

## Opinion 09-2022 of the Scientific Committee established at the FASFC on the chronic exposure of the Belgian population to residues of plant protection products through fruit and vegetable consumption (period 2014-2020)

### Background & Terms of reference

Plant protection products are used to protect crops from pests or to control weeds. However, their use may result in the presence of residues in food, which represents a potential risk to public health.

Every year, the Federal Agency for the Safety of the Food Chain (FASFC) verifies the residue levels of some 600 different plant protection product residues in more than 3,000 foodstuffs. Of the approximately 14,500 samples of fruit and vegetables, cereals and other products of plant origin monitored between 2014 and 2020, 97% to 98% complied with the legal limits, and no residue was detected in 31% of the samples. Although these data give some indication, they lack the necessary information to evaluate the risk for consumers. To do this, exposure must be calculated and compared with health-based reference values, such as the 'acute reference dose' (ARfD) and the 'acceptable daily intake' (ADI).

The Scientific Committee already evaluated in previous opinions the risk for the Belgian consumer related to the presence of residues in fruit and vegetables (SciCom opinions 31-2007, 02-2010, 18-2015). These evaluations generally showed that chronic or long-term exposure to residues of plant protection products through consumption of fruit and vegetables on the Belgian market did not pose a risk to the health of the consumer. The Scientific Committee is requested to repeat this evaluation on the basis of FASFC control results for the period 2014-2020.

### Method

For the risk evaluation, 44 residues monitored were selected on the basis of their reporting frequency (i.e. the percentage of samples with a residue concentration above the reporting or limit of determination), their toxicity and their representativeness (i.e. a sufficient number of samples were analysed). In addition, some residues were selected because of past media coverage or because they were considered in the previous exposure study (SciCom opinion 18-2015).

In a first step, the chronic exposure (mg/kg body weight per day) is estimated by means of a deterministic approach. For this purpose, the FASFC control results were linked to the Belgian consumption data of fruit and vegetables obtained from the 2014 food consumption survey and reported in the EFSA 'Comprehensive European Food Consumption Database'. To evaluate the risk, the exposure was compared to the ADI and expressed as a % of the ADI. In case this first evaluation indicated a high exposure or a potential risk, exposure to the relevant residue was further refined in a second step, for instance by applying process factors to account for the possible impact of processing on residue levels. In a final step, it is considered whether the selected residues and/or results are suitable for cumulative exposure estimation.

### Conclusions

Between 2014 and 2020, a decrease in reporting frequency is observed for glyphosate, boscalid, captan, carbendazim, chlorpyrifos, cyprodinil, deltamethrin, dimethoate, omethoate, linuron, imidacloprid, iprodione, penconazole, propamocarb, pyraclostrobin and thiacloprid. This decrease in reporting frequency can partly be explained by the fact that the use of several of these plant protection products was restricted or banned in Europe (e.g. iprodione, linuron). In contrast, an increasing trend in reporting frequency is observed for acetamiprid, fluopyram, mepiquat (until 2019), pyrimethanil, spirotetramat and trifloxystrobin.

Although the estimated exposure of children is generally higher than that of adolescents and adults, the average exposure for the different age categories of consumers between 2014 and 2020 to each of the 44 residues evaluated is lower - and for the majority of the residues evaluated up to 100 times lower - than the corresponding ADI. Also for persons consuming relatively large amounts of fruit and vegetables, the estimated exposure for the majority of the residues considered is 10 to 20 times lower than the ADI. This estimation is based on the 97.5th percentile or P97.5 of consumption, which is a marked overestimation as it is implicitly assumed that large portions of all food containing all residues are consumed daily by one person.

For each selected residue the estimated mean, median and P97.5 exposure of children (3 - 9 years), adolescents (10 - 17 years) and adults (18 - 64 years) according to three scenarios where results below the reporting limit (LOR) were replaced by 0, the LOR/2 or the LOR, are presented in the opinion. The highest exposure (in terms of % ADI) is observed for omethoate, followed by the dithiocarbamates, chlorpyrifos, dimethoate, chlorpropham, imazalil and lambda-cyhalothrin. The exposure to these residues and the contribution of fruit and vegetables are discussed in more detail in the opinion.

Regarding omethoate and dimethoate, it is noted that the use of omethoate has not been authorised in Europe since 2003, but it is the main metabolite of dimethoate that is monitored in controls. The use of dimethoate has been banned since 2019 (with a transition period until 2020). Since a genotoxic potential cannot be excluded, the ADI is no longer applicable. The risk associated with the exposure was therefore also evaluated via the 'margin of exposure' (MOE) approach as explained in the SciCom opinion 05-2021. Also based on this approach, the exposure to dimethoate and omethoate via fruit and vegetables between 2014 and 2020 did not appear to be of public health concern.

Similarly for chlorpyrifos, for which the authorisation was withdrawn in 2020, the risk assessment can no longer be based on the ADI because a genotoxic potential cannot be excluded. Based on the ADI still applicable before 2020, exposure to chlorpyrifos via consumption of fruit and vegetables did not pose a risk to the Belgian consumer. However, when applying the MOE approach as outlined in SciCom opinion 05-2021, it appears that exposure may have been of concern between 2014-2019, but this is no longer the case in 2020. Depending on the scenario considered, the MOE values calculated for 2020 are two to ten times higher than those calculated for 2014-2019, illustrating the positive impact of the chlorpyrifos ban in 2020.

Also for chlorpropham, the European authorisation was withdrawn in 2019 due to possible adverse effects on human health. Nevertheless, comparison of the estimated exposure with the ADI, which still applies, shows that exposure to chlorpropham via consumption of fruit and vegetables between 2014 and 2020 did not pose a risk to human health.

As regards the dithiocarbamates, the authorisation of maneb was not renewed in 2017, of propineb and thiram in 2018 and of mancozeb in 2021. The dithiocarbamates include several active ingredients that cannot be distinguished from each other by the analytical method applied, which is based on the formation of carbon disulphide (CS<sub>2</sub>). The risk was therefore assessed on the basis of the most and least toxic substance, i.e. ziram and maneb respectively. Until 2018, a slight increase in exposure as well as in reporting frequency is observed for all age groups. However, it is difficult to link the increase in exposure to an increase in the residue level in a specific foodstuff because the same number of the same foodstuffs are not sampled every year. The decreasing trend in exposure and reporting frequency after 2018 can be explained by the fact that the use of a number of dithiocarbamates was no longer authorised as of 2017.

Even though the P97.5 exposure between 2014 and 2020 could be up to more than half of the ADI of ziram, it is assumed that exposure to dithiocarbamates through fruit and vegetable consumption did not pose a risk to health between 2014 and 2020. Indeed, not only the risk characterisation based on the ADI of the most toxic dithiocarbamate ziram overestimates the actual risk because not all the measured CS<sub>2</sub> concerns ziram. Not only is the exposure sufficiently lower than the ADI, but also the risk characterisation based on the ADI of the most toxic dithiocarbamate ziram overestimates the actual risk because not all of the measured CS<sub>2</sub> concerns only this compound.

Overall, based on FASFC control results for the period 2014 to 2020, it can be concluded that the long-term exposure of the Belgian consumer, including children, to residues of plant protection products via consumption of fruit and vegetables did not pose a risk or was not a cause for concern, even with a high consumption of fruit and vegetables. The uncertainties associated with the risk assessment and listed in the opinion most probably led to an overestimation of the risk. Plant protection products for which there are indications that exposure is harmful to human health, namely genotoxic carcinogens, substances toxic to reproduction or endocrine disruptors, are no longer authorised.

It should be mentioned that the Belgian food consumption survey of 2014 showed that the consumption of fruit and vegetables of the Belgian population is relatively low compared to the recommended amount. If more fruit and vegetables are consumed, the exposure to plant protection product residues will also be higher. However, this should not prevent consumers from consuming more fruit and vegetables. The residue levels to which a consumer is exposed to depend on the crop with variable concentrations between products, and any pre-consumer processing, such as washing and peeling, as illustrated in the opinion for chlorpyrifos and imazalil, among others. In addition, at higher fruit and vegetable consumption, the exposure for the majority of the plant protection product residues and for the majority of the consumers will still be sufficiently low not to pose a risk, as also indicated by the estimated P97.5 exposure values.

Not all of the residues considered in the opinion have a similar toxicological effect on a specific organ, tissue or system, so that they cannot all be added or considered together in the risk assessment. Moreover, a European study indicated that the cumulative exposure to plant protection product residues that have an acute effect on the nervous system or a chronic effect on the thyroid gland is not of concern. A similar conclusion was drawn in a Belgian study regarding the evaluation of the cumulative risk of exposure to triazole pesticides. Therefore, a cumulative risk assessment was not carried out in the context of this opinion.

The full text is available on this website in dutch and in french.