

Irene Djalim IP Consultant irene.d@tilleke.com

Amendment to Regulation on Food Registration in Indonesia

¶ ood regulations issued by the Indonesia National Agency of Drug and Food Control (NADFC) are known to be dynamic and prone to change, and the regulations concerning food registration were amended again in late 2017 through the issuance of the Head of NADFC Regulation No. 27 of 2017, which came into force on January 8, 2018.

Clarification and Codification of Current Practice

The amended regulation generally clarifies and codifies current food registration procedures and practice, by including provisions and requirements for food registration that are already required in practice but were not included in its predecessor, Head of NADFC Regulation No. 12 of 2016.

As an example, the amended regulation now states that, in addition to contaminant parameters, namely microbiology and heavy metals, the safety criteria for food registration also include compliance with food additive and processing aid requirements. In practice, however, it has been a requirement for at least the last two years for companies to provide laboratory test results on certain carry-over food additives contained in food ingredients, as declared in the ingredient specifications. Another example is the requirement for a photo of the product for imported food products—this was not listed as one of the technical requirements in the former regulation, but is now listed in the amended regulation. In practice, however, product photos were already required for registration of imported

Other key changes brought about by the amendment are detailed below.

- **Letter of Appointment.** The old regulation required an exclusivity clause to be included in the Letter of Appointment, indicating whether the applicant company has issued the Letter of Appointment on an exclusive or non-exclusive basis. The amended regulation expands upon this to state that the food registration process may be placed on hold if there is a dispute over a non-exclusive Letter of Appointment and will resume after the dispute has been settled between the parties involved.
- Change of importer's or distributor's address. The old regulation considered a change of importer's or distributor's address to be a minor data change with no restrictions. The amended regulation restricts this status, requiring the new address to be in the same province as the old address to be considered a minor data change.
- Inclusion of logos other than Halal and Indonesian National Standard (SNI). The old regulation stated that the inclusion of Halal and SNI logos are considered minor data changes. The amended regulation expands this to include other logos, not related to claims, in the

definition of minor data changes.

Despite the changes in the amended regulation that are intended to clarify and codify the current practice of food registration, the amended regulation does not provide enough guidance for a registrant to fully understand all the requirements for registering a food product. There are many regulations relating to food registration in addition to the regulation on food registration procedure. In order to fully guide a potential registrant, the amended regulation would need to point out, at the very least, the other regulations that stipulate the basic requirements for food registration. Examples of these regulations are provided below, but they should not be considered an exhaustive list:

- Head of NADFC Regulation No. 23 of 2017 which establishes the maximum limit of heavy metal contaminants
- Head of NADFC Regulation No. 16 of 2016 which establishes the maximum limit of microbial contaminants in
- Head of NADFC Regulation No. 10 of 2016 which provides a positive list of enzymes
- Head of NADFC Regulation No. 33 of 2012 which provides a positive list of food additives and establishes the maximum limit for each type of food additive
- Head of NADFC Regulation No. 9 of 2016 which provides the Recommended Dietary Allowance values
- Head of NADFC Regulation No. 13 of 2016 which provides a list of claims allowed in food labels and advertisements
- Head of NADFC Regulation No. HK.00.06.51.0475 (and its subsequent amendments) which provide guidance on formatting a nutrition table

Priority Service

Another key change in the amended regulation is the provision of "priority service" in the process of obtaining food registration, which allows an application for registration to be approved within 10 working days. However, a registrant must meet certain criteria in order to qualify for the priority service, the most notably challenging of which is that the registrant must not have received a request for additional information or documents during the registration process for their last five applications.

This requirement will be challenging for new registrants and companies that have only recently been established in Indonesia. Companies registering imported food products under the name of new Indonesian entities—even food products that have been previously registered through a local distributor and have been distributed in the market for many years—are more likely to receive various requests for additional information or documents from the food evaluators during the registration process. The priority service may provide a solution to expedite the lengthy registration process, but the NADFC is also expected to remain focused on the safety and quality of the food product.

Conclusion

The provisions in the amendment are definitely a step in the right direction for clarifying the Indonesian food regulatory regime, but there is still a way to go before complete clarity is achieved. While the new priority service will benefit experienced long-term applicants, new registrants are likely to be ineligible. As such, the system is certainly on the way to becoming clearer, but for new market entrants the process can still be lengthy and arcane. 🐔