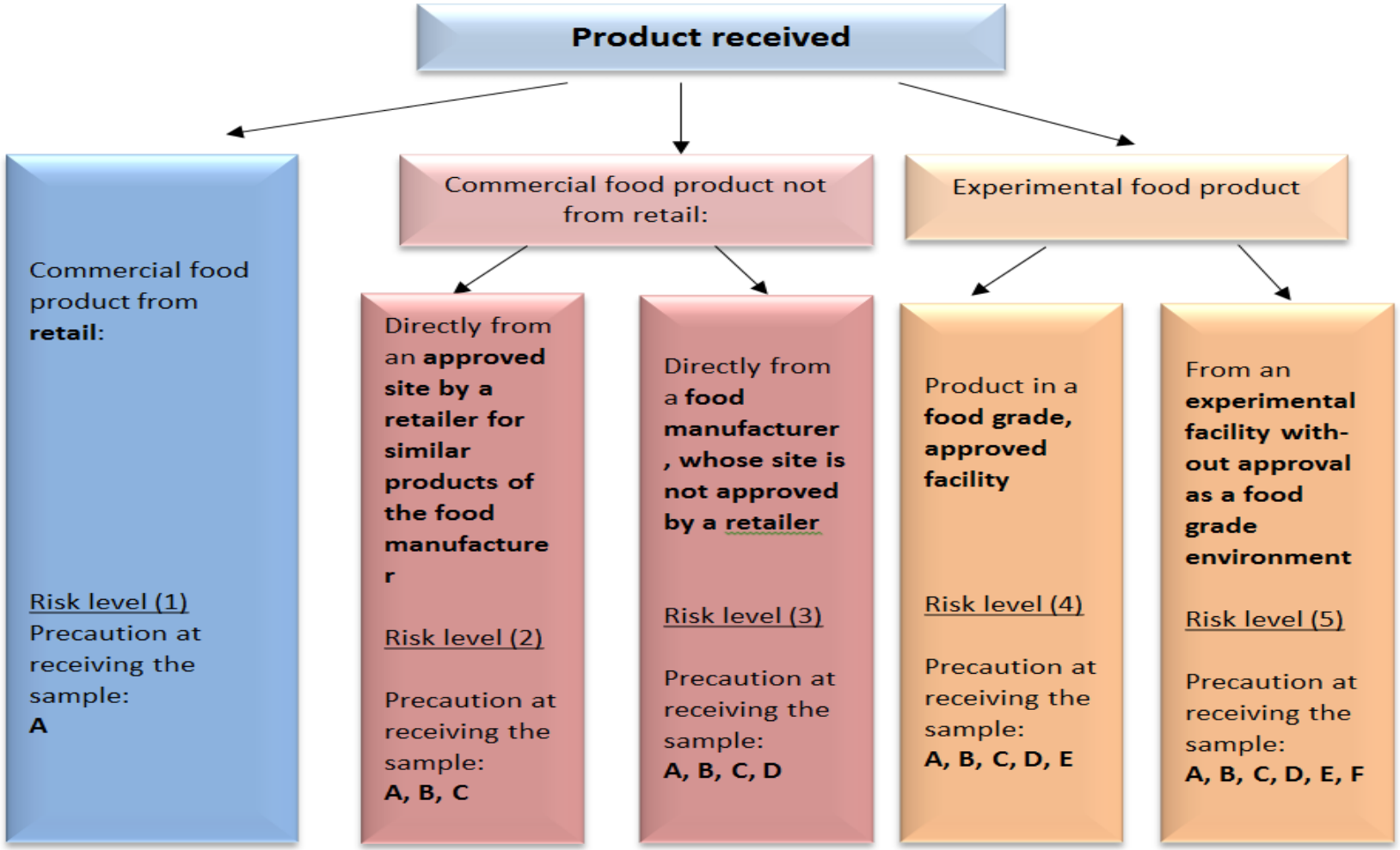
Ensuring food safety

- Product specific HACCP study is mandatory for all test and control products, sensory and intervention consumer testing, human intervention studies – responsibility of the manufacturer
- Compliance to food safety requirements should be checked by the user – hierarchy of precaution requirement

The hierarchy of precautions to ensure the food safety of samples



The hierarchy of precautions to ensure the food safety of samples



Ensuring food safety

- Special attention has to be paid to the potential adverse effect of a bioactive constituent at high concentration,
- Proper segregation of experimental production from standard products to avoid cross contamination

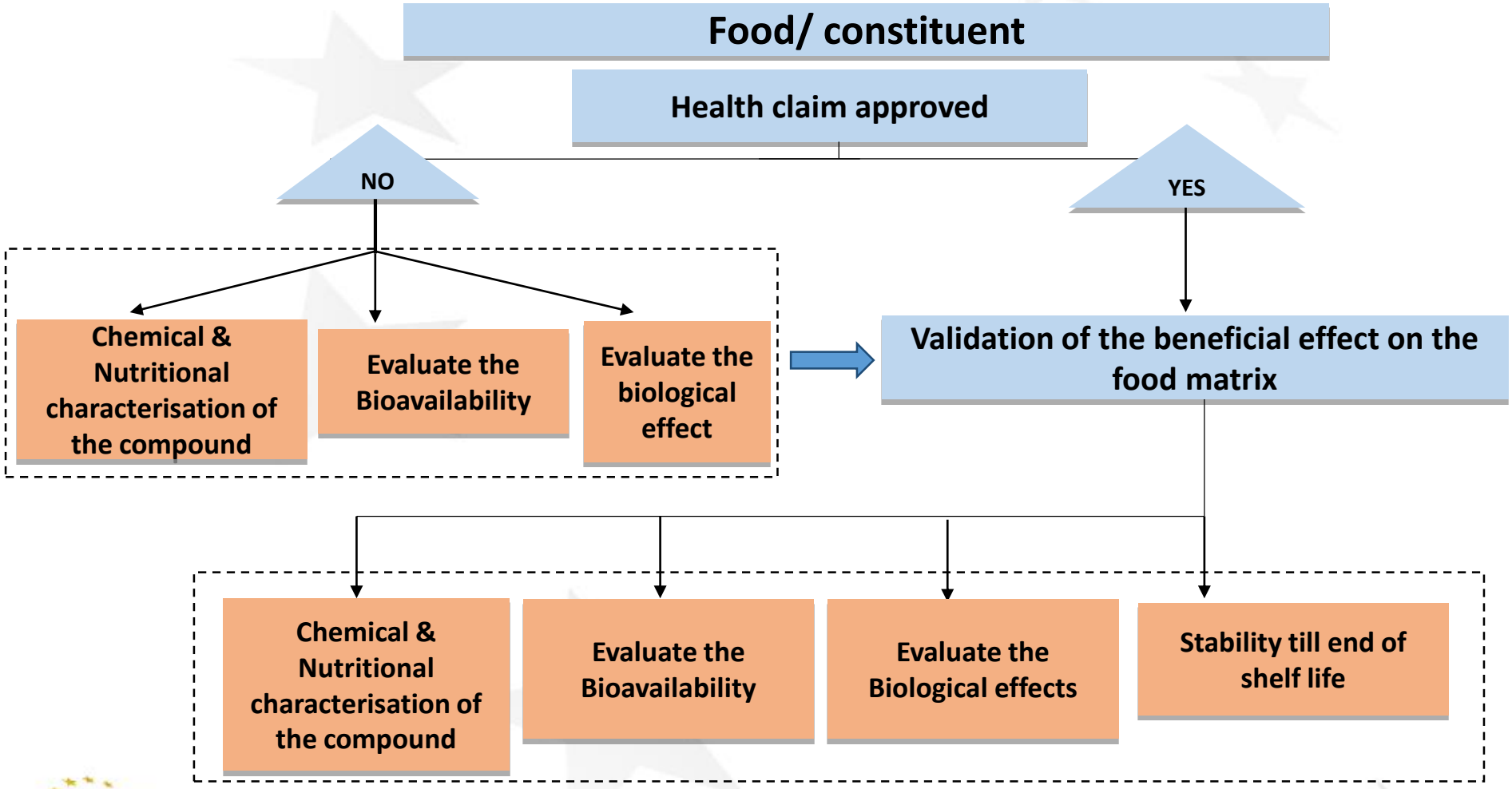
Shelf-life of the test and the control product

- Basic requirements towards the product samples
  - Remain safe
  - Retain desired sensory, chemical, physical and microbiological characteristics during the entire shelf life
  - For products with health claims
    - stability and consistency of the concentration of food/bioactive constituent which is expected to exert the claimed effect - during the whole shelf-life
  - Retain nutritional parameters to comply with any label declaration of nutritional data

Scientific validation of the cause-effect

- Aspects to consider:
  - **Bioavailability** of the food/constituent within the matrix which is influenced by the composition of the matrix through the synergies between the different components of the food
  - **Functionality/bioactivity** of the food/constituent: includes events linked to the way the nutrient or bioactive compound is transported and reaches the target tissue, how it interacts with biomolecules, the metabolism or biotransformation

Aspects of the validation of the claim



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Identifying the role of the new product with health claim in a business (1)

- Developing a business plan is critical
- Key aspects to be considered to assess the impact on the business
  - greater level of interaction with third parties
  - higher cost, increased level of necessary testing
  - increased time : + 18-30 months
  - dedicated marketing and communication
  - potential for enhanced revenue.

Identifying the role of the new product with health claim in a business (2)

- A business risk analysis should be carried out covering:
  - sourcing the critical/new raw material (health benefit);
  - consistency of supply;
  - ability to provide stable product of consistent quality with added components;
  - likelihood of achieving a health impact in the final product;
  - approval of the claim

Market and product launch concepts

- The launch phase is an opportunity to build awareness based on the “condition” being targeted e.g. bone health, eye health
- Compliance with acceptable practice of the country should always be checked.

General considerations (1)

- ✓ Systematic design of the product and the product development process
- ✓ Careful planning of the activities, including timing
- ✓ Regular review of the results and the progress

  is crucial to ensure
  - ✓ the availability of the required concentration of the bioactive constituent to excerpt the claimed effect during the whole shelf-life till consumption
  - ✓ high reproducibility and uniformity of the properties - low variability within a batch and batch to batch, particularly for the bioactive constituent.

General considerations (2)

- ✓ is **crucial** to ensure (continued)
- ✓ availability of the test and control product for human intervention studies and all analysis
  - ✓ at the right place
  - ✓ at the right time
  - ✓ an the right quality and quantity

  ⇩

  to avoid
  - ✓ unnecessary costs
  - ✓ delays

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Thank you for your kind attention!

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SEVENTH FRAMEWORK PROGRAMME