Nederlandse Voedsel- en Warenautoriteit
Ministerie van Economische Zaken

MVO notifying requirements on Pesticides

Guidelines of MVO regarding notifying exceedances of maximum residue levels of pesticides in vegetable oils for food or feed application to the competent authorities. This document has been developed in cooperation with the Netherlands Food and Product Consumer Safety Authority (NVWA).

Obligation to notify

According to Article 14 and 15 of the General Food Law (Regulation (EC) No 178/2002), food or feed shall not be placed on the market if it is unsafe. Food shall be deemed to be unsafe if it is considered to be injurious to health or unfit for human consumption. Feed shall be deemed to be unsafe for its intended use if it is considered to have an adverse effect on human or animal health or to make the food derived from food-producing animals unsafe for human consumption. According to Article 19 and 20 of the General Food Law (Regulation (EC) No 178/2002), food and feed business operators should inform the competent authorities in case they have placed a food or feed on the market that is unsafe.

A business operator must notify the NVWA in case a product intended for human or animal consumption that does not meet the legal limits, has been put on the market. In addition, for products intended for the feed chain, the NVWA must also be notified even if the product has not been put on the market (according to the Dutch Animal Act (Wet Dieren)).

Maximum residue limits of pesticides in oils and fats

With regards to the exceedances of maximum residue levels of pesticides in vegetable oils for food or feed application, two factors are of importance: 1. the transfer factor of pesticides in processed products and 2. the measurement uncertainty.

Ad 1. Transfer factor

Regulation (EC) No 396/2005 sets maximum residue limits for primary products, like oilseeds. MRLs for pesticides in processed products, like crude oils (and refined oils), are not specifically set in EU legislation. According to Article 20 of Regulation No. 396/2005, MRLs for pesticides in processed products have to be derived from the MRLs for raw agricultural products, taking into account the concentration caused by the drying process as well as the concentration caused by processing (transfer factor).

For oils and fats, the transfer factor depends on the type of processing and the extent to which the pesticide is transferred to the meal and crude oil during the crushing process. This can be

determined experimentally or can be established by taking into account the fat solubility of a certain pesticide and the oil/fat content of the specific crop. In general it can be stated that the transfer factor is inversely proportional to the oil/fat content. FEDIOL has issued a paper on this subject, in which some transfer factors are laid down.

The pesticide database of the EC indicates which pesticides are fat soluble (by putting (F) behind the particular pesticide). It should be noted that this information only provides general guidance which cannot be regarded as conclusive for some particular pesticides, *i.e.* some pesticides that are not identified as fat soluble do behave as such.

One of the criteria that can be used to predict the behaviour of a certain pesticide during oil/fat extraction, is its polarity. The octanol-water partition coefficient (log Pow) of a pesticide indicates to what extent a pesticide is water or fat soluble. When a log Pow of a pesticide exceeds 3, the pesticide is considered fat soluble. For consultation of the log Pow for a certain pesticide, the following website can be used: http://sitem.herts.ac.uk/aeru/ppdb/en/index.htm

Another factor to be taken into account is the affinity of the substance for the extraction solvent. In fact, some pesticides with a log Pow below 3, which are not expected to concentrate in the oil/fat, can show the tendency to concentrate in the oil/fat due to their solubility in solvents like *e.g.* hexane. Pesticides with a significant solubility in organic solvents as compared to water, will follow the oil/fat phase. The behaviour of pesticides with a solubility in the oil phase close to the solubility in water, will have to be analysed on a case-by-case basis. This is the responsibility of the food or feed business operator. Proof has to be provided by the food or feed business operator to the NVWA on request.

Appendix 1 gives some examples for applying transfer factors in industrial practice.

Please note that Directive 2002/32/EC on undesirable substances in animal feed sets limits for some specific organochlorine pesticides in processed products (section IV of Annex I). For these cases the transfer factors are not applicable.

Ad 2. Measurement uncertainty

All cases where exceedance of legal limits have been established, have to be reported to the NVWA, irrespective of the measurement uncertainty. Since the food or feed business operator is responsible for putting safe food and/or feed products on the market, the obligation to notify is also valid in case the analytical result exceeds the maximum level by less than the measurement uncertainty. Apart from notifying the NVWA about the exceedance of the legal limit, the food or feed business operator also has to inform the NVWA on the destination of the party concerned (if already known).

Relationship between processing and compliance

On the basis of Article 20 of Regulation (EC) No 882/2004 (on official controls for verification of compliance with feed and food law), it is allowed under certain conditions to treat or process non-compliant feed or food to bring it into line with the requirements of Community law. This means that the NVWA allows the removal of pesticides during the normal operation conditions of the refining processes (physical or chemical refining), or in a specific plant specialized in removing pesticides or contaminants.

Physical refining: during physical refining the free fatty acids (FFA) are removed by distillation. This type of refining is generally applied by stand-alone refineries that source crude oils (and hence do not crush oilseeds) and therefore often applied to tropical oils such as palm oil, palm

kernel oil and coconut oil. Integrated crushing and refining plants may however also apply physical refining to seeds oils. During physical refining, fatty acid distillates are formed, which can be supplied to the feed industry in case the MRL (taking into account the transfer factor) is not exceeded (see example 3).

Chemical refining: in addition to physical refining**,** chemical refining includes a neutralization step in which FFA are removed and soap stocks are formed. In chemical refining, volatile compounds such as pesticides and light polycyclic aromatic hydrocarbons strongly concentrate in the deodistillates. For this reason, deodestillates are not allowed in feed applications (without further processing).

NOTE: for more information on oilseed crushing and refining and information on the products formed during these processes (including the Feed Catalogue numbers) please consult the Process description and flow diagrams of the EFISC sector document for the vegetable oil and protein meal industry.

Dilution of products exceeding the limits

Dilution of products in order to redeem compliance with legal limits for pesticides (or contaminants) is NOT allowed. The NVWA tolerates a certain dilution that takes place under normal operation conditions of a continuous process as this is part of the normal operation conditions and not carried out with the intention to dilute a consignment exceeding the MRL. The NVWA shall, for example, accept mixing of small barges (*e.g.* 500 metric tons) into a big tank (*e.g*. 2500 metric ton) before the analytical results of the individual small barges are available. If it subsequently turns out that some of the individual barges contained pesticide(s) above the MRL (taking into account the transfer factor), and the value for this particular substance in the big tank did not exceed the MRL (taking into account the transfer factor), the substance in the big tank can be placed on the market. However, in this case the food or feed business operator has to notify the competent authorities and is obliged to take corrective actions.

Appendix 1. Examples

1. Deltametrin, a fat soluble pesticide (that is difficult to remove by refining)
An example of a pesticide, which concentrates in the oil phase is deltamethrin. The MRL for deltamethrin in sunflower seed is 0,05 mg/kg. The EU database gives (F), indicating that deltametrin is a fat soluble pesticide, which is confirmed by experimental data. The fat content in sunflower seed is 40-45%. The transfer factor is 2,5, see the table in FEDIOL position paper.

This implicates:
- MRL for sunflower seed is 0,05 mg/kg
- MRL for crude oil (taking into account the transfer factor) is 0,125 mg/kg
- MRL for refined oil, acid oils and soap stocks is also 0,125 mg/kg
- MRL for meal is 0,05 mg/kg.

In case the crude oil exceeds the MRL of 0,125 mg/kg, none of the oil refining oily by-products in which concentration takes place, can be supplied to the feed industry, except if during processing there is proof of reduction/removal of the pesticide by a certain processing step and the final by-product is below the MRL multiplied by the transfer factor.

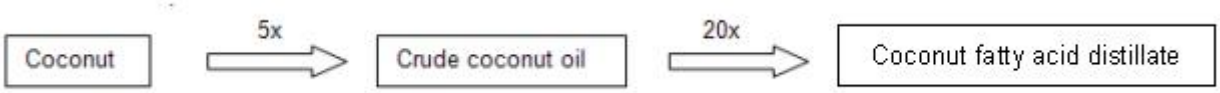
2. Metalaxyl, a non fat soluble pesticide
An example of a pesticide, which is not fat soluble, is metalaxyl. The MRL for metalaxyl in sunflower seed is 0,1 mg/kg. The EU database gives no (F), indicating that metalaxyl is not fat soluble, which is confirmed by experimental data. The log Pow of metalaxyl is 1,7, indicating a high tendency to concentrate in the water phase during oil extraction. After extraction, metalaxyl is found in both crude oil and meal. In this case no transfer factor is applicable.

This implicates:
- MRL for sunflower seed is 0,1 mg/kg
- MRL for crude oil is 0,1 mg/kg
- MRL for refined oil, acid oils and soap stocks is 0,1 mg/kg

MRL for meal can be higher than 0,1 mg/kg due to concentration, provided that it is demonstrated that the original seed is compliant. In case the crude oil exceeds the MRL of 0,1 mg/kg, none of the oil refining oily by-products in which concentration takes place, can be supplied to the feed industry, except if during processing there is proof of reduction/removal of the pesticide by a certain processing step and the final by-product is below the MRL multiplied by the transfer factor.

3. A fat soluble pesticide which concentrates in the oil (that subsequently concentrates in the distillate during physical refining)
An example of a pesticide, which concentrates in the oil phase (and subsequently in the distillate) is pirimiphos-methyl. MRL for pirimiphos-methyl in oilseeds and oilfruits is 0,05 mg/kg. The EU database gives (F), indicating that pirimiphos-methyl is a fat soluble pesticide, which is confirmed by experimental data.

Consider an amount of FFA in the crude oil of 5%*), meaning that, after distillation, a 20-fold concentration of the pesticide into fatty acid distillates. In the case of coconut oil (fat content 20%, implicating a transfer factor of 5):



*) Good Merchantable Quality (GMQ) crude oil contains a FFA content of 5% maximum. Oil for food or feed use with a higher FFA content cannot be placed on the market according to commercial contracts. In case of a lower FFA content, the concentration factor is higher. To be on the safe side a maximum concentration factor of 20 is used in all cases.

This implicates:

- MRL for coconut is 0,05 mg/kg
- MRL for the crude oil is 0,25 mg/kg (taking into account the transfer factor for coconut)
- MRL for the fatty acid distillates is 5 mg/kg
- MRL for the acid oils is 0,25 mg/kg

4. A situation in which two or more products are blended for meeting the appropriate nutritional composition (blending of products is often done for specific feed applications)
An example of a pesticide which concentrates in the oil phase, is pirimiphos-methyl. MRL for pirimiphos-methyl in oilseeds and oilfruits is 0,05 mg/kg. The EU database gives (F), which is confirmed by experimental data.

This implicates:

- MRL for pirimiphos-methyl in rapeseed crude oil is 0,125 mg/kg (oil content 40-45%, implicating a transfer factor of 2,5)
- MRL for pirimiphos-methyl in rapeseed acid oils is 0,125 mg/kg (C1)
- MRL for pirimiphos methyl in crude coconut oil is 0,25 mg/kg (fat content 20%, implicating a transfer factor of 5)
- MRL for pirimiphos-methyl in coconut fatty acid distillate is 5 mg/kg (C2) (see example 3a)

Requirement: before blending the acid oils and fatty acid distillates should meet the applicable regulations for that particular fat.

For the evaluation of the applicable MRL of the blend (when companies are buying a blend) *e.g.* 80% rapeseed acid oils (N1) with 20% coconut fatty acid distillate (N2):

- MRL mixed product: 0,8*0,125 + 0,2*5 mg/kg = 1,1 mg/kg *{MRLx = {(N1C1 + N2C2 + N3C3 + …)}*

NOTE: The examples above apply for either fat soluble (example 1, 3 and 4) or non-fat soluble (example 2) pesticides. However, this is not always pronounced for all pesticides.