19 June 2019

Briefing document issued by the CIPC Task Force after the non-renewal decision for the active substance Chlorpropham (CIPC)

European review of Chlorpropham

Chlorpropham (CIPC) has been undergoing a routine review in Europe since 2015 and it has been discussed at successive SCoPAFF (Standing Committee on Plants, Animals, Food and Feed) meetings and the Appeal Committee, and no opinion was reached. In this event the decision rests with the European Commission and they have concluded on 17 June 2019 that CIPC cannot be renewed.

Consequences of non-renewal of the authorisation for CIPC

The implementing regulation (EU 2019/989 of 17th June) for non-renewal was published in the Official Journal (OJ) and will enter into force 20 days after publication.
The following end-dates for withdrawal of the registrations and disposal, storage, placing on the market and use of existing stocks have been set in the regulation:

- 8 January 2020 for all member states to withdraw authorisations of products containing CIPC
- 8 October 2020 for disposal, storage, placing on the market and use of existing stocks.

Each individual national authority will need to decide on suitable withdrawal periods within the maximal periods set in the non-renewal regulation. The TF companies will enter into discussion with the national authority on the national timelines, which eventually will be published in the withdrawal certificates for each approved product. It will be illegal to use CIPC in any European country beyond these end dates and growers/store managers are advised to check with their supply chain partners/customers prior to treating the crop with CIPC. The maximum residue limit (MRL) for all crops (currently 10ppm for potatoes, various for other crops (herbicide use)) is expected to be in place until the end of the grace period.

Because the active substance is not renewed, the MRL will fall to near zero (limit of quantification- LoQ) after the grace-period and the import or sales of products with residues of CIPC above this level will not be permitted in the EU.

An application for a temporary MRL for potatoes only to cover previous store contamination is being sought by UPL and Certis to prevent the MRL falling to LoQ in the short term. This tMRL would be sufficiently high to take into account residues from storage contamination and sufficiently low to exclude residues from illegal use.

Why has this decision been reached by the European Commission?

Although this decision did not achieve universal acceptance in Europe amongst its Member States, the European Commission decided that, based on the advice of EFSA (European Food Safety Authority), none of the defended uses could be regarded as safe. The main reason for this conclusion was the identified chronic consumer risk driven by the residues in potatoes but calculated on a complete diet. In the absence of data, assumptions have been made on inputs into the consumer risk assessment. The

consumer risk model has inputs for the variability factor (vF) and the processing factor (pF). Europe previously used a reduced vF for the post-harvest application in potatoes. Since the data supporting the previous vF was no longer sufficient according to EFSA and while additional data to support this reduced vF was available since June 2017 but could not be considered as part of the evaluation, EFSA used the higher default vF. Moreover, due to the European consumer-risk model, it has not been possible to take into account the different ways potatoes are consumed and EFSA used a pF of 1 in the risk modelling, effectively assuming that tubers are eaten unwashed and raw. This results in a calculated exceedance of the Acute Reference Dose (ARfD).

Based on newly submitted metabolism data for the herbicidal use, additional metabolites were included into the residue-definition. Since this change happened very late into the renewal-process, there was no opportunity for the applicants to generate and submit new residue data in line with the proposed residue-definition. A comparable conservative approach as used for the potato-application demonstrated no unacceptable consumer-risk. However, lack of the necessary residue-data, it was concluded no acceptable consumer-risk could be demonstrated for the defended herbicidal uses.

Disappointing outcome

It is disappointing that a dossier considered complete at the start of the review was found lacking in the closing stages, without an opportunity to submit further data. Any further consideration of CIPC in Europe would be as a new active substance.

Glossary

The ARfD (Acute Reference Dose) to define (on the basis of all known facts at the time of the evaluation) an estimate of a chemical substance in food (or drinking water), expressed on a bodyweight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer . Acute exposure

- intake over a single meal or day
- takes account of peaks when large consumption of single food
- no averaging

Variability factor vF a factor which takes into account the unit to unit variability of a pesticide residue.

Processing factor pF used to take into account residue decreases or increases on processing steps e.g. washing/peeling/cooking methods.