[Workshop] [10/11/2003(Sat) 13:00-14:00/ Grand Ballroom 101]

The Introduction of Proposed Law about Functional Health Food

Dai Byung Kim

Division of Functional Health Food Evaluation, KFDA

People usually try to take in nutrition component which is necessary for physical growth, developing and maintaining the health through usually balanced dietary life. However in looking over the results of recent national nutrition survey, even if the nation's average taking in nutrition condition is fairly good, considering the individual cases there has happened a problem about the balance of taking in nutrition due to the wrong dietary life.

On the other hand, it turned out much greater problems that the decreasing population mainly due to the declining of birth rate, increasing higher ages and emerging of old aged society, increasing of chronic disease such as obesity and diabetes and increasing of relevant medical expenses and decreasing of medical expense bearer due to the being higher age of population structure.

As a result, the interests for national health becomes gradually higher and the function demanding from the food is getting complicated and diversified. Each corporate enterprise also has developed various kinds of food by using new scientific techniques which is suitable for those customers' demand.

Therefore recently there has happened the cases more than frequent then ever that even the discrimination between medicine and food turned out very ambiguous due to the new component which is beneficial to health following by the development of technique other than the useful component among food.

In fact, even the functional food is widely prevailed, it is actual situation that even the definition in other countries is not clear other than Korea. In general, there is a definition that it is a general food with lots of containing functional component and the term of "nutraceutical" is mostly used and this is the combined term between nutrient and pharmaceutical. That is to say the although it has a shape of medicine but it is not medicine

and it is made as a shape(tablet, capsule) of medicine of the functional components.

Besides several kinds of term is used such as pharmafood, vitafood, foodaceutical, designer food however the legitimate authorized term is dietary supplement in US and food with health claims in Japan. In Canada, there used to be a separation of the concept between functional food and nutraceutical

In case of Korea, at present, the supplementary health food which can be described the utility, nutrition supplementary food, Jinsaeong products belong to the category of functional food.

Those functional food has been accompanied with the history of the food, however in recent times, the interests reached the high point and in each countries, there has been actively progressing about the discussion and opinion of the regulations.

Last year, it has been established that the law of health functional food at legislation of national assembly. The main part is to bring the manufacturing and processing the functional food which has been manufactured with functional components such as vitamins, minerals, and new resources and herbs etc into publicly open and specify the description of functionality.

Health functional food is not regarded as conventional food however in that way, it is hard to regard it as medicine so it is in the intermediate category between food and medicines therefore it is very important to prove the functionality by the scientific assessment and stability.

Based upon current practicing Food Sanitary Law, it is impossible to use and describe the warning notice to the material which may cause side effects so it is very hard to authorize the functional material as raw material of food based on food Sanitary Law.

Unlikely to the conventional food, there should be written description of warning for attention and side effect for health functional food even there happens a side effect in some degree, then the use of new resources would be available.

However on the contrary, the raw material from new resources which has a possibility of side

effect should be completely restricted so that it can not be used in conventional food.

If the material of health functional food can be freely used in all of conventional food, there happens to cause lots of problems such as to have difficulties to restrict the subject persons to take in and dosage of usage therefore the Food Sanitary Law and the Law of Health Functional food should be clearly discriminated in this aspect.

Besides in the aspect of quality management, the matter should be classified with conventional food is that the health functional food should have clear quality control in its dosage because the health functional food is used by the material of functionality.

In case of final product which has been manufactured with various kinds of resources by those natural raw material as major materials, in reality, it is very hard to have quality control by analyzing the final products because the matrix is very complicated and would be very different per each manufacturers. Therefore in case of health functional food with that functionality as main taking purpose, it would be quite essential to introduce GMP which is managing the manufacturing procedure including the managing material production process or quality of material.

As a result, It is actual situation that the health oriented food is taken in expecting the special efficacy and effect despite that it is not medical product and in those products, by and large, the dosage of the specific component which might cause the potential risk for long term taking in that product has been strictly restricted and also it has the various and wide level of consumer groups and in case of risk occurred, it would be expected widely ranged damage than that of medical product therefore it is quite necessary to have various and systematic management such as the scientific proof and inspection, providing the precise and exact information and customer orientation for the right choice and selection.