Insects and the new Novel Foods Regulation

On 25 November 2015, the EU legislators adopted Regulation (EU) 2015/2283. This regulation replaces Regulation (EC) 258/97 and stipulates the procedure which can authorise "Novel Foods" for commercialisation on the EU market. The new Regulation will apply from 1 January 2018, but foods currently 'lawfully placed on the market' are granted an additional two year transition period.
In this document, IPIFF – the International Platform of Insects for Food and Feed – outlines the regulatory changes, their impact on the insect sector and the position of IPIFF on each of these.

1. General Remarks

Whilst the status of whole insects as Novel Food (NF) was unclear under Regulation 258/97, the new Regulation explicitly covers "whole insects and their parts" (recital 8). This means that, unless evidence can be provided of consumption before 15 May 1997, all insect products will be subject to a pre-market authorisation procedure including a safety assessment. For this purpose, applicants need to submit a dossier containing scientific evidence demonstrating safety.

Mainly composed of start-ups and SMEs, the insect sector is highly impacted by the new Regulation and Novel Food application procedure. As such, IPIFF highlights the importance of:

1. rules which **can be realistically complied with** by food operators and are **harmoniously and efficiently implemented** across the EU;
2. **sufficient guidance** from the European institutions and the European Food Safety Authority (EFSA) to food operators seeking to apply for authorisation;
3. **suitable transitional measures** accompanying the implementation of the new Regulation in order to enable the insect sector to adapt and conform to the new rules.

2. Ensuring implementable, harmonious and efficient new rules

a) Scope of regulation and procedure

Since Regulation (EU) 2015/2283 explicitly includes insects within its scope, all food operators seeking to place insect food-products on the EU market need an authorisation to do so.

The procedure for getting this authorisation has changed significantly. Currently, applications are often assessed by both a Member State (MS) and EFSA. Under Regulation 2015/2283, however, applications are assessed only by EFSA after which MS Experts vote to determine whether a product can be placed on the EU market (see Ch. III).

IPIFF welcomes the simplification of the application procedure and its harmonisation across MSs. With EFSA charging no application fee, costs will be reduced and by centralising the assessment of dossiers, the duration of the procedure is expected to shorten from 36 to 18-24 months.

IPIFF is closely following the Implementing Acts foreseen under article 13 of the new Regulation to ensure that the administrative and scientific requirements are not unnecessarily burdensome.

b) Generic authorisations and joined applications

While under Regulation 258/97 authorisations are only granted to the food operator who submitted a dossier, Regulation 2015/2283 awards 'generic' authorisations to all those producing the NF product in question. This should facilitate applications by groups of producers covering a single product or a variety of related products.

The International Platform of Insects for Food and Feed (IPIFF) is the non-profit organization representing the interests of the insect sector at the EU level. IPIFF aims to make the insect industry prosper by promoting insects as a top-tier source of animal proteins for both human consumption & animal feed.

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IPIFF greatly appreciates the move towards 'generic authorisations' and the encouragement to create joined dossiers, which, we hope, will benefit SMEs & start ups in the insect sector.

IPIFF continues to closely monitor the Regulation's implementation in order to ensure that the aims of the legislators are fulfilled. IPIFF also underlines the importance of clear guidance on the different types of NF products that can be put together in one dossier.

c) Data protection and confidentiality

Unlike Regulation 283/97, Regulation 2015/2283 distinguishes between protected (ch. V) and confidential (art. 23) data. Newly developed scientific evidence can be 'protected'. In this case, an authorisation will, for a 5 year period, be granted to the owner of this data only. Data may be kept 'confidential' when their disclosure would harm a company's competitive position. If confidentiality is granted, a generic authorisation will still be issued.

In the fast-developing insect-sector, scientific data and intellectual property are highly valued. The possibility to allow for data protection and confidentiality is thus of the utmost importance.

IPIFF seeks to ensure, however, that restrictions on these provisions when applying as part of a joined application do not hamper operators' incentives to apply as a group.

3. Providing sufficient guidance to food operators

In order to provide guidance to food operators seeking to submit a novel food application, the EC has asked EFSA to outline the scientific requirements of applications in a guidance document. This document specifies the scientific requirements of Novel Food applications and will form the standard according to which EFSA will form its opinion on application dossiers.

IPIFF highly values the efforts made by EFSA to guide operators in submitting a dossier. Also the consultation round by EFSA on the draft version of this document was highly valuable.

IPIFF does seek to ensure however, that some additional aspects of the Regulation will be clarified in due course. Additional guidance could be given regarding data protection, the submitting of joined dossiers and the possible scope of individual NF dossiers. IPIFF would gladly contribute and cooperate in this process.

4. Ensuring suitable and harmonious transitional measures

As outlined in Art. 35 of the new Regulation, products 'lawfully placed on the market' can continue to be sold for at least two years following its entry into application (i.e. until 2 January 2020). If a novel food application has been filed before this date, the product may continue to be placed on the market until a final decision has been taken on the dossier. Whether a product is 'lawfully placed on the market' is to be defined by each MS individually.

For IPIFF the transitional measure as outlined above is highly valuable and ensures that insect producers will not be forced to discontinue their production process whilst preparing a Novel Food application dossier.

IPIFF fears, however, that MSs have diverging interpretations as to what constitutes 'lawfully placed on the market'. It is important to have clarity on MS implementation on this provision.

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