Many food products on the Chinese market contain ingredients derived from genetically-modified organisms (GMO) directly or indirectly. For instance, genetically-modified microorganisms and certain GMO-derived enzymes are already indispensable for industrial food processing. The application of GMO in the food industry has recently become a heated topic thanks to the public listing of Beyond Meat, and quite a number of these new “artificial meat” products are derived from GMOs.

Although consumers rarely question the legal status of GM foods, if one takes a closer look into the current regulatory process to clear a new food ingredient derived from genetically-modified organisms (“GMO food ingredients” hereafter), as a practical matter, such a simple question may call for a bit complicated answers.

There are two major regulatory frameworks concerning the clearance of GMO food ingredients in China—the Agricultural GMO Regulation and the New Food Ingredient Regulation.

**Agricultural GMO Regulation**

The State Council announced the Regulation on Safety Administration of Agricultural Genetically-modified Organisms (“Ag GMO Regulation”) in 2001, which becomes the umbrella regulation regarding agricultural GMOs.

Article 3 of the Ag GMO Regulation defines “agricultural genetically-modified organisms” (Ag GMOs”) as follows:

“Agricultural genetically modified organisms, as referred to in this Regulation, mean animals, plants, microorganisms and their products whose genomic structures have been modified by genetic engineering technologies for use in agricultural production or processing, which mainly include:

1. Genetically modified animals, plants (including plant seeds, breeding livestock and poultry, aquatic fry and seeds) and microorganisms;
2. Products of genetically modified animals, plants and microorganisms;
3. Products directly processed from genetically modified agricultural products;
4. Seeds, breeding livestock and poultry, aquatic fry and seeds, pesticides, veterinary drugs, fertilizers, additives and other products containing ingredients of genetically modified animals, plants and microorganisms or their products."

As one can see, the scope of this Regulation is rather broad to cover not only those agricultural genetically-modified organisms, but also their “products” (or “derivatives” in nature), including food ingredients and food additives derived from GMOs.

Under the authorization of the Ag GMO Regulation, the Ministry of Agriculture (MOA) followed up by promulgating three ministerial level implementing regulations to specify the detailed requirements for biosafety evaluation, import
process and product labelling in 2002. Till then, a pre-market clearance system has been established for new agricultural GMOs and their derivatives, which is still in effect today.

The industry then worked closely with the regulators in developing protocols and guidelines for field testing. As a member of this joint task force myself, I have specialized in GMO laws and regulations since then and I have assisted a number of companies in bringing their GMO related products into China by clarifying and shaping the regulatory process with the relevant authorities.

Regulations on food ingredients

China has a relatively clear pre-market clearance system for new food ingredients and food additives. Article 37 of the Food Safety law provides that “Those who use new food raw materials to produce foods or produce new varieties of food additives or food-related products shall submit safety assessment information of relevant products to the health administrative department under State Council.” Therefore, it is reasonable to assume that a pre-market approval for new GMO food ingredients is required by the Food Safety Law, in addition to the clearance by the Ag GMO Regulation.

Historically, there was once an attempt by the health authorities to combine the review and clearance of food ingredients and food additives derived from GMO under the general term “GMO foods”. The then Ministry of Health (MOH) announced a regulation titled “Measures on Hygiene Administration of Genetically-Modified Food” in 2002. However, this regulation was repealed in 2007 when MOH amended its Regulation on Novel Foods in 2007, Article 28 of which states that “administration of GM foods and food additives should follow the relevant laws and regulations by the State”.

Over the last decade, GMO has become a subject of hot debate, in terms of its safety to human being and to the natural environment. Perhaps reflecting such controversy, in 2014, MOA decided not to accept applications for biosafety clearance for GMO products if they are not related to “agriculture”.

Specifically, the Chinese Confederation of Food Additives and Ingredients (CFAA)\(^1\) filed an inquiry with MOA and received a response letter from MOA dated September 4, 2014, stating that “GMOs for food uses are not within the scope of Ag GMO Regulation, and the Ministry would no longer accept such applications”.

Despite the follow-up inter-agency coordination effort that has been made by CFAA and others, as of today, there is still no clearly resolved procedure for obtaining regulatory approval for GMO food ingredients and food additives.

Does this mean a dead end for the industry to clear any food ingredients derived from GMO? To answer this question would first need some thorough regulatory and scientific analysis. Based on the nature of any given product and its intended use, there might still be ways to bypass the current regulatory ambiguity or to at least mitigate the issue. The details of the product and its manufacturing process need to be taken into account for an overall analysis in order to come up with a viable and effective strategy for regulatory clearance.

\(^1\) China Food Additives & Ingredients Association

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