

## China's Food Safety Law Released for Public Comment

*Below are the two important articles that pertain to the adjustment to China's dietary supplement regulations. Dietary supplements are referred to as health food products (保健食品) in China. The association is currently reviewing the entirety of the regulations and will submit appropriate comments to China's National People's Congress.*

July 3, 2014

### Article 65

The State executes strict regulation over health food. Health food shall not cause acute, sub-acute, or chronic hazard to human body. The label and instructions' content must be true, indicate clearly the suitable and unsuitable groups, functional ingredients or significant ingredients and their content, and state clearly that "this product does not have the functions of disease prevention and treatment". Product functions and ingredients shall be consistent with that indicated in the label and instructions. For health food imported to China for the first time, these products should be approved by the administrative sections in the exported country (or region).

The raw materials used in health food products should be no harm to the human body. Health food claims should be based on scientific study. The list of materials that can be used in health food products but forbidden in food products, as well as the health claims list made by the Food and Drug Administrative Department of the State Council, Health administrative departments of the State Council and the State Pharmaceutical Management Department, will be adjusted and released to the public

### Article 66

For health food using new raw materials and health food imported for the first time, registration management applies; for health food imported for the first time and its raw material, if the safety and health function can be assessed by current national standards and regulations, recording management applies. Specific list will be made, adjusted and released by the state Food and Drug Administration; for other food with claims of special health functions, recording management applies.

For the registration of health food products, the applicant should submit the R&D report, formulations, production process, safety report, health function assessment, labeling information, instruction, samples, as well as relevant certificates and approvals to CFDA for

technical assessment. For those products that meet the requirement of safety standard and health claims, registration will be approved. Those products that failed the registration will be rejected with written statement from CFDA. For health products using new raw materials and being successfully registered, this new raw material should be listed in the health food raw material catalogue.

For recording of the health food, applicant should submit the formula, production process, labeling, instruction, safety report and health function report to the municipal or local FDA. Health food applicants are responsible for the credibility of these materials. The registration or record list of health food will be released and updated regularly to the public.



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