



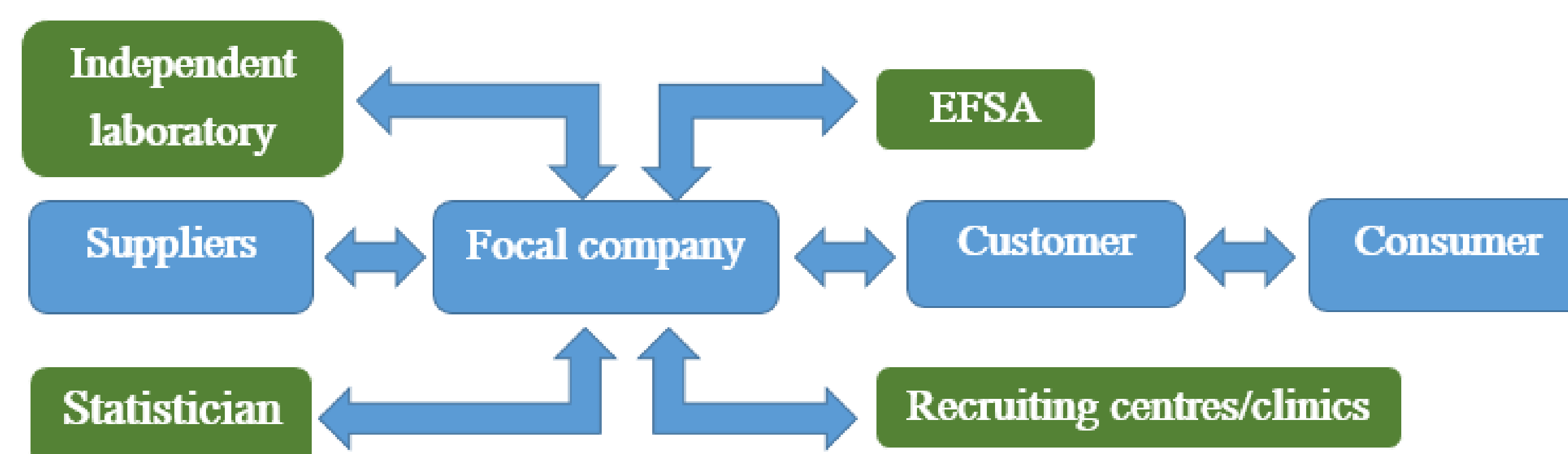
PATHWAY-27- INDUSTRY GUIDELINES ON DEVELOPMENT OF PRODUCTS WITH HEALTH CLAIMS

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The development of products with health claim

- is a more **complex process** than the development of conventional products
- requires high level of **collaboration** and **harmonized interaction** of several disciplines and independent partners.
- includes **costly tests** and **analysis** for provision of **appropriate samples for scientific substantiation**
 - ✓ Shelf-life tests: microbiological, chemical and sensory tests
 - ✓ Characterization of the constituent
 - ✓ Production trials and monitoring the uniformity of the concentration and stability of the constituent within batches and between batches during the whole shelf-life
 - ✓ In vivo and in vitro tests to validate the constituent-effect relationship
 - ✓ Absorption studies
 - ✓ Human intervention studies: complexity of selection of volunteers, drop-outs



Analysis are interrelated to and build on each other ➡ Providing samples

in the RIGHT QUANTITY
in the RIGHT PLACE
at the RIGHT TIME

 for all analysis and human intervention studies

Number of changes should be kept to the minimum and necessary changes should be identified as early as possible.

Changes in composition, packaging, storage conditions ➡ Influence the stability and uniform distribution of the constituent

Shelf-life test has to be repeated and HACCP plan has to be revised

Delay in further activities; increasing cost

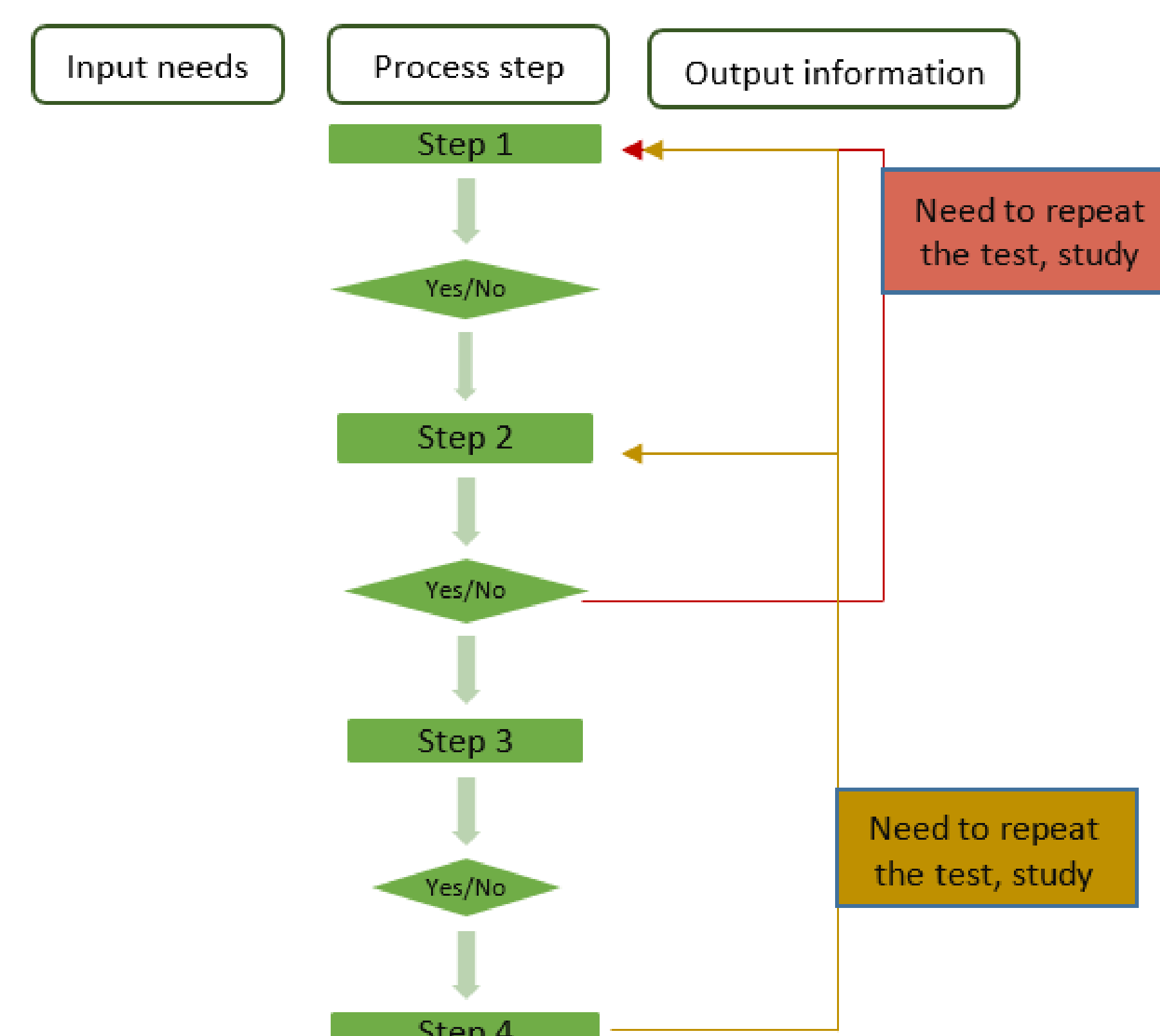
Understanding the fact that any change in the process requires repeated tests

Careful planning and design

Tools to help in planning and organizing the activities:

- Product development brief
- Clear specifications for products, ingredients and packaging
- Early design of the required outputs
- Estimation of the amount of samples
- Careful planning- Gantt chart
- Reproducibility needs
- Set of integrated Guidelines for food industry/SMEs

The draft guidelines are available for public discussion.



FURTHER INFORMATION

<http://www.pathway27.eu>