

EFFA Position Paper

Pesticide Residues in Processed Products and the Application of Processing Factors

1. Background Regulation

Regulation (EC) No 396/2005 on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin ('The Regulation') sets down the provisions relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin.

The Regulation applies to products of plant and animal origin or parts thereof covered by Annex I.

2. Processing Factors

Article 20 of the Regulation sets down provisions concerning processed products and establishes the principle that certain methods of processing may impact the residue levels found in processed products.¹ In such cases the MRLs for processed products shall be those for the raw agricultural product taking into account the changes in the levels of pesticide residues caused by processing i.e. concentration or dilution, both in cases where specific MRLs are established and where the default MRL of 0.01mg/kg applies.

The ratio of residue in the processed product to that in the corresponding unprocessed product is known as the 'processing factor'.

Both the German Federal Institute for Risk Assessment (BfR)² and the European Food Safety Authority³ have created databases of processing factors to support risk assessors and to assist food monitoring authorities in assessing whether processed foods were manufactured using raw materials that complied with relevant MRLs. The published processing factors are not legally binding and are not suitable as the sole basis on which to determine the marketability of a processed product, a decision is required on a case-by-case basis.

In cases where residue levels found in processed products differ from the MRL set for the raw commodity itself, the manufacturer is requested to make sure it can provide sufficient data related to its products e.g.

1. Data demonstrating that the raw commodity used to manufacture the processed product complied with the applicable MRL (e.g. review of supplier residue data for the agricultural commodity and/or increasing the frequency of monitoring to establish risks)
2. Method of determining the processing factor for manufacturer specific process
3. Data and relevant documentation to substantiate the processing/concentration factor applied

¹ Limitations apply, however, for Infant Food. While Infant Food is clearly considered "processed food", the concept of "Processing Factors" to evaluate the legal possible level of Agricultural Residues is heavily restricted. Directive 2006/141/EC sets specific rules on the presence of pesticides residues in infant and follow-on formulae. It requires that infant formula and follow-on formula contain no detectable levels of pesticide residues, meaning not more than 0.01 milligrams of pesticide residues per kilogram.

² BfR PF Database <https://www.bfr.bund.de/cm/349/bfr-compilation-of-processing-factors.xlsx>

³ EFSA PF Database <https://zenodo.org/record/1488653>