[10:00 - 10:30]

Evaluation of Safety and Efficacy for Health/Functional Foods

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The interest in health/functional foods and the corresponding range of products marketed are increasing worldwide. Health/Functional foods now play an increasing role also in Korea. Compared to conventional foods, health/functional foods should exert effects on the improvement of health and the reduction of the risk of developing disease, which go beyond their nutritional effect. The aim of favorably influencing certain body and organ functions as well as the risks for developing specific diseases requires high standards both of the scientific evidence for any effects, which are the subject of so-called health claims, and of their scientifically based evaluation. In addition, for health/functional foods, as for all other foodstuffs, the basic premise is that they must be safe within the limits of the recommended or foreseeable amounts consumed.

Korea Food & Drug Administration (KFDA) has adopted a few of unique regulatory systems for health/functional foods as follows:

1. Regulates them as Food, not as Drug.
2. Covers dietary supplement only.
3. Pre-market authorization. The marketing of health/functional foods requires their prerequisite accreditation from KFDA.
4. Ingredient-, not Product-based Accreditation.

First of all, it is important that the scientific characterization and standardization of the submitted ingredient should be established as follows.

1. The characterization of raw materials. It includes the scientific information of a source plant (scientific name), plant parts used, the growing condition of the plant, the harvest condition (when, where), and the storage condition.

2. The explanation for manufacturing processes. The extraction solvents and/or microorganisms used in manufacturing processes should be characterized in detail. In a case of chemical syntheses, the purity of a synthetic compound should be substantiated.
3. The substantiation for the contents of a functional or indicating component. The standard compound and detection methods for a functional or indicating component should be presented. The contents of a functional or indicating component should be estimated at each step of manufacturing processes.

The scientific characterization and standardization of the submitted ingredient may form the basis of the quality control as well as safety of it.

Health/Functional foods must be hazardous to the health of the consumer and it is required that they are thoroughly investigated and evaluated in this respect. Targeted investigations of their functional effects in humans may only be initiated, when no indication of a risk to health is apparent in the light of current knowledge.

The comprehensive safety evaluation of KFDA is made up of several assessments of the history of safe use, safety information, the intake/exposure level, interactions with other components, toxicological studies, and bioavailability. Recently, KFDA has developed a decision tree for safety evaluation to determine the extent of required safety investigations. The decision tree for safety evaluation implies the following questions:

- Is the submitted ingredient registered in 'The Negative List of Health/Functional Food Ingredients'?
- Are there historical records of safe use of the submitted ingredient?
- Do the manufacturing processes of the submitted ingredient include more complex process steps than simple drying/crushing or extraction using water/fermented ethanol as an extraction solvent?
- Is the submitted ingredient natural or chemically synthesized?

- Compared to the normal intake/exposure of the submitted ingredient, does sponsor suggest an excess intake amount of it?
- Have the adverse effects of the submitted ingredient been reported?

This decision tree may assign the submitted ingredient to one of 4 safety classes, determining the extent of required safety investigations.

A health/functional food produce-according to the intended claim-one or several effects, which exceed those that may be archived by a comparable product consumed in comparable amounts as part of a balanced diet. Evidence for a special effect is the precondition for any desired claim. A claim represents the linguistic description of product-specific properties, which extend beyond the properties of a comparable foodstuff. This claim serves as the basis for defining the type and extent of the necessary studies.

For the scientific proof of any functionality it is necessary to carry out prospective studies in humans after assurance of the safety to health. Evidence of the claimed effect should be produced for the product under examination. Preliminary pilot studies are frequently useful for deciding about the final study design and the targeted parameters. In this connection the type and extent of the necessary studies in humans are to be determined depending on the actual health/functional food, its functional principle, and the intended claim. A minimum of two independent studies is desirable, of which at least one human study is essential, preferably following the design of a controlled, randomized double-blind study against a non-functional comparable product. The choice of the study population depends on the intended target population group. Apart from this, the study has to be based on normal amounts consumed and conditions have to be chosen which represent a characteristic nutritional habit for the selected target population group. The study plan must be designed in the way that the study goal can be reached with an adequate precision. Generally such studies will have parallels to studies required for the registration of medical preparations.

The studies should be so designed that they also record undesirable effects. Important quality criteria for human studies to demonstrate the functional effect of a food are listed as key phrases:

- Procedure to follow a hypothesis
- Prospective character
- Test parameters for the effect to be fixed in advance of study
- Control groups
- Study plan
- Biometry
- Adequate power of the study
- Informed consent of participants, agreement of ethics commission
- Randomization
- Double-blind study
- Stratification according to factors influencing the functional effect
- Criteria for discontinuing the study
- Compliance
- Adequate biometric evaluation
- Monitoring to confirm the quality of the diet
- Accounting for adverse reactions
- Report of results to follow recognized criteria