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# DEVELOPMENT AND MARKETING OF NEW PROTEINS; TOOLS FOR TAKING LEGISLATIVE HURDLES

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## Background

The introduction of new proteins, like proteins derived from insects, on the EU food market is experienced as complex, time consuming and rather expensive. The most important hurdles which companies perceive in the development and marketing of new proteins are (Van Wagenberg et al., 2012):

- the complex and opaque procedures and requirements of the EU Regulation (EC) No 258/97 on novel foods and novel food ingredients (NFR);
- insufficient acceptance from consumers and producers.

## Introduction

To overcome the complex procedures and requirements of the Novel Food Regulation, tools have been developed in a research project for the Dutch Ministry of Economic Affairs and a public private partnership (PPP) project. Developed are:

- a decision tree;
- a guideline.

In the PPP project producers of new proteins derived from insects, algae, sugar beet leaves and duck weed worked together with researchers to understand the complex procedures and requirements of the NFR in order to fill their application dossiers in an efficient way.

## Decision tree

The Decision Tree Novel Food can be used by companies to determine whether a new product is a Novel Food, and whether an authorisation or notification is needed. When it is decided that a product is a Novel Food, an application dossier should be compiled.


**Figure 1.**
Novel protein source: insects.

## Guideline

A guideline was established to support companies in composing their application dossiers (Van Wagenberg et al., 2014). It is essential that companies tell a convincing story in this dossier, substantiated with sufficient data that the new protein is safe for human consumption. A dossier should contain all information which is necessary to prove this.

The guideline:

- describes in detail the items to be addressed in an application dossier
- gives references to guidance documents of competent authorities (CAs)
- provides examples of earlier assessments and dossiers
- gives recommendations on the information for each item that might be considered to be sufficient by CAs

For many items there are no clear-cut criteria, however. It should be stressed that each application dossier for a novel protein will have a different content due to specific product related characteristics. The opinion from member states' CAs and the European Food Safety Authority (EFSA) cannot be predicted in advance.

## User experiences

Producers of new proteins experienced the compilation of their dossiers as complex, time consuming and expensive. Though the guideline is a very helpful tool, compiling a dossier still will take at least 1-2 years. Moreover, for small producers of new proteins who have no or hardly any experience in compiling a dossier, it is difficult to fulfil the scientific requirements in describing data gathered to prove a product is safe.


**Figure 2.** Development and marketing of new proteins;
Experienced impediments and solutions

## References


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