

Non-GMO, Gluten Free 등과 관련한 FDA 라벨링(Labeling) 규정

□ 유전자 조작 농산물 및 식품{Genetically engineered plant(GE plant) and Food derived from genetically engineered plant(GE food)}의 규제

○ 안전성 요건(Safety Requirements) :

미국 식품 의약청 (FDA)은 Plant biotechnology consultation program의 자문절차에(Consultation process) 따라, 유전자조작 농산물 및 식품 (Genetically engineered or Bio-engineered Plants and Food)의 개발자가 평가한 안정성 자료를 제출 받아 재평가하여 안전성 여부를 확인한다. 유전자조작 농산물 및 식품은 유전자 재조합기술(Biotechnology or Recombinant DNA Technique)을 이용하여 어떤 생물체의 유용한 유전자를 다른 생물체의 유전자와 결합시켜 특정한 목적에 맞도록 유전자 일부를 변형시켜 만든 생물체를 의미하며, 지금까지 개발된 것은 대부분 식물이기 때문에 통상 유전자 재조합 농산물 및 식품을 가리킨다.

○ 라벨링 요건 : 미국 식품 의약청 (FDA)은 유전자 조작 농산물 및 식품(Genetically engineered or Bioengineered Plants and Food)의 라벨을 자발적으로 표시하도록 권장한다.

- 유전자 조작 농산물로 만든 식품의 라벨(Statements about foods that are derived from genetically engineered plants) 표시의 예는 다음과 같다.

“Genetically engineered”, or “This product contains cornmeal from corn that was produced using modern biotechnology.”, or “Some of our growers plant soybean seeds that were developed through modern biotechnology to be drought tolerant”

- 유전자 조작 농산물이 포함되지 않은 식품의 라벨(Statements about foods that are not derived from genetically engineered plants) 표시의 예는 다음과 같다.

“Not Bioengineered.”, or

“Not genetically engineered.”, or

“Not genetically modified through the use of modern biotechnology.”, or

“We do not use ingredients that were produced using modern biotechnology.”, or

“This oil is made from soybeans that were not genetically engineered.”, or

“Our corn growers do not plant bioengineered seeds.”

- 허위 부정확하게 표시한 유전자 조작식품(Misbranded GE Food)의 규제 유전자조작 농산물로 만든 식품이라고 라벨표시하거나, 혹은 유전자조작 농산물을 포함하고 있지 않은 식품이라고 표시한 라벨이 구체적인 입증자료에 근거하지 않은 허위 사실인 경우는 부정확하게 표시한 식품(Misbranded Food)으로 간주되어 수입이 거부 될 수 있다.

□ Gluten-Free Labeling

- 규정 : On August 2, 2013, FDA issued a final rule defining “gluten-free” for food labeling, which will help consumers, especially those living with celiac disease, be confident that items labeled “gluten-free” meet a defined standard for gluten content.
- 배경 : An estimated 3 million people in the United States have celiac disease. In people with celiac disease, foods that contain gluten trigger production of antibodies that attack and damage the lining of the small intestine. Such damage limits the ability of celiac disease patients to absorb nutrients and puts them at risk of other very serious health problems, including nutritional deficiencies, osteoporosis,

growth retardation, infertility, miscarriages, short stature, and intestinal cancers.

○ 내용 : The final rule provides a uniform standard definition to help consumers with celiac disease manage a gluten-free diet. Gluten-free foods must contain less than 20 parts per million (ppm) gluten. Foods may be labeled “gluten-free” if they are inherently gluten free; or do not contain an ingredient that is:

1) a gluten-containing grain (e.g., spelt wheat); 2) derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour); or 3) derived from a gluten-containing grain that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 ppm or more gluten in the food.

* Gluten-Free Labeling은 중증 만성소화 장애증(Celiac Disease) 환자를 위한 제도로 식품에 함유된 글루텐의 함량이 20PPM 이하인 경우에는 Gluten-free 라벨을 붙일 수 있다.