

### ○ "Food for Specified Health Uses" containing soy isoflavone

In January and May 2004, MHLW issued a request for the assessment of three "Foods for Specified Health Uses (FSHUs)" which had soy isoflavone as their ingredient exhibiting health functions (the component that affects the physiological function of the body).

After two years of prudent discussion, taking into account the amount of isoflavone from foods derived from soy beans that is taken by Japanese in their regular diet, in May 2006, notification based on the results of the assessment of the three FSHUs was issued to the MHLW: "The safe limit of daily supplementary intake<sup>4</sup> of soy isoflavone (as aglycone<sup>5</sup>) via the FSHUs is 30mg per adult person", and "Pregnant women, fetuses, infants and young children are not recommended to ingest supplementary soy isoflavone over regular diet, because of the lack of scientific data for the risk assessment of those subjects". Along with the notification, the Commission emphasized the soy itself is a nutritious food rich in protein and calcium of plant origin, and that, compared to the Western diet pattern rich in animal protein and dairy products, the traditional Japanese diet pattern rich in soy protein is relatively low in fat and calories, and hence considered healthy in some aspects.

In response to the notification, MHLW has prepared guidelines and has been providing guidance to health food businesses on the management of the soy isoflavone FSHUs.

<sup>4</sup> Daily supplementary intake: This is the amount of soy isoflavone aglycone consumed via "Food for Specified Health Uses" in addition to that consumed as part of a regular diet.

<sup>5</sup> Soy isoflavone aglycone: Normally, in food, the soy isoflavone molecule is bound to a sugar molecule (glycosylated form). In the body, the sugar is removed from the soy isoflavone (aglycone form) mainly by the enzyme activities of bacteria in the intestine, and the aglycone is absorbed from the intestinal tract into the blood stream.

### ○ Coenzyme Q10

In August 2005, MHLW requested the assessment of the "so-called functional food"<sup>6</sup> Coenzyme Q10.

As a result of the discussion at FSC, since there was insufficient information on tests relating to the long-term intake and on the effects on the endogenous metabolic systems, it was concluded that it would be difficult to establish the safe upper intake level of Coenzyme Q10 based on the information submitted. Notification was issued to MHLW in August 2006. FSC also indicated to the Ministry that "it should provide thorough guidance to business operators so that they should: take responsibility for confirming the safety of the long-term intake on the basis of dosage; provide information on ingestion precautions; and collect case examples of health hazards".

In response to these assessment results, MHLW broadly publicized the assessment results of FSC to local governments and relevant organizations, and provided its own guidance to business operators.

<sup>6</sup> So-called functional foods: Of foods sold and used as that contributing to the maintenance and promotion of health, this refers to foods other than "foods with health claims" (being foods that contribute to the replenishment of nutrients or to specific applications, and which are divided into "foods with nutrient function claims" and "foods for specified health uses"), which is regulated by the government.