Available online at www.centmapress.org

INTERNATIONAL JOURNAL ON FOOD SYSTEM DYNAMICS

Proceedings in
System Dynamics and Innovation in Food Networks 2016

Importance of Coordinated Interactions of Multiple Stakeholders for Developing Products with Health Claims

András Sebők[1], Adrienn Hegyi[1], Zsófia Kertész[1,] Alessandra Bordoni[2]

[1] Campden BRI Magyarország Nonprofit Kft., H-1096 Budapest, Haller u. 2. Hungary

[2] ALMA MATER STUDIORUM-Universitá di Bologna (UNIBO), Viale Fanin 44, Bologna, Italy

a.sebok@campdenkht.com, a.hegyi@campdenkht.com, z.kertesz@campdenkht.com, alessandra.bordoni@unibo.it

ABSTRACT

During the development of products with health claims the collaboration and interaction of several disciplines and independent partners is necessary such as the production, quality, marketing, legal functions of the company, the external providers of the knowledge on the constituent having the claimed physiological effect, the clinics carrying out the human intervention studies, statisticians, laboratories providing testing services, etc. This results in a higher dependency from each other and less flexibility compared to the development of a conventional product where mostly in-company functions work together. Therefore systematic coordination of the multiple interactions, careful design of the product and its development process is particularly important.

***Keywords**: health claim; coordinated interactions; multiple stakeholders; new product development*

1. Introduction

Since 14 December 2012 any unauthorised health claims that are not listed in the EU register are no longer permitted for use on products sold in the European Union. The EU register includes the outcome of separate European Commission evaluations of health claims relating to new science or proprietary data, reduction of disease risk and children's development and health. These published lists offer opportunities for food and beverage manufacturers to use authorised claims on current products (providing the conditions of use are met) or to reformulate products in order to comply with the conditions.

Despite of the guidance of EFSA on health claim substantiation (EFSA Journal, 2011), industry is facing difficulties in meeting the requirements established by the EU and national authorities for health claim substantiation (Hegyi, et al. 2015).

Between 2007 and 2013, the European Commission received 412 applications. 35% of the applications were evaluated negatively due to the dossiers did not meet with the requirements. The three main reasons of the negative evaluation are: a not appropriate study was presented, an issue with the characterization of the constituent and the last one is the issue with the target group and the claimed effect (Martin, 2013).

DOI 2016: pfsd.2016.1609

2. Obstacles of the product development of products with health claim from the organization point of view

The development of products with health claim is a multi-step and complex process. It requires high level of collaboration of different actors. Beside the product development team, external laboratories, statisticians, and clinical centres are involved in the development process. The main aim is to produce a product which is appropriate to be involved in a clinical trial and for proving the relationship between the chosen food/constituent and the targeted effect. In order to do that the company producing the sample, has to provide samples with standardized composition and with low variability of each product parameters (particularly the concentration of the food constituent). Low variability in the bioactive content, the composition and structure of the food sample is necessary to ensure the statistical validity of the established relationship between the bioactive and the claimed effect. A critical aspect of provision of samples for the scientific substantiation is to ensure that the standardised concentration of the constituent having the beneficial physiological effect should be maintained and all activities related to the human intervention studies should be standardised to reduce any factors which may increase variability. To achieve that the stability of the bioactive constituent during the whole shelf life, the uniformity of its concentration within a batch and low variability from batch to batch should be ensured. Food safety, stability of the bioactive constituent and sensory appeal of the food should be maintained.

The samples for the clinical trials have to be available in the right quality and quantity, at the right time, at the right place. The key of the organization such activities, is careful and forehanded planning. The outputs necessary to achieve the main target- e.g. the availability of the appropriate sample- have to be considered at each step together with the necessary inputs which ensure safety, sensory appeal, and effective concentration of the bioactive constituent during the clinical trial. Recruitment of adequate number of volunteers with the appropriate health and nutrition profiles needs significant efforts and time. This complexity of interactions results in higher lead times for provision of samples after any changes and high cost of the modifications. Changes should be kept to the minimum and necessary changes should be identified as early as possible. Therefore systematic coordination of the multiple interactions, careful design of the product and its development process is particularly important. All participating actors have to understand that any change in the process, packaging or in the product may result in the need of the repetition of tests and stages of the process to meet the above mentioned criteria. It increases the cost of the development and the time spent on it.

3. Adapted value chain management approach

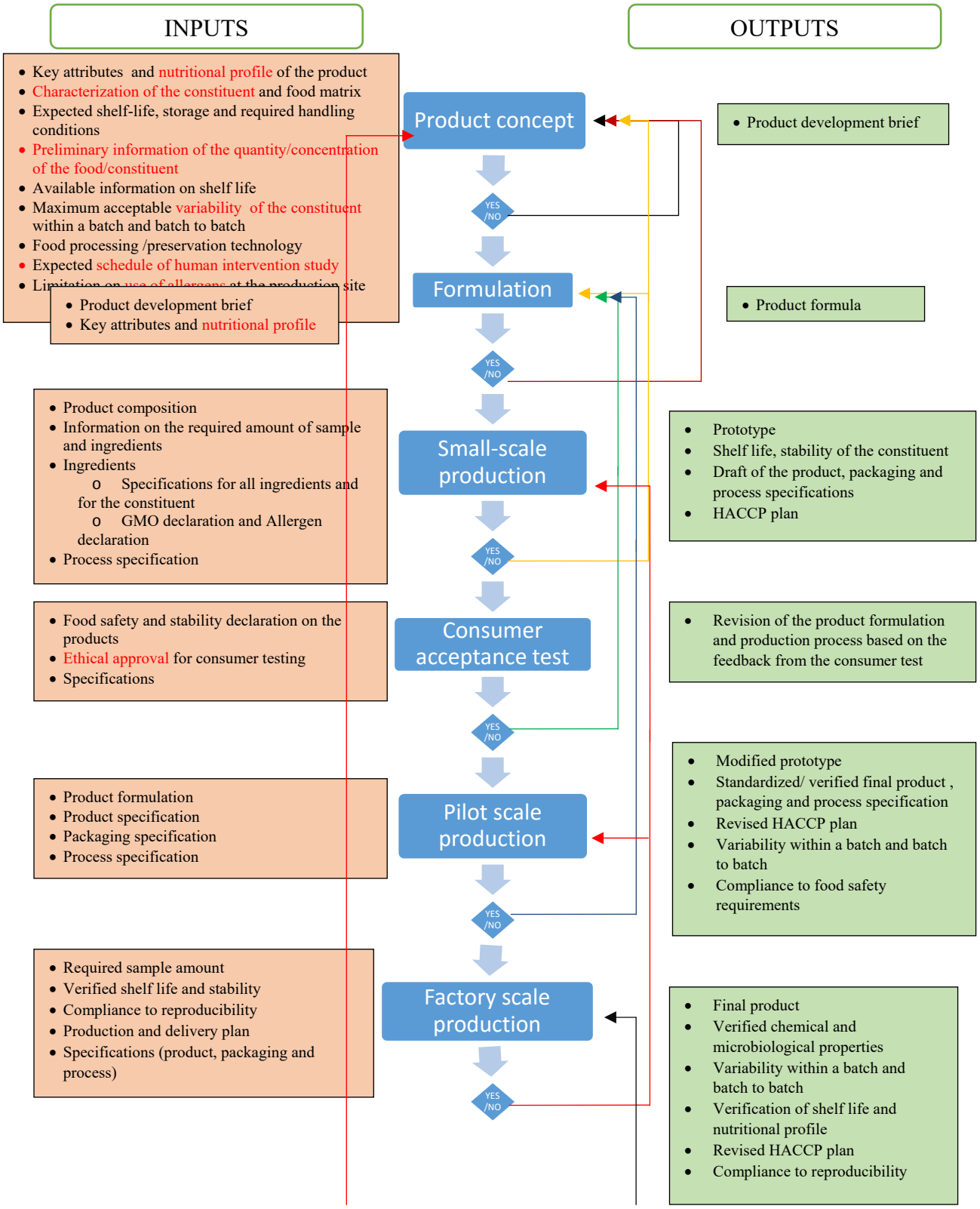
Coordination of interactions of multiple stakeholders can be improved by mapping their interactions following a chain approach and specifying needs for inputs of information and samples and timing of each partner involved and necessary outputs and timeline from each partner in a network structure.

Figure 1. shows the main stages of the development of products with health claim. The interrelations of each stage are indicated by the coloured arrows. The key measures which needs to be reviewed for a careful planning are the followings: the product development brief, the product and ingredient specifications, the process specification, the shelf-life, the stability of the bioactive constituent, required sample amount for the human intervention study, the production and the delivery plan of the samples for clinical trial, the recruitment of volunteers for the clinical study and the design of the clinical trial. The typical mistakes at each consecutive step which influence the progress are the followings:

As a starting point, the product key attributes, the nutritional profile and the characterization and the required concentration of the constituent to achieve the targeted effect have to be known. In that case if the nutrient

DOI 2016: pfsd.2016.1609

profile of the product does not match to the requirements, the claim cannot be indicated on the product, and the entire process should be started again.



DOI 2016: pfsd.2016.1609

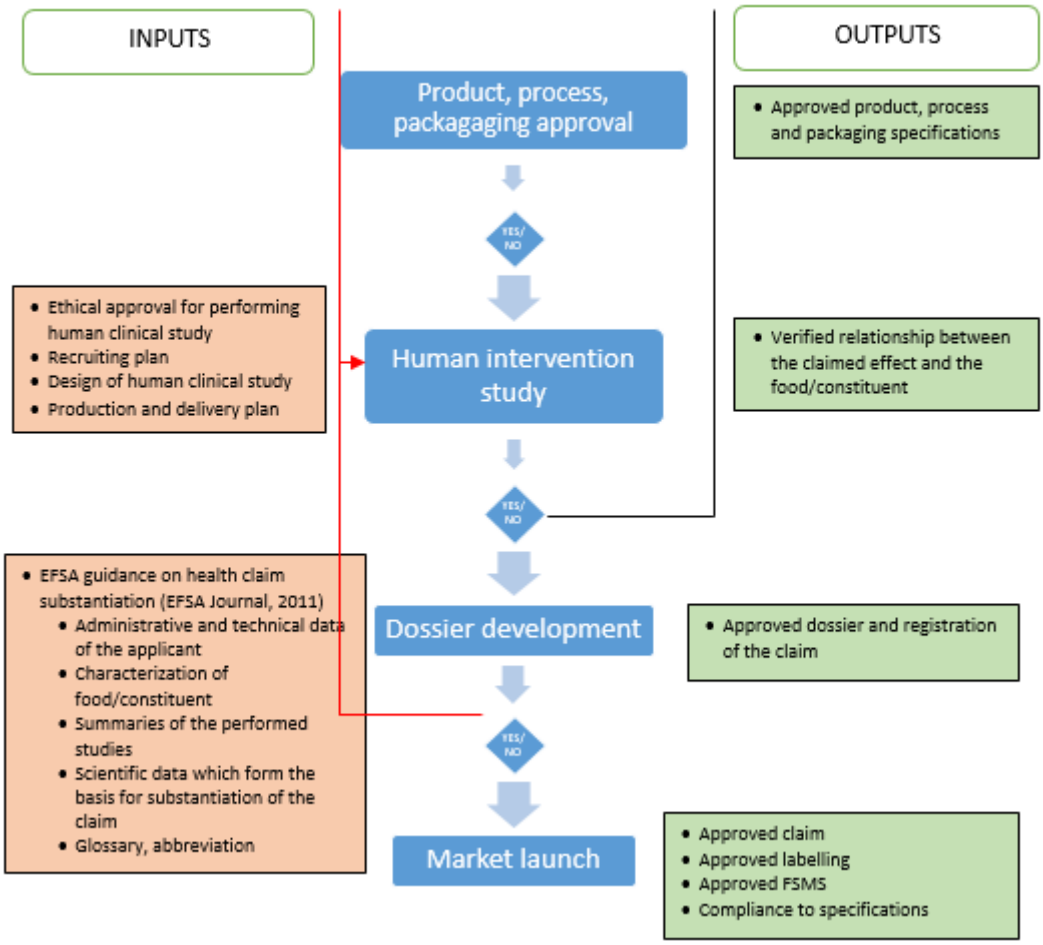


Figure 1: The process of development of products with health claims

The characterization of the constituent and the establishment of the maximum acceptable variability of the constituent is also essential since it is influencing the reliability of the clinical trial. The processing technology might influence the degradation of the constituent during the processing and the shelf life and in the final product the concentration of the constituent would be lower than the acceptable limit and the targeted effect cannot be achieved and proven during the human studies. Furthermore, preliminary information is required on the expected shelf life of the product and on the length of the clinical trial to be able to harmonize these aspects.

The nutritional profile has to be calculated during the product formulation, and checked whether it meets the legal requirements.

During small-scale production, the first prototypes are created. The preliminary shelf life of the product is determined at this stage and the stability of the constituent is measured. Any detected problem with the stability of the product or the concentration of the constituent requires to revise the product concept or the formulation of the product. Food safety has to be ensured and guaranteed by the manufacturer for consumption tests. The stability of the constituent during clinical trial should be ensured otherwise the reliability of the results may be compromised. Based on the results of the consumer test, modifications of the composition or the processing technology of the product may be necessary. At this stage, the reproducibility of the product should be verified, with a special attention to the variability of the constituent within a batch and from batch to batch. Any deviation from the verified final product, packaging and process specification leads back to previous steps and requires the repetition of the tests.

DOI 2016: pfsd.2016.1609

Before the factory scale production, the needed amount of the produced final product samples for human intervention studies, the production plan and the delivery plan have to be cross-checked with the clinical centres' recruitment plan and the design of the clinical trial. The microbiological and chemical properties of the final product have to be verified by laboratory testing, before it can be delivered to the clinical centres. If the variability of the constituent within a batch or between batches is higher than the acceptable limit established in the product development brief, the cause of the problem has to be identified by returning to previous stages, if it is necessary, till the small-scale production.

Human intervention studies are not flexible processes, the recruitment of the volunteer is time consuming and a very strict test design is followed. The schedule of the trial cannot be changed in short notice. Therefore, the timing of the production and delivery of the samples should be adjusted to meet of the sample needs of the clinical trial. Products have to be at the right time, in the right quantity and quality, at the right place. If these aspects are not fulfilled, additional production dates and delivery options have to be arranged. Both of them increase the cost of the process and cause delay in the clinical trial.

The negative evaluation of the prepared dossier for health claim substantiation require the re-evaluation of the process and based on the explanation of the failure, the whole process should be restarted from the beginning.

In the case of positive evaluation of the dossier, the product will be registered and until then the product can be labelled with the claim.

4. Conclusion

As one of the main innovative trends, products with beneficial effect on health are in the focus of product developers. However, complexity of the process hinders the development of such products.

Product developers have to collaborate with several external experts, as statisticians, clinical centres or external laboratories in order to produce samples which

- are stable in terms of their microbiological, chemical properties
- contain the constituent in an acceptable and standardized concentration
- can be produced in a reproducible way.

The production of the samples has to be harmonised with the clinical studies to prove the relationship between the targeted effect and the food/constituent.

This multi stakeholder process requires high level of forehanded planning. There are tools which can help in planning. Detailed and clear product development brief should be prepared at the beginning of the development. Ingredient, final product, process and packaging specifications should be available and they should be updated if it is necessary. Gantt chart is a common tool to harmonize activities in time.

In the framework of PATHWAY-27, a guideline targeting the industry is being prepared offering a structured product development approach focusing on all aspects what the industry should consider when designing products with health claim.

5. Acknowledgement

The research leading to these results has received funding from the European Union Seventh Framework Programme (FP7/2007-2013) under grant agreement n°311876: PATHWAY-27. We also thank to the valuable contribution of Dr. Lidia Thomas (AINIA), Dr. Stéphane Vidry (ILSI Europe) and Dr. Peter Putz (ILSI Europe).

DOI 2016: pfsd.2016.1609

6. References

EFSA Journal. (2011). *Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim.* Retrieved from http://www.efsa.europa.eu/en/efsajournal/pub/2170

Hegyi, A., Viola, K., Gyuró, Á., Vidry, S., Putz, P., & Bánáti, D. (2015). Needs and difficulties of food businesses in the substantiation of health and nutrition claims. *No 206235, 2015 International European Forum, February 17-21, 2014, Innsbruck-Igls, Austria, International European Forum on Innovation and System Dynamics in Food Networks.*

Martin, A. (2013). *EFSA expereince in reviewing human studies submitted for the scientific substantiation of health claims .* Parma: EFSA Technical meeting .

7. Short vitae of the authors

dr. András Sebők, general manager of Campden BRI Hungary, Chairman of the R+D expert group of FoodDrinkEurope, Vice-Chairman of cooperation of the national food technology platforms of ETP, 40 years' experience in food industry R+D, particularly in food processing, food transparency, knowledge transfer, training, capacity building and project management.

Dr. Adrienn Hegyi graduated as food engineer. Manager of sensory and consumer department and the marketing activities of the Campden BRI Hungary. She participates in the work of the European Sensory Network. She graduated on the Postgraduate Sensory Science Course at the University of Nottingham. She obtained a PhD in marketing at the Szt. István University Gödöllő, Hungary.

Zsófia Kertész graduated with M.Sc. level as a biochemical engineer from Technical University of Budapest in 2014, specialized in food quality control. Trained in sensory and consumer test evaluation. Experience in technology transfer and in knowledge transfer. Works at Campden BRI Hungary Ltd. as a development engineer.

Alessandra Bordoni MD, PhD, is the leader of the Nutrition Unit at the Campus of Food Science, University of Bologna, where she is teaching "Human Nutrition" and "Applied Nutrition". Her research activities regard several topics of human nutrition, nutritional biochemistry and nutrigenomics. In these fields, she devoted special attention to polyunsaturated fatty acids and bioactive components of foods. She is the PATHWAY-27 project Coordinator.

DOI 2016: pfsd.2016.1609