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# The 2020 European Union report on pesticide residues in food

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#### **Abstract**

Under European Union legislation (Article 32, Regulation (EC) No 396/2005), the EFSA provides an annual report which examines pesticide residue levels in foods on the European market. This report is based on data from the official national control activities carried out by EU Member States, Iceland and Norway and includes a subset of data from the EU-coordinated control programme, which uses a randomised sampling strategy. For 2020, 94.9% of the overall 88,141 samples analysed fell below the maximum residue level (MRL), 5.1% exceeded this level, of which 3.6% were non-compliant, i.e. samples exceeding the MRL after taking the measurement uncertainty into account. For the subset of 12,077 samples analysed as part of the EU-coordinated multiannual control programme, 1.7% exceeded the MRL and 0.9% were non-compliant. To assess acute and chronic risk to consumer health, dietary exposure to pesticide residues was estimated and compared with health-based quidance values. Dietary exposure to pesticides for which health-based quidance values were available is unlikely to pose a risk to EU consumer health. In the rare cases where dietary exposure for a specific pesticide/product combination was calculated to exceed the health-based guidance value, and for those pesticides for which no health-based guidance value could be established, the competent authorities took appropriate and proportionate corrective measures to address potential risks to consumers. Recommendations are proposed to increase the effectiveness of European control systems, thereby continuing to ensure a high level of consumer protection throughout the EU.

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# **Summary**

The 2020 EU report on pesticide residues in food provides an overview of the official control activities on pesticide residues carried out in the EU Member States, <sup>1</sup> Iceland and Norway. It summarises the results of both the EU-coordinated control programme (EU MACP) and the national control programmes (MANCP). The report also includes the outcome of the risk assessment for both programmes.

The analysis of the results from all reporting countries is presented in Annex I, a data visualisation format to provide stakeholders with a comprehensive, easily digestible analysis of the European situation related to the findings. The conclusions and recommendations derived from the results remain within this report, giving risk managers a tool for designing future monitoring programmes and taking appropriate decisions on which pesticides and food products should be targeted.

# EU-coordinated multiannual control programme (EU MACP)

The EU MACP covers the most consumed food products by EU citizens as indicated in the EU MACP Regulation (EU) 2019/533 and sampled randomly. The listed food products are distributed across a 3-year cycle, so that every 3 years the same products are analysed. A snapshot of the situation in 2020 of the pesticide residues present in those food products is provided and compared with 2017 and 2014.

For the 2020 EU MACP, 12 food products were selected: carrots, cauliflowers, kiwi fruits (green, red, yellow), onions, oranges, pears, potatoes, dried beans, brown rice, rye grain, bovine liver and poultry fat. A total of 12,077 samples were analysed.<sup>3</sup> Overall, 68.5% (8,278 samples) were found to be without quantifiable levels of residues (residues < LOQ). The number of samples with pesticide residues within legal limits (at or above the LOQ but below or at the MRL) was 3,590 (29.7%). MRLs<sup>4</sup> were exceeded in 209 samples (1.7%), 113 of which (0.9%) were found to be non-compliant based on the measurement uncertainty. Reporting countries analysed on average 60% of domestic products (i.e. samples from the reporting country), 22% from other EU countries, 14% from third countries and 4% of unknown origin.

Some countries were unable to meet the sampling targets required by the EU MACP Regulation due to the COVID-19 pandemic.

### EU-coordinated and national programmes (EU MACP + MANCP)

The overall EU pesticide monitoring programmes for 2020 incorporate both the results of the EU-coordinated control programme (EU MACP) and the individual national programmes (MANCP), as implemented by the 28 Member States, Iceland and Norway.

A total of 88,141 samples were analysed. The total number of samples decreased by 9.3% compared to 2019 (96,302 samples) mainly due to the COVID-19 pandemic. The reporting countries analysed 659 pesticides, with an average of 264 pesticides per sample (233 pesticides in 2019).

Of the total number of analysed samples, 94.9% (83,666 samples) fell within legal limits (83,666 samples) (96.1% in 2019); of these, 48,181 samples (54.6%) did not contain quantifiable residues (results below the LOQ for each pesticide analysed) while 40.3% of the samples analysed contained quantified residues not exceeding the legal limits (35,485 samples). In total, MRLs were exceeded in 5.1% of the samples (4,475), an increase compared with 2019 (3.9%). When taking into account the measurement uncertainty, it was found that 3.6% (3,156 samples) of all the samples triggered legal sanctions or enforcement actions, an increase compared with 2019 (2.3%).

#### Dietary exposure and risk assessment

An analysis of the health risk to consumers has been performed using the deterministic Pesticide Residues Intake Model (PRIMo rev. 3.1), considered to be a conservative assessment methodology.

Overall, for most of the samples analysed in the framework of the 2020 pesticide monitoring programmes (EU MACP and MANCP), dietary exposure to pesticides for which health-based guidance

<sup>&</sup>lt;sup>1</sup> As of 31 January 2020, the United Kingdom became a third country. The United Kingdom (UK) data have been included and evaluated in the present report because in accordance with the Agreement on the Withdrawal of the UK from the EU and with the established transition period (i.e. until 31/12/2020), the EU requirements on data sampling also applied to the UK.

<sup>&</sup>lt;sup>2</sup> A dedicated website where EU MACP and MANCP results are presented: https://multimedia.efsa.europa.eu/pesticides-report-2020/

These samples exclude those of baby food requested under the EU MACP.

<sup>&</sup>lt;sup>4</sup> The 'maximum residue level' (MRL) is defined as the upper legal level of concentration for a pesticide residue in or on food or feed set in accordance with Regulation (EC) No. 396/2005, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers.



values (HBGV) are available is unlikely to pose a risk to EU consumer health. In the rare cases where dietary exposure for a specific pesticide/product combination was calculated to exceed the health-based guidance value (using conservative assumptions), and for those pesticides for which no HBGV could be established, the competent authorities took appropriate and proportionate corrective measures to address potential risks to consumers.

In future reports on pesticide residues in food, the deterministic exposure assessments will be accompanied by probabilistic assessments of single substances, allowing better quantification of the possible risks, and the associated uncertainties.



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#### 1. **Background**

#### 1.1. **Legal Basis**

Pesticide residues,<sup>5</sup> resulting from the use of plant protection products<sup>6</sup> on crops or food products that are used for food, can potentially pose a risk to public health. For this reason, a comprehensive legislative framework has been established in the European Union (EU), which defines rules for the approval of active substances used in plant protection products, their use and their residues in food. To ensure a high level of consumer protection, legal limits, or so-called 'maximum residue levels' (MRLs)<sup>4</sup> are established in Regulation (EC) No 396/2005.<sup>8</sup> EU-harmonised MRLs are set for more than 1,300 pesticides covering 378 food products/food groups. A default MRL of 0.01 mg/kg is applicable to nearly 690 of these pesticides which are not explicitly mentioned in the MRL legislation. Regulation (EC) No 396/2005 imposes the obligation on Member States to carry out controls to ensure that food placed on the market is compliant with the legal limits. This regulation establishes both EU and national control programmes:

- EU-coordinated control programme: This programme defines the food products and pesticides that should be monitored by all Member States. The EU-coordinated programme (EU MACP) relevant for the calendar year 2020 was set up in Commission Implementing Regulation (EU) No 2019/5339 hereafter referred to as '2020 EU MACP Regulation' or '2020 monitoring programme',
- National control programmes: Member States usually define the scope of national control programmes, focussing on certain products, which are expected to contain residues in concentrations exceeding the legal limits, or on products that are more likely to pose risks for consumer safety (Article 30<sup>10</sup> of Regulation (EC) No 396/2005).

According to Article 31 of Regulation (EC) No 396/2005, Member States are requested to share<sup>11</sup> the results of the official controls and other relevant information with the European Commission, EFSA and other Member States by the 31 August each year. Under Article 32 of the above-mentioned Regulation, EFSA is responsible for preparing an Annual Report on pesticide residues, analysing the data in view of the MRL compliance of food available in the EU and the exposure of European consumers to pesticide residues. In addition, based on these findings, EFSA derives recommendations for future monitoring programmes.

Specific MRLs are set in Directives 2006/125/EC12 and 2006/141/EC13 for food intended for infants and young children. Following the precautionary principle, the legal limit for these types of food products was set at a low level (limit of quantification); in general, a default MRL of 0.01 mg/kg is

<sup>&</sup>lt;sup>5</sup> The term pesticide residue is used throughout this report and its annexes, to refer to measurable amounts of an active substance and/or related metabolites and/or degradation products that can be found on harvested crops or in foods of animal

<sup>&</sup>lt;sup>6</sup> The term plant protection products (PPP) used throughout this report and its annexes, pertains to a product containing an active substance and other substances added and/or their products to ensure, among others, plant protection against harmful organisms, influence their life processes (e.g. growth regulators), destroy or prevent growth of undesired plants or parts of them in the fields, etc.

<sup>&</sup>lt;sup>7</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009,

<sup>&</sup>lt;sup>8</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.

<sup>&</sup>lt;sup>9</sup> Commission Implementing Regulation (EU) 2019/533 of 28 March 2019 concerning a coordinated multiannual control programme of the Union for 2020, 2021 and 2022 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin. OJ L 88, 29.3.2019, p. 28-41.

<sup>&</sup>lt;sup>10</sup> Article 30 of Regulation (EC) No 396/2005 remains applicable until 14/12/2022 according to Regulation (EU) No 2017/625. From 15/12/2022, the MANCP will be established by Member States in accordance with Regulation (EU) No 2021/1355.

 $<sup>^{11}</sup>$  Within EFSA terminology, the term share refers to fully accept the data in EFSA's sDWH.

<sup>&</sup>lt;sup>12</sup> Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and

young children. OJ L 339, 6.12.2006, p. 16–35.

Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. OJ L 401, 30.12.2006, p. 1-33.



applicable unless lower legal limits for the residue levels are defined in these Directives. Regulation (EU) No 609/2013<sup>14</sup> repeals the aforementioned Directives; however, the pesticide MRLs of Directive 2006/125/EC and 2006/141/EC were still applicable in 2020.

It is noted that some of the active substances for which legal limits are set under Regulation (EC) No 396/2005 are also covered by Commission Regulation (EU) No 37/2010 on pharmacologically active substances. For these so-called dual use substances, Member States perform controls in accordance with Council Directive 96/23/EC<sup>16</sup> for veterinary medicinal products (VMPR). Results of the controls for dual use substances are reported within this report if MS Competent Authority has flagged as so in the remit of the ChemMon data collection (EFSA, 2021b). Otherwise, results are reported in another EFSA output on VMPR residues (EFSA, 2022a).

It should be highlighted that for organic products, no specific MRLs are established. The MRLs set in Regulation (EC) No 396/2005 apply equally to organic food and to conventional food. However, Article 5 of Regulation (EC) No 889/2008<sup>17</sup> on organic production of agricultural products defines the restrictions in place for the use of plant protection products.

Regulation (EU) 2019/1793<sup>18</sup> lays down rules concerning the temporary increased level of official controls to be carried out on a list of food of non-animal origin and feed which based on known or emerging risks, requires increased levels of controls prior to their introduction into the EU. The food products, the country of origin of the products, the frequency of checks to be performed at border control posts (BCPs) or at control points (CPs) into the EU territories and the hazards (e.g. pesticides residues, not approved food additives, mycotoxins, pentachlorophenol, dioxins and microbiological contamination) are specified in Annex I and II to this regulation which is regularly updated; for the calendar year 2020, it was amended twice. <sup>19,20</sup>

Finally, due to the pandemic situation, Regulation (EU) No 2020/466 allowed Member States to apply temporary measures in relation to official controls and other official activities due to the coronavirus disease (COVID-19) such as disruptions in planned official controls.

### 1.2. Terms of Reference

In accordance with Article 32 of Regulation (EC) No 396/2005, EFSA shall prepare an annual report on pesticide residues concerning the official control activities for food carried out in 2020.

The annual report shall include at a minimum the following information:

- an analysis of the results of the controls on pesticide residues provided by EU Member States,
- a statement of the possible reasons why the MRLs were exceeded, together with any appropriate observations regarding risk management options,

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Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009. OJ L181, 29.6.2013, p. 35–56.

<sup>15</sup> Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 015 20.1.2010, p. 1.

Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. OJ L 125, 23.5.1996, p. 10.

Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control. OJ L 250, 18.9.2008, p. 1–84.

Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660. OJ L 277, 29.10.2019, p. 89–129.

Commission Implementing Regulation (EU) 2020/625 of 6 May 2020 amending Commission Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Implementing Regulation (EU) 2015/943 and Commission Implementing Decision 2014/88/EU. OJ L 144, 7.5.2020, p. 13–33.

<sup>&</sup>lt;sup>20</sup> Commission Implementing Regulation (EU) 2020/1540 of 22 October 2020 amending Implementing Regulation (EU) 2019/1793 as regards sesame seeds originating in India. OJ L 353, 23.10.2020, p. 4–7.

<sup>&</sup>lt;sup>21</sup> Commission Implementing Regulation (EU) 2020/466 of 30 March 2020 on temporary measures to contain risks to human, animal and plant health and animal welfare during certain serious disruptions of Member States' control systems due to coronavirus disease (COVID-19). OJ L 98, 31.3.2020, p. 30–33.



- an analysis of chronic and acute risks to the health of consumers from pesticide residues,
- an assessment of consumer exposure to pesticide residues based on the information provided by Member States and any other relevant information available, including reports submitted under Directive 96/23/EC<sup>22</sup>.

In addition, the report may include a recommendation on the pesticides, products or combinations of them that should be included in future monitoring programmes.

#### 2. Introduction

This report provides a detailed insight into the control activities at European level and the results from the official control activities performed by the EU Member States, including Iceland and Norway as members of the European Free Trade Association (EFTA) and of the European Economic Area (EEA). The main purpose of the data analysis presented in this report is to give risk managers the necessary information to decide on risk management issues. At the same time, the report aims to address questions such as:

- How frequently were pesticide residues found in food?
- Which food products frequently contained pesticide residues?
- Compared with previous years, are there any notable changes?
- In which products were breaches of the legal limits identified by the Member States? And in which could be the reasons for these breaches?
- What actions were taken by the national competent authorities responsible for food control to ensure that pesticide residues in food not complying with the European food standards are not placed on the EU market?
- Do the residues in food pose a risk to consumer health?

This report aims to answer these questions in a way that can be understood without deep knowledge on the subject. Furthermore, EFSA developed a data visualisation tool to help end users gain insights from the vast amount of data underpinning this report. The 2020 EU-coordinated programme results, as defined by Commission Implementing Regulation (EU) No  $2019/533^8$  and the national programme results as defined in Article 30 of Regulation (EC) No  $396/2005^7$ , are presented in Annex I. An overall summary evaluation can still be found in Sections 3 and 4 of this report, but figures, maps and tables are in Annex I. The results of the dietary exposure assessments to individual pesticides are described in Section 5, complementary graphs on the acute risk assessment to the EU MACP food products are presented in Appendix B – whereas results of PRIMo tool deterministic risk assessments to single substance are presented in Annex II.

The websites of the national competent authorities can be seen in Appendix A of this report.

The raw data provided by reporting countries and anonymised by EFSA can also be downloaded from the Open Science platform Zenodo<sup>23</sup> by typing: 'Member-State-Name results from the monitoring of pesticide residues in food'.

Furthermore, separate tables under Annex III are published in Zenodo.<sup>24</sup> These are:

- Table 3.1 The 2020 EU-coordinated multiannual programme of the Union
- Table 3.2 List of samples exceeding the MRLs, including information on the measured residue concentrations and the origin of the samples
- Table 3.3 Scope of analysis of pesticides reported
- Table 3.4 Regulation (EU) 2019/1793 on the temporary increase of official controls extract of the controls to be performed of pesticides in food
- Table 3.5 Health-based guidance values (HBGV)
- Table 3.6 Processing factors used to refine acute exposure assessment

In addition, EFSA compiled a technical report (EFSA, 2022b) containing the descriptive information of the pesticide monitoring activity by year and submitted by the reporting countries. Here, further details at national level are provided.

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Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. OJ L 125, 23.5.1996, p. 10–32.

<sup>23</sup> https://zenodo.org/search?page=1&size=20&q=results%20from%20the%20monitoring%20of%20pesticide%20residues%20in %20food

<sup>&</sup>lt;sup>24</sup> https://doi.org/10.5281/zenodo.6322020



# 3. EU-multiannual coordinated control programme (EU MACP)

In compliance with the 2020 EU monitoring programme satisfying Annex I of Regulation (EU) No 2019/533<sup>8</sup>, reporting countries sampled and analysed a given number of pesticide/food product combinations. These included carrots, cauliflowers, kiwi fruits (green, red, yellow), onions, oranges, pears, potatoes, dried beans, brown rice, rye grain, bovine liver and poultry fat. These were compared with the same food products sampled in 2017 and 2014 for the EU monitoring programmes. Exceptions including kiwi fruits (green, red, yellow), cauliflower, onions, dried beans and rye grain were only compared with 2017 results as in 2014 these were not required. The 2020 results for bovine liver were only compared with the corresponding 2014 results.

Overall, 186 pesticide residues were included in the 2020 EU MACP presented in Annex III – Table 3.1. Of those, 163 were to be analysed in plant commodities, nine in animal commodities and 14 both in plant and animal commodities. Compared to 2017 (171 pesticides) and 2014 (213 pesticides) programmes, the 2020 EU MACP included 15 additional pesticide residues (ametoctradin (RD), cyazofamid (RD), cyflufenamid, emamectin (RD), etoxazole (RD), fenpyrazamine, fluopicolide (RD), fluxapyroxad (RD), metrafenone (RD), omethoate (RD), proquinazid (RD), prosulfocarb (RD), spirotetramat (RD), thiodicarb (RD) and tricyclazole (RD)). Therefore, a direct comparison with the two previous years is not possible. Haloxyfop (RD) and prothioconazole (RD) results in 2020 have been compared only with 2014 as they were reintroduced in 2020 only. Isoprothiolane (RD) and triadimefon (RD) in 2020 have been compared with 2017 only, as they were not part of the 2014 EU MACP.

From the 12 food products in 2020 EU MACP, samples from organic production systems were to be taken too in proportion to the market share of each commodity within each reporting country with a minimum of 1. In total, 941 organic samples<sup>25</sup> were analysed. In addition, five samples of infant formulae and five more of follow-on formulae were to be sampled. The total number of samples reported under baby food categories amounted to 413 samples.<sup>26</sup> A comprehensive analysis of these results is reported in Section 4.3.2 where the data for all baby food samples are pooled. This category of samples has not been included in Annex I – EU MACP chapter.<sup>2</sup> The lack of compliance with the EU MACP Regulation on the number of minimum samples to be taken was reported by nine EU MSs (Bulgaria, Lithuania, Luxembourg, Malta, Cyprus, Ireland, Austria, Estonia, United Kingdom) due to the COVID-19 pandemic situation. Based on Regulation (EU) 2020/466,<sup>27</sup> MS could inform EFSA of a reduced number of samples to be taken with respect to their programme due to these exceptional circumstances. On the contrary, Romania, Poland, Spain, Italy, France and Germany sampled more than 5% of what was required.

The EU MACP Regulation also sets a minimum of 683 samples to be monitored per food product to estimate a minimum of 1% MRL exceedances with a margin of error of 0.75%. These numbers were distributed among EU Member States depending on their population size. The limits ranged from 12 to 97 samples per food product. The minimum number was not reached for rye grain (638 samples). However, it was noticeably increased for poultry fat (1,595 samples compared to 483 in 2017). The increased number of poultry fat samples could be due to the inclusion of footnote 7 in the Regulation allowing the sampling of meat (as well as fat) in accordance with Table 3 of the Annex to Directive 2002/63/EC. Another reason may be the pooling of VMPR samples reported under the harmonised Chemical Monitoring common data collection, as well as the increased concern of animal welfare and new VMPR control programmes foreseen.

Bearing in mind that EU MACP samples are not only used to check for MRL compliance but also for carrying out deterministic and probabilistic exposure assessments to individual and multiple pesticides (see Section 5), EFSA recommends revisiting the calculation on the minimum number of samples to be taken by commodity as well as their distribution among EU MSs (EFSA, 2020a).

<sup>&</sup>lt;sup>25</sup> The minimum number of 12 samples mentioned in the EU MACP on organic were not reported by Hungary (five samples), Slovenia (six samples), Slovakia (eight samples), Estonia (nine samples) and Ireland (10 samples).

<sup>&</sup>lt;sup>26</sup> The minimum number of five samples per baby food category mentioned in the EU MACP were not reached by Estonia (eight samples), Finland (three samples), France (four samples), Latvia (two samples), Portugal (five samples), Romania (nine samples) and Sweden (two samples).

<sup>&</sup>lt;sup>27</sup> Regulation (EU) 2020/466 of 30 March 2020 on temporary measures to contain risks to human, animal and plant health and animal welfare during certain serious disruptions of Member States' control systems due to coronavirus disease (COVID-19). OJ L 98, 31.3.2020, p. 30–33.



In compliance with the EU MACP Regulation, 12,077<sup>28</sup> samples were analysed. Overall, in 68.5% of samples (8,278 of the 12,077 samples analysed), no quantifiable levels of residues<sup>29</sup> were reported (residues were below the LOQ). The number of samples with pesticide residues within the legal limits<sup>30</sup> (at or above the LOQ but below or at the MRL) was 3,590 (29.7%). MRLs were exceeded in 1.7% of samples (209 samples), while 0.9% (113 samples) were found to be non-compliant based on the measurement uncertainty.<sup>31</sup> In preparation of the EU MACP, reporting countries took on average 60% of domestic products (i.e. samples of the same origin as the reporting country), 22% from other EU countries, 14% originated in third countries and 4% were of unknown origin. Countries with more than 80% of samples originated by domestic production were Lithuania (100%), Spain (93%), Italy (87%) and France (81%). Whereas countries sampling more than 30% from third countries were Romania (42%) and Finland (31%). Belgium (28%), Ireland (12%) and Iceland (11%) had more than 10% of samples of unknown origin.

The 2020 and 2017 EU MACPs had all commodities in common except for bovine liver. Based on this, a direct comparison on the averaged overall MRL exceedance rate between the 2 years is possible resulting in an increase from 1.7% in 2017 to 2.1% 2020. Among individual food commodities MRL exceedance rates rose from 2014 to 2017 and to 2020 in rice (from 2.1% to 5.1% and to 6.7%), oranges (from 1.5% to 1.1% and to 2.9%), pears (from 1.6% to 2.3% and to 2.3%) and poultry fat (from a 0% in 2014 and 2017 to 0.06%). An increased trend from 2017 to 2020 (as it was not requested in 2014 EU MACP) was also observed in dried beans (from 2.3% in 2017 to 4.9% in 2020), kiwi fruits (green, red, yellow) (from 1.3% in 2017 to 1.96% in 2020) and cauliflower (from 0.8% in 2017 to 1.0% in 2020). Exceedance rates fell for carrots (from 2.1% in 2014, to 1.9% in 2017 and 1.2% in 2020), potatoes (from 1.1% in 2014 to 1.2% in 2017 and to 0.8% in 2020), rye (from 1.9% in 2017 to 1.1% in 2020) and onions (from 0.3% in 2017 to 0.2% in 2020). Bovine liver remains steady with no MRL exceedances in 2014 and 2020 programme years.

Of the 12,077 samples, 3,799 samples had quantified results (31.5%) and 2,199 samples (18%) had more than one pesticide quantified. By food product, oranges (762 samples), followed by pears (696 samples), carrots (250 samples) and rice (134 samples) had the highest number of samples with multiple residues. The highest frequency of multiple residues was found in rice in one sample of unknown origin where 15 different pesticides were quantified. Two of these quantifications led to a non-compliant sample. In another pear sample, 14 pesticides were quantified all below the MRL.

Among the EU MACP commodities grown in the EU territory, the following 12 non-EU approved active substances<sup>32</sup> were reported to be non-compliant in 28 samples: dimethoate (RD) (seven results) in six orange samples and one kiwi sample, chlorpropham (RD)<sup>33</sup> (four results) in two carrot samples, one orange sample and one dry beans sample, chlorpyrifos (RD) (three results) in potatoes, pears and rye grain, one sample each, iprodione (RD) (three results) in two pear samples and one carrot sample, linuron (RD) (three results) in two carrot samples and one orange sample, triadimenol (RD) (two results) in dry beans samples, diphenylamine (RD) (two results) in pear samples, thiacloprid (RD) (one result) in rye grain, hexachlorobenzene (RD) (one result) in poultry fat, thiamethoxam (RD) (one result) in rice, dieldrin (RD) (one result) in carrot, chlorpyrifos-methyl (RD) (one result) in carrot and fipronil (RD) (one result) in potato. Most of the non-compliant results (26 results) resulted in an

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<sup>&</sup>lt;sup>28</sup> This number does not include samples of infant formulae and follow-on formulae which are presented under MANCP section of the report.

<sup>&</sup>lt;sup>29</sup> In the context of this report, samples without quantifiable residues refer to results where the analytes were not present in concentrations at or exceeding the limit of quantification (LOQ). The LOQ is the smallest concentration of an analyte that can be quantified with any reliability. It is defined as the minimum concentration of the analyte in the test sample that can be determined with acceptable precision and accuracy.

<sup>30</sup> Samples with quantified residues within the legal limits (below or at the MRL) in the context of this report refers to samples containing quantified residues of one or several pesticides in concentrations below or at the MRL but above the limit of quantification.

Non-compliant samples in the context of this report refer to samples containing residue concentrations clearly exceeding the legal limits, considering the measurement uncertainty. The concept of measurement uncertainties and the impact on the decision of non-compliance is described in Figure 1 of the 2018 guidance document on reporting data on pesticide residues (EFSA, 2018b; EC, 2020). It is required in official controls that the uncertainty of the analytical measurement is considered before legal or administrative sanctions are imposed on food business operators for infringement of the MRL legislation (Codex, 2006; Ellison et al, 2012).

<sup>32</sup> Active substances that are not allowed to be used in plant protection products applied on crops grown in the EU and/or commodities produced in the EU.

<sup>&</sup>lt;sup>33</sup> As per Commission Implementing Regulation (EU) 2019/989 of 17 June 2019 concerning the non-renewal of approval of the active substance chlorpropham (OJ L 160, 18.6.2019, p. 11–13), uses of chlorpropham were to be withdrawn from the market by January 2020, with a maximum period of grace until 8 October 2020.



administrative action except for two RASFF notifications (of which one was in triadimenol (RD) in dried beans and the other for dimethoate (RD) in oranges), one lot withdrawn from the market (triadimenol in dried beans) and another lot not released on the market (chlorpyrifos (RD) in rye). Seven of these active substances have been not renewed within the years 2019 and 2020 (i.e. chlorpyrifos, chlorpyrifos-methyl, dimethoate, triadimenol, thiacloprid and thiamethoxam).

Among the EU MACP samples grown outside the internal market and submit by reporting countries, the following 34 non-EU approved active substances were found to be non-compliant in 27 samples: chlorpyrifos (RD) (nine results) in seven dry beans samples, one pear and one rice sample, bromopropylate (RD) (four results) in orange samples, tricyclazole (RD) (four results) in rice samples, carbendazim (RD)<sup>34</sup> (three results) in two rice samples and one orange sample, iprodione (RD) (two results) in carrot samples, profenofos (RD) (two results) in oranges and rice, one sample each, fenitrothion (RD) (two results) in dry beans samples, fenbutatin oxide (RD) (two results) in orange samples, hexaconazole (RD) (two results) in dry beans and rice, one sample each, carbaryl (RD) (one result) in dry beans, triazophos (RD) (one result) in rice, spirodiclofen (RD) (one result) in kiwi sample and thiamethoxam (RD) (one result) in rice sample. The actions taken by EU MS were three RASFF notifications (one in dried beans in a lot coming from Madagascar reporting chlorpyrifos (RD), another one in dried beans from Brazil reporting chlorpyrifos (RD) and the other one rice from Pakistan reporting carbendazim), two other lots were recalled from the market (one in rice coming from Pakistan with findings on profenofos (RD) and triazophos (RD)) and the other 22 were administrative consequences. Further, 10 more non-compliant samples were of unknown origin, of which one lot was withdrawn from the market (chlorpyrifos in dried beans) and another lot was notified via RASFF (tricvclazole in rice).

Among commodities of animal origin (i.e. bovine liver and poultry fat), fat soluble persistent organic pollutant pesticides were the substances most frequently quantified (i.e. DDT(RD) in 15 samples and hexachlorobenzene (RD) in 13 samples and beta-hexachlorocyclohexane (RD) in nine samples). These substances are no longer used as pesticides but are very persistent in the environment and can therefore still be found in the food chain. The non-compliance was reported in hexachlorobenzene (RD) in one poultry fat sample. This sample followed an administrative action.

Of the pesticides listed in the EU MACP Regulation, those having a narrower coverage by reporting countries were bromide ion (RD), dithianon (RD), haloxyfop (RD), 2,4-D (RD), 2-phenylphenol (RD), glyphosate (RD), mepiquat chloride (RD), cyflufenamid (RD), ethephon (RD), dithiocarbamates (RD) and fenbuconazole (RD). These are mostly substances amendable to single residue methods (SRMs). Thus, EFSA recommends that MS should take the necessary measures to be able to enforce properly these substances.

Detailed analyses are presented in Annex I.<sup>2</sup>

# 4. Overall monitoring programmes (EU MACP and MANCP)

This chapter incorporates both the results of the EU-coordinated multiannual control programme (EU MACP) and the Multiannual National Control Programme (MANCP), as implemented by the 28 Member States<sup>1</sup>, Iceland and Norway.

Compared with the EU MACP, the MANCP are risk-based sampling programmes in accordance with Article 30 of Regulation (EC) No. 396/2005. The focus is set on products likely to contain pesticide residues or for which MRL infringements were identified in previous monitoring programmes. These programmes are not designed to provide statistically representative results for residues expected in food placed on the European market. The reporting countries define the priorities for their national control programmes considering several factors such as the importance of food products in trade or in the national diets, products with historically high residue prevalence or non-compliance rates in previous years, the use pattern of pesticides and national laboratory capacities. The results of national control programmes cannot be directly compared and can vary between reporting countries due to the specific needs in each country, its dietary habits and access to local products along with the specific targeting scope of national control programmes, that may differ among them. The number of samples and/or the number of pesticides analysed by any reporting country is determined by the capacities of their national control laboratories and available budget resources.

Carbendazim is a non-approved active substance. However, it is a metabolite of thiophanate methyl. Residues of carbendazim could be attributed to the use of plant protection products containing thiophanate-methyl which was non-renewed according to Regulation (EC) No 2020/1498 with a maximum period of grace for use until 3 February 2021.



The data analysis of this section is also presented in Annex I.<sup>2</sup> The data are displayed onto three different sections: geospatial visualisation based on overall number of samples by reporting countries, findings at residue level and analysis at food product level. Non-compliant findings are considered by risk managers to take decisions on designing the risk-based national monitoring programmes in future years. The findings are also a valuable source of information for food business operators and can be used to enhance the efficiency and safety of self-control systems. Lastly, the reasons for MRL exceedance remain in the body text of this report.

# 4.1. Geospatial findings

In 2020, a total of 88,141 samples of food products covered by Regulation (EC) No 396/2005 were analysed for pesticide residues by 30 reporting countries. The total number of samples analysed in 2020 decreased by 9.3% compared to 2019 (96,302 samples) mainly due to the COVID-19 pandemic situation. Additionally, 11 countries reported 1,379 feed samples and 962 fish samples. Although under Regulation (EC) No 396/2005, no MRLs are in/on fish, a short summary of the pesticide findings in fish has been included in the data visualisation<sup>2</sup>.

Of the total 88,141 samples taken in 2020, 51.6% (45,521 samples) were domestic samples (i.e. grown on the country that reports the sample), 15.3% (13,505 samples) were grown in another reporting country (i.e. grown in another EU Member States, Iceland or Norway than the country reporting the sample) and 28.4% (25,014 samples) were imported in the EU from a third country. The samples of unknown origin (4,101 samples; 4.7%) significantly decreased compared to previous years (11.3% in 2019 and 10% in 2018). Overall, the sampling rates of food produced in EU increased in 2020 compared to 2019 (from 63.5% in 2019 to 66.9% in 2020) as well as for third countries (from 25.3% in 2019 to 28.4% in 2020, respectively) in detriment of the lowering of the samples of unknown origin. This is a significant improvement of reporting countries and food business operators that have made this information available to inspectors and have been accessible throughout all stages of the entire food chain.

The countries with the highest sampling rates of imported products from third countries were Bulgaria (94.3%), Croatia (50.2%), Finland (47%), Romania (42.5%) and Sweden (41.4%); while on the other hand, Lithuania, Italy, Spain, Greece, France focussed mainly on domestic sampling (more than 70% of the samples analysed). Furthermore, despite the observed improvement, Belgium, Germany, Iceland, Luxembourg reported more than 10% of their samples of unknown origin.

More information on the national control programmes can be found in a separate EFSA technical report that summarises the national results (EFSA, 2022b).

# 4.2. Results by pesticide residues

The results presented in these sections refer to complete data sets for unprocessed and processed food products, comprising results from surveillance samples (meaning samples that were taken without targeting specific growers/producers/importers or consignments likely to be non-compliant) and enforcement samples (where a suspect sampling or targeted strategy was applied).

The number of surveillance samples decreased in 2020 (76,539 samples, 87.0%) compared to 2019 (85,719 samples, 89.0%). The remaining 13.0% of samples were enforcement samples (11,602 samples), a slightly higher percentage than the one observed in 2019 (10,583 samples; 11.0%).

Considering all samples, the reporting countries analysed in total, 659 different pesticides. A large analytical scope at country level was noted for Luxembourg (659 pesticides), Malta (643 pesticides), Germany (626 pesticides), France (619 pesticides) and Belgium (617 pesticides). On average, 264 different pesticides were analysed per sample (233 pesticides in 2019) being the countries with highest average of pesticide sought by sample Austria (548 pesticides) and Malta (474 pesticides). The diversity of national control programmes needs to be kept in mind when examining the results from different reporting countries.

Overall, 94.9% of the 88,141 samples analysed in 2020 fell within the legal limits (83,666 samples) (96.1% in 2019); of these, 48,181 samples (54.7%) did not contain quantifiable residues (results below the LOQ for all pesticides analysed) while 40.3% of the samples analysed contained quantified residues not exceeding the legal limits (35,485 samples). In total, MRL exceedance rate increased from 3.9% in 2019 (3,720 samples) to 5.1% in 2020 (4,475 samples). When taking into account the measurement uncertainty that is implemented by food regulatory authorities across Europe, it is found that 3.6% of all samples analysed in 2020 (3,156 samples) triggered legal sanctions or enforcement



actions. These samples with clear exceedances or breaches of their respective MRLs considering the measurement uncertainty are considered as non-compliant with the legal limits.

Out of the 59,026 samples originating from the reporting countries, 41.3% were found to be below the LOQ while 24.1% contained residues at or above the LOQ but below or equal to the MRL; 1.6% of the samples exceeded the MRL and 0.9% were non-compliant with the MRL. Samples imported from third countries (25,014 samples) were found to have no quantifiable residues in 10.8% of the samples, while in 14.2% quantifiable residues at or above the LOQ but below or equal to the MRL were reported. The MRL exceedance rate (3.3%) and the non-compliant rate (2.6%) were higher compared to food produced within the EU. The remaining 4.7% (4,101 samples) were reported as origin unknown.

MRL exceedances were found in 6,741 analytical determinations in 4,475 samples. The not approved pesticides with the highest MRL exceedance rate (with at least five samples reported as exceedance) were found to be ethylene oxide (RD) (21.3%), chlorates (RD) (2.9%), chlordecone (RD) (0.9%), chlorpyrifos (RD) (0.4%) and anthraquinone (RD) (0.2%).

- Ethylene oxide: Forty-nine samples out of the 230 reported were found to exceed the MRL. Forty-six of those samples were sesame seeds (MRL set at 0.05 mg/kg limit of quantification); the others for which only one sample was notified were curcuma, peppercorn and buckwheat. In the autumn of 2020, Member States<sup>35</sup> notified in the Rapid Alert System for Food and Feed<sup>36</sup> a potentially serious food safety risk related to consignments of sesame seeds exported from India, due to contamination at high level with residues of this pesticide for which no safe levels were established in the Union. Thus, due to the amendment of Regulation (EU) 2019/1793<sup>18</sup> by Regulation (EU) 2020/1540,<sup>20</sup> the frequency of control at borders increased at 50% resulting to a higher MRL exceedance rate for this substance with respect to others. The EURL-SRM<sup>37</sup> developed analytical methods to be fully implemented by official control laboratories.
- Chlorates: One hundred and sixty-six samples out of the 5,763 reported were found to exceed the MRL mainly in lettuces (20 samples) and lamb's lettuce (15 samples), tomatoes (10 samples) and beans with pods (10 samples). Chlorate is not approved for use as a pesticide in the EU but its presence results as a by-products of chlorine solutions (chlorine dioxide, chlorite and hypochlorite salts) used as sanitising and disinfection agents in the food industry and as biocides. These uses, being necessary to ensure good hygiene of food products, lead to detectable residues of chlorate in the food chain. Already, Regulation (EU) No 2020/749<sup>38</sup> set temporary MRLs accounting for the different sources and entry points of chlorate residues in the manufacturing processes.<sup>39</sup> A significant decrease of the MRL exceedance rate is observed compared to last year (7.2% in 2019).
- Chlordecone: Twenty-seven samples out of the 2,916 reported were found to exceed the MRL mainly in cassava roots (13 samples from the French oversea territories) and in chicken eggs (eight samples). EFSA derived temporary MRLs for chlordecone in certain products of animal origin with new health-based guidance values derived by the French authorities to whom the presence of this pesticide is known (EFSA, 2020b). In accordance with the policy for persistent organic pollutants, existing MRLs should be regularly reviewed, taking onto account results from pesticide monitoring programmes, since contamination of food is expected to gradually decrease over time.
- Chlorpyrifos (RD): Three hundred and twenty-seven samples out of the 73,874 reported were found to exceed the MRL in a diversity of samples mainly in sweet peppers/bell peppers (mainly from Turkey 21 samples), grape leaves and similar species (mainly from Egypt 17 samples), dried beans (mainly from Madagascar eight samples), pomegranates (mainly from Turkey 15 samples), potatoes (mainly from Greece 12 samples) and teas (mainly from China 8 samples). Most of the exceedance came from third countries. This substance is not approved for use in the EU since 16 April 2020.

<sup>35</sup> https://ec.europa.eu/food/safety/rasff-food-and-feed-safety-alerts/ethylene-oxide-incident-food-additive\_en

<sup>36</sup> https://ec.europa.eu/food/system/files/2021-08/rasff\_pub\_annual-report\_2020.pdf

<sup>37</sup> https://www.eurl-pesticides.eu/docs/public/tmplt\_article.asp? LabID=200&CntID=1164&Theme\_ID=1&Pdf=False&Lang=EN

<sup>&</sup>lt;sup>38</sup> Commission Regulation (EU) 2020/749 of 4 June 2020 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products. OJ L 178, 8.6.2020, p. 7–20

<sup>&</sup>lt;sup>39</sup> These temporary MRLs Will be reviewed no later than 8 June 2025.



• Anthraquinone: Fifty-eight samples out of the 26,976 reported were found to exceed the MRL mainly in teas (mostly from China – 39 samples). Anthraquinone is known to be a bird repellent (EFSA, 2012), a product for drying and recently uses as a dyeing agent have been reported. Its toxicity has never been evaluated at EU level.

Details on the samples exceeding the MRL can be consulted in Annex III – Table 3.2.

# 4.2.1. Multiple pesticide residues

Multiple residues in one single sample may result from the application of different types of pesticides (e.g. application of herbicides, fungicides or insecticides against different pests or diseases) or the use of different active substances aiming at avoiding the development of resistant pests or diseases and/or uptake of persistent residues from soil from treatments used in previous seasons or spray/dust drift to fields adjacent to treated fields. In addition to multiple residues resulting from agricultural practice, multiple residues may also occur as a result of mixing or blending of products with different treatment histories at different stages in the supply chain, including contamination during food processing. According to the present EU legislation, the presence of multiple residues within a sample remains compliant, as long as each individual residue level does not exceed the individual MRL set for each active substance.

Multiple residues were reported in 24,057 samples of the total 88,141 samples (27%, as was the case in 2019); in an individual strawberry sample with unknown origin, up to 35 different pesticides were reported.

The frequency of multiple residue samples in concentrations higher or equal to the LOQ was higher in unprocessed products (23,063 samples; 28.9%; 28% in 2019) as it usually is, compared to processed products (994 samples; 11.6%; 16.8% in 2019). In 574 samples (0.6%; 0.3% in 2019), more than 10 pesticides were found in the same sample. Of those, 135 samples corresponded to processed products and 439 to unprocessed products.

The highest frequency of multiple residues in unprocessed products was reported for sweet peppers/bell peppers, apples, oranges, pears, strawberries, table grapes, mandarins and peaches.

The highest frequency of multiple residues in processed food samples was found for wine (3%), dried vine fruits (2.7%), orange juice (0.3%), wheat wholemeal flour (0.3%), poppy seeds (0.3%) and paprika powder (0.3%).

# 4.2.2. Results on glyphosate

Glyphosate is currently approved for use in the EU until 15 December 2022. The EU re-evaluation of glyphosate is now ongoing. All interested parties had access to the joint scientific evaluations prepared by Hungary, France, the Netherlands and Sweden national competent authorities.

In 2020, glyphosate was analysed by 27 reporting countries. Overall, 14,125 samples of different food products and 474 samples of animal feed were analysed for glyphosate residue. The results showed that in 97.4% of the samples (13,760 samples), glyphosate was not quantified. In 2% of the samples (283 samples), glyphosate was quantified at levels above the LOQ but below the MRL and in 82 samples (0.6%), the residue levels exceeded the MRL. The exceedance rate was higher than in 2019 (0.1%). Considering the measurement uncertainty, 56 samples (0.4%) were non-compliant. Glyphosate residue was analysed in 262 baby food samples. In one sample of processed cereal-based foods for infants and young children (i.e. in a biscuits, rusks and cookies sample for children), the MRL was numerically exceeded but compliant.

AMPA, a metabolite of glyphosate (EFSA, 2019e), was analysed in 4,534 food samples and 242 feed samples. In feed, it was quantified in 31 samples (12.8%). In food, it was quantified in 0.2% of the samples (four samples of pulses, five samples of cereals, one sample of oranges and one sample of onions).

<sup>&</sup>lt;sup>40</sup> In the framework of this report, unprocessed food products are considered those to which an MRL is directly applicable and are listed in Annex I to Regulation (EC) No 396/2005, i.e. products such as fermented tea, dried spices, dried herbal infusions, etc.

<sup>&</sup>lt;sup>41</sup> https://www.efsa.europa.eu/en/news/glyphosate-consultations-over-400-submissions-collected



# 4.2.3. Results on import controls

According to the provisions of Regulation (EU) 2019/1793<sup>18</sup> on import controls, certain foods were subject to an increased frequency of official controls for certain pesticides at border control posts (BCPs) into the EU territory. These specific import controls are *inter alia* based on previously observed high incidences of non-compliant products imported from certain countries from outside the European Union. Some of these controls may enter the Rapid Alert System for Food and Feed<sup>34</sup> of the European Commission.

Overall, 9,275 samples were reported to EFSA. Of those, 16.5% (1,529 samples) were considered as non-compliant with EU legislation on pesticide residues.

Among food commodity and country of origin, those combination above a 10% non-compliance rate were grape leaves and similar species from Turkey (55.6%), chili peppers from Vietnam (50%), pomegranates from Turkey (38%), chili peppers from India (33%), oranges from Turkey (27%), mandarins from Turkey (26%), yard-long beans from Dominican Republic (25%), breadfruits from Malaysia (17%), chili peppers from Uganda (14%), sweet peppers from Turkey (14%), sesame seeds from India (12%) and lemons from Turkey (11%).

The results presented in this section are based on the data reported directly to EFSA for the sampling year 2020. Other data might have been reported directly to DG SANTE. Therefore, this section may not give the whole picture of the situation. $^{42}$ 

A description of the required controls regarding hazard analysis, type of food products and countries of origin, relevant for the calendar year 2020 can be found in Annex III – Table 3.4.

# 4.3. Results by food products

The results presented in these sections refer to complete data sets for unprocessed and processed food products, comprising results from surveillance samples (meaning samples that were taken without targeting specific growers/producers/importers or consignments likely to be non-compliant) and enforcement samples (where a suspect sampling or targeted strategy was applied). If an analysis is restricted to a subset of results, this is clearly indicated in the relevant section.

Out of the 88,141 samples, 8,559 samples (9.7%) were reported as processed food. The compliance in these products is checked against MRLs in the raw agricultural commodity after applying the respective processing factor as per Article 20 of Regulation (EC) No 396/2005<sup>43</sup>. The MRL exceedance rate in processed food products for a total 8,559 samples was 2.6% and 1.2% non-compliant. The highest MRL exceedance rate in processed food products for which more than 10 samples were reported, were grape leaves and similar species (74%), Brazil nuts (25%), sweet peppers/bell peppers paprika powder (23%) and wild fungi dried (22%).

Among the 79,582 samples (90.3%) reported as unprocessed food products,<sup>41</sup> in 5.3% of the samples contained residues exceeding their corresponding MRLs (3.8% were non-compliant samples). The non-compliant rate is slightly higher than in 2019 (2.4%) but lower than in 2018 results (4.7%). The highest MRL exceedance rate came from grape leaves (56%), cumin seed (48%), mate (45%) and wild terrestrial vertebrate animals mainly deer and boar (41%) among the highest.

Although the number of non-compliant identified for these risk-based samples is not indicative of the average pesticide levels expected to be found in the EU market, the monitoring and reporting of these results is a call for action at Member State level in line with Article 50 of Regulation (EC) No. 178/2002<sup>44</sup>. Generally, Member States reply with appropriate measures (e.g. administrative fines, RASFF notifications<sup>45</sup> and follow-up actions, etc.).

# 4.3.1. Results on organic products

Organic products MRLs are those set in Regulation (EC) No 396/2005. However, Article 5 of Regulation (EC) No 889/2008 on organic production of agricultural products, defines restrictions in place for the use of plant protection products.

<sup>&</sup>lt;sup>42</sup> Through IMSOC system, the real number of samples of import control are collected. More information on this can be requested through SANTE-IMPORT-CONTROLS@ec.europa.eu

<sup>&</sup>lt;sup>43</sup> Information note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors and composite food and feed. SANTE/10704/2021 expected to be noted in February 2022 SCoPAFF meeting.

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

<sup>45</sup> https://ec.europa.eu/food/safety/rasff\_en



In 2020, 5,783 samples of organic food (excluding baby food) were analysed corresponding to a 6.5% of the total, a slight increase respect to 2019 (6.2%). Of those, 2,018 samples were reported under the EU MACP.

Overall, 4,632 samples flagged as organic did not contain quantifiable residues (80.1% of the analysed samples vs. 86.9% in 2019); 1,064 samples contained quantified residues below or at the MRL level (18.4% vs. 11.8% in 2019) and 87 samples were reported with residue levels above their corresponding MRLs (1.5% vs. 1.3% in 2019), of which 36 samples (0.6%) were non-compliant.

The pesticides with higher frequency of detections were copper compounds (RD) (39.1%, mainly in cereals), bromide ion (RD) (6.7%, mainly in rye and in carrots),  $^{46}$  spinosad (RD) (5.6%, mainly in bananas and tomatoes), chlorates (RD) (4.3%, mainly in cucurbits with edible peel, lettuce and spinaches), fosetyl (RD) $^{47}$  (EFSA, 2021d) (3%, mainly in wine grapes and ginger roots) and chlorpyrifos (RD) (2.6%, mainly in teas).

The following pesticides not authorised in organic farming were sporadically found in crops labelled as such: chlorpyrifos, anthraquinone and lambda-cyhalothrin.

Compared to conventionally produced food (non-organic), the MRL exceedance and quantification rate trends are generally lower in organic food. In 2020, this tendency was followed except in animal product samples as it was the case in 2019. Samples reported as being grown under organic production for animal products, presented a higher quantification rate (16%) than conventional production (7%), whereas MRL exceedances rates were closer among each other (1.2% conventional vs. 1.9% organic). Most of the exceedances in organic production were coming from POPs, i.e. pesticides used in the past (hexachlorobenzene (RD) and DDT (RD)). While as per Directive 2002/32/EC, <sup>48</sup> legal limits are set for POPs in feed, Member States should try to elucidate the reasons for these exceedances.

The occurrence of other pesticides not authorised in organic farming can – as for conventional products – be the result of spray drift, environmental contaminations or contaminations during handling, packaging, storage or processing of organic products. This occurrence could also be linked to the incorrect labelling of conventionally produced food as organic food. Therefore, Member States should try to elucidate the reasons for the presence of pesticides found occasionally in organic food, which are not permitted in these types of products (e.g. chlorpyrifos, anthraquinone, lambdacyhalothrin).

# 4.3.2. Results on baby food

Reporting countries analysed 1,641 samples as defined in Regulation (EU) No 127/2016<sup>49</sup>, Regulation (EU) No 609/2013<sup>14</sup> and Directive 2006/141/EC<sup>13</sup> of herein referred to as foods for infants and young children or baby food. The types of baby food samples were 580 baby foods other than processed cereal-based food samples, 305 follow-on formulae samples, 395 infant formulae samples and 361 processed cereal-based foods for infants and young children. From the overall number of baby food samples analysed, 413 samples were flagged as organic samples. Of the total, 413 baby food samples were flagged under EU MACP.

The percentage of samples with no quantifiable residues was 91.7% (1,505 samples), lower than in 2019 but practically the same as in 2018 (97.8% in 2019 and 90.3% in 2018). Quantified residues (at or above the LOQ but below the MRL) were found in 6.5% of cases (107 samples), which was higher than in 2019 (0.9%) but lower than in 2018 (9.7%). The MRL exceedance rates was reported at 1.7% (29 samples), slightly higher than in 2019 and 2018 (1.3%). Considering the measurement uncertainty, 0.1% of the samples were non-compliant (three samples).

Regarding the analytical determinations, 792 different pesticides were analysed, of which nine different substances were quantified in concentrations at or above the LOQ. The most frequently found

<sup>&</sup>lt;sup>46</sup> Bromide ion concentration in organic ranged between 0.13 mg/kg and 54.5 mg/kg.

<sup>&</sup>lt;sup>47</sup> Its findings may include residues of two approved fungicides: disodium phosphonate and phosphonic acid, the latter resulting from the use of potassium and disodium phosphonates (which can also be used as foliar feed fertiliser). A new residue definition for enforcement expressed as phosphonic acid is derived by EFSA (2021d).

<sup>&</sup>lt;sup>48</sup> Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed – Council statement. OJ L 140, 30.5.2002, p. 10–22.

<sup>&</sup>lt;sup>49</sup> Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. OJ L 25, 2.2.2016, p. 1–29.



pesticides (in more than five samples) were copper compounds (108 samples), bromide ion (13 samples) and chlorates (six samples).

Copper presence was found in follow-on formulae, infant formulae and processed cereal-based baby foods. It is a microelement authorised in the formulae's manufactured from cows' milk proteins or protein hydrolysates<sup>47,50</sup> (EFSA, 2014).

Bromide ion was found in 'baby foods other than processed cereal-based foods' type. 51

Chlorates was found in follow-on formulae, infant formulae and processed cereal-based foods for infants and young children also derived from sanitation practice in food industrial processes.

Assessing the risk on baby food samples is done using a different methodology than the one applied in this report (EFSA, 2018c). However, the one used in section 5 (EFSA, 2019f) uses food consumption data from children.

# 4.3.3. Results on animal products

Animal product results were reported for 12,142 samples. Of those, 11,167 samples were free of quantifiable residues (92.0% vs. 91.2% in 2019) while 830 samples (6.8% vs. 8.8% in 2019) contained one or several pesticides in quantifiable concentrations but below or equal to the MRL. MRL exceedances were identified in 145 samples (1.2% vs. 0.6% in 2019 vs. 1.7% in 2018) of which, 94 samples (0.8%) were non-compliant considering measurement uncertainty.

The most frequently quantified substances (above 50 samples reported) were copper compounds (RD) (488 samples), DDT (RD) (131 samples), hexachlorobenzene (RD) (118 samples), thiacloprid (RD) (88 samples), mercury (RD) (52 samples).

Among the pesticide findings leading to MRL exceedances, copper compounds (RD) (43 samples) mainly bovine liver (19 samples) and in honey (16 samples), bromide ion (RD) (42 samples)<sup>52</sup> mainly in bovine liver (19 samples) and honey (14 samples), BAC (RD) (13 samples) and DDAC (RD) (eight samples) in bovine liver (15 samples) and cream products (12 samples), chlordecone (RD) (eight samples) in chicken eggs and chlorfenvinphos (RD) in honey (seven samples) were the highest.

Copper findings tend to be linked not only as a used as a pesticide but as feed supplement taken up by dietary in livestock. If in the soil, can be taken up by the plant and in the flowering season taken up by bees explaining its presence in honey.

The persistence of DDT and hexachlorobenzene as known POPs would explain their presence in fat tissues and milk.

Findings of mercury compounds are due to its ubiquitous distribution, both from natural and anthropogenic sources, and capability of organomercury species to permeate through biological membranes. BAC/DDAC findings due to chlorinated by-products mainly found in cream as a milk-derived product.

In honey, 879 samples were reported. In 710 samples (80.7%), no quantifiable levels of residues were reported (residues were below the LOQ). The number of samples with pesticide residues within the legally permitted levels (at or above the LOQ but below or at the MRL) were 121 samples (13.8%). MRLs were exceeded in 48 samples (5.5%), of which 31 samples (3.5%) were found to be noncompliant based on the measurement uncertainty. In total, 30 different pesticides were found. The most frequent were thiacloprid (88 samples) and acetamiprid (26 samples) but lead to two and one MRL exceedances, respectively. Thiacloprid grace period lasts until 3 February 2021 when uses should stop at EU level.

EFSA recommends reporting countries keep analysing animal products for these substances.

Despite no MRLs are applicable to fish under Regulation (EC) No 396/2005, 962 fish samples were reported covering an analytical scope of 318 pesticides. Sixty-one samples (6.3%) were reported to have pesticide residue levels quantified at or above the limit of quantification in five different pesticides (47 results in DDT (RD) mainly in sea bass, Pacific salmon and herrings), six determinations in pendimethalin (RD) mainly in Rainbow trout, four determinations in hexachlorobenzene (RD) in herrings, three determinations in BAC (RD) and one determination in glyphosate (RD)).

Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes. OJ L 25, 2.2.2016, p. 30–43.

<sup>&</sup>lt;sup>51</sup> Bromide ion concentrations found range between 0.18 mg/kg and 2.2 mg/kg.

 $<sup>^{52}</sup>$  Bromide ion concentration ranged from 0.1 mg/kg to 5.8 mg/kg  $\,$ 



### 4.4. Reasons for MRL exceedances

The legal limits (MRLs) are established based on supervised residue trials that reflect the residue levels expected under field conditions or, for animal products, animal feeding studies based on appropriate dietary requirements of different food-producing animals. The MRL value is estimated using statistical methods and is usually established to cover at least the upper confidence interval of the 95th percentile of the expected residue distribution. Therefore, a percentage of approximately 1% of MRL exceedances are expected even if good agricultural practices (GAP) are fully respected.

In 2020, out of 88,141 samples reported, 5.1% of samples contained pesticide residues exceeding their respective MRLs (4,475 samples). The MRL exceedance rate in 2019 was 3.9% and in 2018 was 4.5%.

Several possible reasons for MRL exceedances are summarised below:

- For samples coming from third countries:
  - The use of non-approved pesticides for which no import tolerance is in place (either because not requested or because having done so, the request was unsuccessful) (e.g. chlorpyrifos in sweet peppers, and grape leaves, chlorpyrifos-methyl in sweet peppers or pomegranates, carbendazim in grape leaves and rice, thiamethoxam in rice, chlorfenapyr in tomatoes, tricyclazole in rice.
  - GAP not respected: use of approved pesticide beyond the recommended dose (pyridaben and acetamiprid in sweet peppers/bell peppers)
  - Degradation product of an approved pesticides (approval of dimethoate during 2020 degrading into omethoate in chili peppers)
  - Presence of contaminants with unknown origin in concentrations exceeding the legal limit (e.g. anthraquinone in tea).
  - Processing techniques used in third countries mainly with the view to reduce microbiological contamination (i.e. Salmonella sp. In sesame seeds), found to lead to harmful residues (e.g. ethylene oxide in sesame seeds)
- For samples originating from the internal market (reporting countries):
  - GAP may not be adhered to changes to the published GAP application rates, preharvest intervals, number or method of applications of the pesticide product (e.g. iprodione in kales, propamocarb in table grapes).
  - Degradation product of an approved pesticides (approval of dimethoate during 2020 degrading into omethoate in peaches)
  - Drift contamination resulting from inappropriate application during adverse weather conditions (e.g. prosulfocarb)
  - Misuses of an approved pesticide: use of an approved pesticide not authorised on the specific crop as recommended in the GAP (e.g. lambda-cyhalothrin and cyantraniliprole in kales, glyphosate in millet)
  - Use of non-EU approved pesticides (e.g. linuron in celeriacs/turnip-rooted celeries) that have not been subject to emergency authorisations<sup>53</sup> granted during 2020.
  - Natural presence of the substance in the crop (e.g. bromide ion in organic) and ubiquitous contaminants (e.g. mercury in animal matrices)
  - Presence of biocide residues used as pesticides in the past and continuing to be monitored under the pesticide legislation (Regulation (EU) No 528/2013<sup>54</sup>) (e.g. chlorate in lettuce and salads).
  - Contamination of commodities stored in facilities where non-approved fumigants were used in the past (e.g. chlorpropham in carrots, oranges and dried beans).
  - Environmental contamination of persistent organic pollutants (POP) included in the Stockholm Convention of prohibited substances (UNEP, 2001). These substances are no longer used as pesticides but are very persistent in the environment and found to contaminate and concentrate in the food chain (e.g. Hexachlorobenzene (RD) in fat of different species: bovine, poultry and sheep).

<sup>&</sup>lt;sup>53</sup> An emergency authorisation in accordance with Article 53 of Regulation (EC) 1107/2009<sup>7</sup>.

<sup>&</sup>lt;sup>54</sup> Regulation (EU) No 528/2012 of the European Parliament and of the council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L167, 27.6.2012, p. 1–123



More details on the pesticide/crop combinations exceeding the legal limits are compiled in Annex III – Table 3.2.

# 5. Dietary exposure and analysis of health risks

Regulation (EC) No 396/2005, Article 32, requests EFSA to conduct an analysis on the health risks to European consumers and publish this within its annual report on pesticide residues. This analysis is based on the results from the official controls provided by reporting countries. The analysis of the risk to health posed by the finding of residues is aided by the assessment of data on food consumption.

Monitoring data are reported to EFSA based on two different sampling plans. One, the EU MACP which relies on random sampling. The other derives data from the various national programmes (MANCP) that are carried out following risk-based sampling (Art. 30 of Regulation (EC) No 396/2005).

The analysis of the health risk to consumers within this report has been performed using the deterministic Pesticide Residues Intake Model (PRIMo) (EFSA, 2019f). This methodology bases its calculations on conservative model assumptions and integrates the principles of the WHO methodologies for acute and chronic risk assessment (FAO, 2017). The model has been adjusted to allow for food consumption data from the EU population. The file including the exposure assessments is presented in Annex II.

Two types of dietary exposure assessment were performed:

- The acute exposure assessment assumes that a 'large portion' of a commodity is consumed within a short period of time, typically on a single day or meal. There have been no changes to this approach from that published previously (EFSA, 2016b,2019a).
- The chronic exposure assessment estimates the dietary exposure from the average concentration of a pesticide residue in food commodities and the average daily consumption of these over a prolonged time period. The chronic dietary exposure to pesticides was estimated for all food items for which average consumption data were available in PRIMo revision 3.1 and for which residue concentrations were reported.

To analyse acute (short-term) and chronic (long-term) risks to consumer health, EFSA relates dietary exposure to the amount of a residue consumed with its corresponding health-based guidance value. Health-based guidance values set residue intake levels at a limit, above which possible negative health effects cannot be excluded, i.e. there is a possible risk to consumer health.

- For acute risk assessment, the acute dietary exposure from a pesticide residue is compared to the substance's acute reference dose (ARfD, in mg of residue/kg body weight (bw)).
- For chronic risk assessment, the chronic dietary exposure from a pesticide residue is compared to the substance's acceptable daily intake (ADI, in mg of residue/kg bw per day). In some cases, and due to the absence of derived ADI, tolerable daily intake (TDI, in mg of residue/kg bw per day) was used.

Based on current scientific knowledge, when the dietary exposure to a substance is found to be lower than or equal to its health-based guidance value, the risk to health for the consumer is low. When it exceeds its health-based guidance value, then possible negative health outcomes cannot be excluded.

With respect to cumulative risk assessment (CRA), a joint action plan<sup>55</sup> was agreed in February 2021 between the European Commission and EFSA for accelerating the development and gradual implementation into regulatory practice.

Within the action plan, a prioritisation method is being developed to identify the most relevant active substances and organs/systems for CRA. This method is based on probabilistic modelling and will be implemented for the first time on the basis of the pesticide monitoring data collected under the 2019 EU-coordinated control programme. The outcome will be described in an EFSA scientific report to be issued in 2022 and will govern the future establishment of cumulative assessment groups (CAGs).

At longer term, the prioritisation of substances and organs/systems is intended to be repeated on a triennial basis, and gradually integrated in the annual report on pesticide residues. This will allow EFSA to better identify possible changes in exposure patterns to single pesticides which may impact the level of cumulative risks.

<sup>55</sup> https://ec.europa.eu/food/system/files/2021-03/pesticides\_mrl\_cum-risk-ass\_action-plan.pdf



### 5.1. Acute risk assessment

The acute risk assessments were restricted to the pesticide/crop combinations as laid down in the 2020 EU MACP, but used the data collected under both the EU MACP and the MANCP sampling plans.

Preference was given to ARfDs established by EFSA under regulations (EC) No 1107/2009. Active substances for which EFSA's most recent assessment could not conclude on the establishment of HBGVs were treated according to one of the following two cases:

- a) The substance lacks a demonstrated genotoxic potential *in vivo* (e.g. insufficient data). In such case, a tentative acute risk assessment was conducted using an ARfD based on the current knowledge.
- b) The substance was concluded to be an *in vivo* mutagen. In such cases (e.g. omethoate), is considered not possible to set any HBGV and any residue of the substance needs to be considered as causing a health risk (EFSA, 2017).

For substances that were never reviewed by EFSA, ARfDs established by other bodies were used. In cases were due to lack of toxicological data or no assessment done there was not available ARfDs, ADI/TDI values were used as a surrogate of the ARfD. These assessments were sometimes considered tentative.

The ARfD values used in this assessment for the active substances covered by the 2020 EU-coordinated multiannual programme are reported in Annex  $\overline{\text{III}}$  – Table 3.5, indicating if the assessment is considered tentative.

Overall, the acute assessment considers the results submitted for  $186^{56}$  pesticides covering the 12 food products in the 2020 EU MACP: carrots, cauliflowers, kiwi fruits (green, red, yellow), onions, oranges, pears, potatoes, dried beans, rice, rye, bovine liver and poultry fat from a total of 17,494 samples. Nearly 30.1% of samples (5,417 samples) were taken under the framework of the national programmes for the above-mentioned crop/pesticide combinations.

# **5.1.1.** Methodology for the estimation of acute exposure

The acute dietary exposure to pesticides was calculated using the International Estimation of Acute Intake (IESTI) equation, based on the methodology as described by the experts of the Joint Meeting on Pesticide Residues (JMPR) (FAO, 2017). This methodology was implemented by EFSA into the PRIMo model as follows:

- Each food item records the highest measured residue concentration reported to EFSA and it is assumed that a large portion<sup>57</sup> per item is consumed. Thus, the highest residue level measured at or above the LOQ was identified for each single pesticide/crop or product combination and used in the acute exposure estimate. This also applied to bulk samples in the context of this report (e.g. dried beans, rice or rye) where normally for these types of commodities, the average value is used. This is an extra conservatism in the approach followed by EFSA. To retrieve the highest residue concentration for rye, results from raw grains and whole grain flour<sup>58</sup> were pooled. To retrieve the highest residue concentration for rice, results from polished were pooled to husked rice.<sup>59</sup>
- The residue concentration in the first unit of a food product consumed can be five to seven times higher than that measured in the samples. The approach followed by EFSA uses the so-called unit variability factor which aims to cover the non-uniform residue distribution among the individual samples. For food commodities with a unit weight of more than 250 g (i.e. cauliflower), a variability factor of 5 is applied. For mid-sized products (i.e. carrots, kiwi fruits (green, red, yellow), onions, orange, pears and potatoes) with a unit size anywhere from 25 to 250 g, a variability factor of 7 is applied; no variability factor is used for commodities with unit

<sup>&</sup>lt;sup>56</sup> The total number of pesticides covered by 2020 EU MACP is 186. However, for dithiocarbamates entry, six different scenarios are considered for the different active substance quantified as CS<sub>2</sub>, raising the number to 191 pesticides.

Normally, the 97.5th percentile of the daily food consumption reported in food surveys considers only those people who have consumed the pertinent food item during the reference period.

<sup>&</sup>lt;sup>58</sup> According to the 2020 EU MACP control programme, samples of rye whole grain flour could have been taken in case samples of grain were not available for monitoring purposes.

<sup>&</sup>lt;sup>59</sup> Despite MRLs in rice are applied to husked rice, the EU MACP allowed the sampling of polished rice grain.



weights less than 25 g, or composite or animal products (i.e. dried beans, rice, rye, bovine fat or poultry fat).<sup>60</sup>

- The exposure calculations were carried out independently for each pesticide/crop or product combination as it is considered unlikely that a consumer would eat two or more different food products in large portions within a short period of time and that all these food products would contain residues of the same pesticide at the highest level observed during the reporting year.
- The analysis of samples refers to the unprocessed raw commodity which has not undergone any treatment. Considering that some food items may undergo treatment before consumption (e.g. washing, peeling, cooking, etc.), processing factors were introduced in the estimation of the exposure for specific pesticide/crop combinations when available (e.g. use of peeling factors for the estimation of the exposure to imazalil in oranges). The source to retrieve processing factor to refine exposure was the EU processing factor database (Scholz, 2018). For those assessed commodities without a PF, it is assumed that before and after treatment, the same residual levels are present and consumed. Annex II Table 2.6 contains a list of the processing factors for pesticide/crop combinations used in the context of this report.
- To be aligned with the approach used in CRA on the type of samples included in the assessment, only samples obtained through selective or objective sampling were retained (SSD codes ST10A and ST20A). Samples obtained through suspect sampling (ST30A) were considered not representative for this assessment and as such excluded (EFSA, 2021b).
- Residue levels of fat-soluble pesticides reported as poultry meat<sup>61</sup> for which results were expressed on the whole product, were recalculated to fat basis, assuming a default fat content of 10% (if fat percentage was not reported) (FAO, 2017). This approach was implemented only in the case of samples with quantified residues (results ≥ LOQ).
- Pesticide/commodity combinations for which no sample had quantified residues were not considered in the acute exposure assessment. These are assumed to represent a no-residue/ no-exposure situation.
- The exposure estimation to pesticides was based on the residue definition employed for enforcement (which is in accordance with the EU MRL legislation), and not the residue definition for risk assessment. The residue results for commodities tested under the monitoring programmes refer only to the residue definition for enforcement.

The above constitutes the assumptions to calculate the acute exposure to pesticides for each food item analysed.

#### **5.1.2.** Results

The results of the acute risk assessment are summarised in Figure 1. The numbers in the cells are read and interpreted based on the following information:

- Numbers in the cells express the exposure as a percentage of the ARfD (or ADI/TDI, if ARfD not available). Each result corresponds to the sample containing the highest residue concentration in the respective pesticide/food combination (this is the most conservative estimate).
- When PF have been used to refine the exposure, the % of ARfD resulted has been marked with a `F'.
- When no numbers are reported in the cells, either (i) no residues were quantified in any sample for that specific pesticide/food combination (i.e. residue concentration < LOQ), (ii) the acute risk assessment is not relevant and therefore not calculated (bromide ion)<sup>62</sup> or (iii) the acute risk assessment is relevant but not calculated due to the absence of health-based guidance values or deemed mutagenic (i.e. isocarbophos and omethoate, respectively).

<sup>&</sup>lt;sup>60</sup> In 2017, JMPR recommended using a variability factor of 3 (which is the rounded mean of 2.8) for all commodities (FAO, 2017). At EU level, the choice of the most appropriate variability factor to be used for the acute risk assessment is still under discussion. Under CRA, for Tier II scenario a variability factor of 3.6 is applied to all commodities having a unit weight above 25g (EFSA, 2019c).

<sup>61</sup> Within the 2020 EU MACP, poultry meat could be sampled in accordance with Table 3 of Annex to Directive 2002/63/EC.

<sup>&</sup>lt;sup>62</sup> The absence of acute HBGV for bromide ion based on JMPR/FAO (FAO, 1988) would require a reassessment of its toxicological profile.



The colour of the plot cells should be interpreted as follows:

- White cells in the grid refer to zero quantified residues (i.e. residue concentration < LOQ in all samples) or where an ARfD was unnecessary or not otherwise available.
- Yellow cells indicate that the exposure was lower than the pesticide's ARfD, i.e. where values did not exceed 100% of the acute reference value.
- Red cells indicate a potential risk to consumer health because the exposure is higher than the
  pesticide's ARfD; light red cells correspond to acute exposure estimates ranging from above
  100% to 1000% of the ARfD, and dark red cells correspond to acute exposure estimates
  above 1000% of the ARfD.
- Grey cells refer to pesticide/crop combinations not covered by the 2020 EU MACP.
- Residues marked with an asterisk (\*) refer to pesticide/crop combinations with quantified residues for which the health-based guidance values (ADI/ARfD) are not available.

For the acute risk assessment of the 2020 results, EFSA considered the following:

- For the legal residue definition of fenvalerate containing esfenvalerate (a compound with a different toxicological profile), the acute risk assessment was based on the ARfD of the authorised active substance esfenvalerate.
- In most cases, dithiocarbamates were analysed using a common moiety method measuring CS<sub>2</sub>. However, this method is lacking specificity towards the individual active substances applied in the field. Therefore, five different scenarios assigned the CS<sub>2</sub> concentrations measured to either mancozeb, maneb, propineb, thiram or ziram, as each one of these has a different toxicological profile. For metiram, no ARfD was considered necessary. Thus, no metiram scenario is considered.
- For bromopropylate (RD), chlordane (RD), heptachlor (RD), hexachlorobenzene (RD), alpha-hexachlorocyclohexane (RD), beta-hexachlorocyclohexane (RD), hexaconazole (RD), methoxychlor (RD) and permethrin (RD), the acute risk assessment was performed with the available ADI reference value. ARfD values are not currently available for these pesticides. The use of the ADI instead of the ARfD is a possible additional conservative element to consider in the risk assessment because for most pesticides, the ADI is set at a lower level than the ARfD.

Among the 186 pesticides in 17,494 food samples, the acute risk assessment results were as follows (Figure 1):

- No health-based guidance values (ARfD) were allocated for three pesticides: bromide ion (RD), isocarbophos and omethoate. <sup>63</sup> These pesticides are marked with footnote c) in Figure 1.
- The setting of an ARfD was not necessary for 33 pesticides. Therefore, acute adverse effects to the consumer would not be expected for the following substances: 2-phenylphenol (RD), ametoctradin (RD), azoxystrobin (RD), biphenyl (RD), boscalid (RD), bupirimate (RD), chlorantraniliprole (RD), clofentezine (RD), cyazofamid (RD), cyprodinil (RD), DDT (RD), diethofencarb (RD), diflubenzuron (RD), diphenylamine (RD), ethirimol (RD), etoxazole (RD), fenhexamid (RD), fludioxonil (RD), flufenoxuron (RD), hexythiazox (RD), iprovalicarb (RD), kresoxim-methyl (RD), lufenuron (RD), mandipropamid (RD), metrafenone (RD), pencycuron (RD), pyrimethanil (RD), quinoxyfen (RD), spirodiclofen (RD), tebufenozide (RD), teflubenzuron (RD), tetradifon (RD), triflumuron (RD). These pesticides are marked with footnote a) in Figure 1.
- There were no quantified results for 32 pesticides, in any of the tested samples of the commodities under the 2020 EU MACP. These pesticides were aldicarb (RD), chlordane (RD), cyflufenamid (RD), cymoxanil (RD), dicloran (RD), diniconazole (RD), ethion (RD), fenamidone (RD), fenarimol (RD), fenbuconazole (RD), fenpropidin (RD), fenpropimorph (RD), fenpyrazamine (RD), fenthion (RD), fluquinconazole (RD), flusilazole (RD), formetanate (hydrochloride) (RD), heptachlor (RD), lindane (RD), mepanipyrim (RD), methomyl (RD), methoxychlor (RD), monocrotophos (RD), oxadixyl (RD), oxydemeton-methyl (RD), parathion-methyl (RD), proquinazid (RD), spiromesifen (RD), terbuthylazine (RD), thiodicarb (RD), triadimefon (RD) and vinclozolin (RD). Acute dietary exposure to any of these pesticides would not be expected to pose a concern to consumer health.
- Quantified levels resulting in exposures below the health-based acute reference values in all tested samples of the commodities under the 2020 EU MACP were observed for 87 pesticides.

<sup>&</sup>lt;sup>63</sup> For omethoate no HBGV has been derived due to in vivo mutagenicity being demonstrated (EFSA, 2017.



The specific pesticides were 2,4-D (RD), abamectin (RD), acephate (RD), acrinathrin (RD), azinphos-methyl (RD), bifenthrin (RD), buprofezin (RD), carbofuran (RD), chlorfenapyr (RD), chlorothalonil (RD), chlorpyrifos-methyl (RD), clothianidin (RD), cyfluthrin (RD), cyproconazole (RD), cyromazine (RD), diazinon (RD), dichlorvos (RD), dicofol (RD), dieldrin (RD), difenoconazole (RD), dimethomorph (RD), dithianon (RD), emamectin (RD), endosulfan (RD), epoxiconazole (RD), ethephon (RD), etofenprox (RD), famoxadone (RD), fenazaquin (RD), fenbutatin oxide (RD), fenitrothion (RD), fenoxycarb (RD), fenpropathrin (RD), fenvalerate (RD), fipronil (RD), fluazifop (RD), flubendiamide (RD), fluopicolide (RD), fluopyram (RD), flutriafol (RD), fluxapyroxad (RD), folpet (RD), glyphosate (RD), haloxyfop (RD), alphahexachlorobenzene (RD), beta-hexachlorocyclohexane (RD), hexachlorocyclohexane (RD) hexaconazole (RD), imidacloprid (RD), iprodione (RD), isoprothiolane (RD), linuron (RD), malathion (RD), metalaxyl and metalaxyl-M (RD), methamidophos (RD), methidathion (RD), methoxyfenozide (RD), myclobutanyl (RD), paclobutrazol (RD), parathion (RD), penconazole (RD), pendimethalin (RD), permethrin (RD), pirimicarb (RD), pirimiphos-methyl (RD), procymidone (RD), profenofos (RD), propamocarb (RD), propargite (RD), propiconazole (RD), propyzamide (RD), prosulfocarb (RD), prothioconazole (RD), pyridaben (RD), pyriproxyfen (RD), spinosad (RD), spirotetramat (RD), spiroxamine (RD), tau-fluvalinate (RD), tebufenpyrad (RD), tetraconazole (RD), thiamethoxam (RD), tolclofos-methyl (RD), triadimenol (RD), triazophos (RD), tricyclazole (RD), trifloxystrobin (RD). Acute dietary exposure to these pesticides would not be expected to be of concern to consumer health.

• There were 30 different pesticides quantified in 180 samples out of 17,494 samples (1.0%) of the 2020 EU MACP food items at levels exceeding their respective health-based acute reference values: phosmet (RD) (57 samples), cypermethrin (RD) (24 samples), dimethoate (RD) (17 samples), chlorpyrifos (RD) (11 samples), thiabendazole (RD) (nine samples), indoxacarb (RD) (eight samples), pyraclostrobin (RD) (seven samples), acetamiprid (RD) (five samples), carbendazim (RD) (four samples), deltamethrin (RD) (four samples), lambdacyhalothrin (RD) (three samples), methiocarb (RD) (three samples), thiacloprid (RD) (three samples), bromopropylate (RD) (two samples), tebuconazole (RD) (two samples), fosthiazate (RD) (two samples), chlorpropham (RD) (two samples), oxamyl (RD) (one sample), chlormequat-chloride (RD) (one sample), flonicamid (RD) (one sample), dodine (RD) (one sample), carbaryl (RD) (one sample), mepiquat chloride (RD) (one sample), captan (RD) (one sample) and fenpyroximate (RD) (one sample).

The ARfD exceedances were distributed among pears (106 samples), oranges (45 samples), rice (two samples), potatoes (15 samples), carrots (four samples), cauliflower (three samples), dried beans (three samples), and kiwi fruits (green, red, yellow) (two samples). The available acute health-based guidance values were not exceeded in onions, rye grain and animal commodities (bovine liver and poultry fat).

A more detailed analysis by pesticide exceeding in nine or more samples the ARfD is presented in the following paragraphs.

#### Dithiocarbamates (RD)

Not knowing the precursor dithiocarbamate originating the exceedance of the acute health-based guidance value, the number of samples link to this residue cannot be given. Building different scenarios based on the different precursors, the commodities in which the acute health-based guidance values were exceeded were:

- oranges and pears in maneb scenario,
- oranges and pears in mancozeb scenario,
- oranges, pears and dried beans in propineb scenario,
- oranges, pears, potatoes and dried beans in thiram scenario,
- oranges, pears and dried beans in *ziram scenario*.

In metiram scenario, the ARfD was not deemed necessary; thus, a risk evaluation was not undergone.

In 2020, mancozeb, metiram and ziram were approved for use in the EU. The evaluation for renewal of the approval is pending for metiram and ziram, while for mancozeb, a decision for



non-renewal was taken at the end of 2020.<sup>64</sup> Maneb, propineb and thiram are not approved for use in EU since 2017 (maneb) and 2018 (propineb and thiram). Therefore, exceedances of the ARfD for these dithiocarbamates may only be related to an illegal use.

EFSA is currently performing a comprehensive MRL review for all dithiocarbamates authorised uses, taking into consideration their different approval status, the naturally occurring background levels of CS<sub>2</sub> and any import tolerance in place.

EFSA recommends deriving processing factors to refine exposure assessments in cases where any active substance of the group remains approved for use to allow refining exposure, if needed.

#### Phosmet (RD) (57 samples)

A recent EFSA peer review assessment of the active substance phosmet (EFSA, 2021a) decreased the ARfD from 0.045 to 0.001 mg/kg bw. Thus, 57 samples exceeded the new ARfD value in pears (54 samples), oranges (two samples)<sup>65</sup> and kiwi fruits (green, red, yellow) (one sample).

Phosmet was an approved active substance in 2020, but a decision of non-renewal of approval has been taken in 2022 according to Regulation (EU) No 2022/94.66 Grace period granted by MS shall expire 1 November 2022.

# Cypermethrin (RD) (24 samples)

Cypermethrin is constituted of four diastereomeric pairs of enantiomers (alpha, beta, theta and zeta) falling into a common residue definition cypermethrin including other mixtures of constituent isomers (sum of isomers). In 2020, cypermethrin, alpha-cypermethrin and zeta-cypermethrin were approved for use in EU.

Cypermethrin (RD) residues exceeded the % of ARfD in oranges (16 samples), pears (four samples), dried beans (one sample), carrots (one sample) and potato (one sample).

In oranges, the highest concentration reported was 0.12 mg/kg, whereas in pears and in potatoes, the highest concentration was 0.15 mg/kg and 0.039 mg/kg, respectively. None of these samples were reported to have exceeded the MRL. No PF were available to refine the exposure calculations. Possible consumer intake concerns for some commodities were already highlighted during the peer review for the renewal of cypermethrin and alpha-cypermethrin (EFSA, 2018d,e). Consequently, EFSA is currently performing a comprehensive MRL review of the authorised uses of all cypermethrins. Based on the ARfD exceedances, mostly in oranges, and to the low toxicological reference values, it is recommended requiring the authorisation holder to produce processing factors for oranges.

# Dimethoate (RD) (17 samples)

Dimethoate was not approved for use in 2020, with a grace period until the 30 June 2020 (except for cherries, for which the grace period was set earlier, on the 30 September 2019). In EFSA's peer review, the HBGV were not set due to missing data on genotoxic potential. Thus, the approach followed in this report considers using the one based on most current knowledge HBGV (0.0001mg/kg bw) (EFSA, 2018f). Seventeen samples exceeded the % of ARfD. Two of these samples (one carrot sample with concentration of 0.01 mg/kg and the other dried bean sample with concentration of 0.006 mg/kg) were below the MRL stablished before the grace period ended. The rest of the samples exceeded the MRL in oranges (13 samples), potato (one sample) and kiwi fruits (green, red, yellow) (1 sample). The highest % of ARfD was for an orange sample grown in Europe for which an RASFF notification alert was issued.

As dimethoate will no longer be approved for used in the EU in 2021, EFSA recommends reporting countries continuing monitoring the presence of dimethoate within random sampling programmes to ensure a good representation of the EU market.

Regulation (EU) No 540/2011. OJ L 16, 25.1.2022, p. 33-35.

<sup>&</sup>lt;sup>64</sup> Commission Implementing Regulation (EU) 2020/2087 of 14 December 2020 concerning the non-renewal of the approval of the active substance mancozeb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 423, 15.12.2020, p. 50-52.

<sup>&</sup>lt;sup>65</sup> In oranges, an average peeling factor of 0.04 (Scholz R, 2018) was used to refine exposure.

<sup>66</sup> Commission Implementing Regulation (EU) 2022/94 of 24 January 2022 concerning the non-renewal of the approval of the active substance phosmet, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council



#### Chlorpyrifos (RD) (11 samples)

Chlorpyrifos was not approved for use in 2020, but a grace period was set until the 16 April 2020. In EFSA's peer review (EFSA, 2019b), the HBGV were not set due to missing data on genotoxic potential. Thus, the approach followed in this report considers using the previously stablished HBGV (0.005 mg/kg bw) for a tentative assessment. Residues in 11 samples exceeded the ARfD as well as the MRL, except for one sample with concentration equal to 0.082 mg/kg that was below the MRL on carrots (0.1 mg/kg). Already Regulation (EU) No 2020/1085<sup>67</sup> lowered the MRL to 0.01\*.

To refine exposure for oranges and rye, average PF were used (0.03 peeling factor for oranges and 0.36 refined flour for rye) (Scholz, 2018).

# Thiabendazole (RD) (nine samples)

Residues of thiabendazole (RD) exceeded the % of ARfD in nine samples of oranges using an average peeling factor of 0.17 (Scholz, 2018). Three of these samples exceeded the MRL set at 7 mg/kg and assessed using PRIMo revision 2 (EFSA, 2016a).

A more recent EFSA opinion (EFSA, 2021c), this time using PRIMO rev 3.1, proposes a peeling factor of 0.047. By using this lower PF, the exposure will be significantly reduced. Further, in this opinion EFSA proposed lowering the MRL for oranges to 5 mg/kg. This has not been taken by legislation in the most recent adopted Regulation (EU) No 2021/1807<sup>68</sup> due to an existing CODEX MRL of 7 mg/kg for thiabendazole.

EFSA recommends an update of the EFSA (EU) database on PF.

Regarding omethoate (RD), in the frame of the EU MACP was quantified in orange (three samples), carrots (one sample), onion (one samples) and kiwi fruits (one sample). Despite the residue definition was split, omethoate presence is linked to dimethoate degradation. Omethoate was not approved in the EU in 2020 and has been proven to be *in vivo* mutagenic agent (EFSA, 2017). In 2021, MRLs for omethoate have been lowered to the LOQ value. <sup>69</sup> The exposure estimate using the food consumption data in EFSA PRIMo rev. 3.1 is presented in Table 1.

**Table 1:** Estimated acute exposure to omethoate without ARfD/ADI values

Pesticide	Food product	Acute exposure (in mg/kg bw per day)
Bromide ion (RD)	Rice	0.6430
Omethoate (RD)	Carrots Kiwi fruits (green, red, yellow) Onions Oranges	$1.0 \times 10^{-4}$ $1.0 \times 10^{-3}$ $1.0 \times 10^{-4}$ $1.5 \times 10^{-4}$

In the frame of the EU MACP, bromide ion (RD) was only to be analysed in rice. Pending the revision of the toxicological profile of bromide ion by JMPR, acute exposure calculations were not carried out because an ARfD is not available (EFSA, 2013). An estimation of the acute exposure using the food consumption data from EFSA PRIMo rev. 3.1 is presented in Table 1. The presence of bromide ion in food is likely to be from natural sources. Hence, EFSA recommends reconsidering the available information and the reference values, investigating the degradation of active substances containing bromide ion as well as considering its natural sources.

Overall, the results of the acute exposure assessment reflect the outcome of a deterministic method which uses several conservative assumptions. In all cases, the exposure calculations were performed for extreme consumers, where large portions were considered, the variability factor taken for carrots, kiwi, onions, orange, pears and potatoes was 7 (i.e. the highest residue in one individual unit due to a lack of uniformity for the sample could be seven times higher) and 5 for cauliflower. In

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<sup>&</sup>lt;sup>67</sup> Commission Regulation (EU) 2020/1085 of 23 July 2020 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos and chlorpyrifos-methyl in or on certain products. OJ L 239, 24.7.2020, p. 7–8

<sup>&</sup>lt;sup>68</sup> Commission Regulation (EU) 2021/1807 of 13 October 2021 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, aqueous extract from the germinated seeds of sweet Lupinus albus, azoxystrobin, clopyralid, cyflufenamid, fludioxonil, fluopyram, fosetyl, metazachlor, oxathiapiprolin, tebufenozide and thiabendazole in or on certain products. OJ L 365, 14.10.2021, p. 1–37

<sup>&</sup>lt;sup>69</sup> Commission Regulation (EU) 2021/155 of 9 February 2021 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products. OJ L 46, 10.2.2021, p. 5–33.



some cases, ADI values were used and in others, recent derived ARfD values not known in 2020 increased the conservatism of the assessment. Even if some PFs were applied to refine the exposure considering consumer practices such as peeling, cooking, frying and baking, this was not done consistently for all pesticides due to the lack of appropriate factors.

EFSA recommends a regular update of EFSA (EU) database of PF to be used in the context of enforcement actions stated in the SANTE document. Further, EFSA recommends food business operators (FBO) undergoing processing studies leading to a PF for their own process, later shared with EU MS competent authority to enforce food placed on the EU market, to share that study too with EFSA.

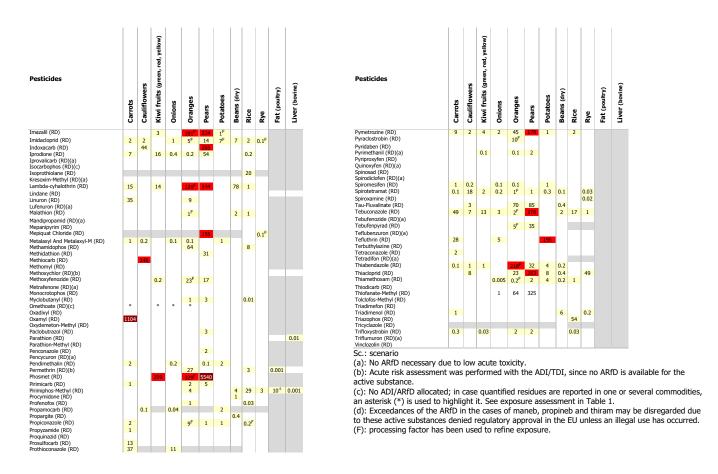
The detailed acute dietary exposure assessment results for the pesticide residues found in the 12 food products covered by the 2020 EU MACP are presented in Appendix B - Figures B.1–B.12. In these charts, the results for samples containing residues at or above the LOQ are presented individually, expressing the exposure as a percentage of the ARfD. The different dithiocarbamate scenarios have not been addressed here.

<sup>&</sup>lt;sup>70</sup> Information note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors and composite food and feed. SANTE/10704/2021.



Carrots	:	Cauliflowers Kiwi fruits (green, red, yellow)	Onions	Oranges	Pears	Potatoes	Beans (dry)	Rice	Rye	Fat (poultry)	Liver (bovine)
	0	.4		26 <sup>F</sup>			0.1	0.04			
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					1						
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a)							12				
				5							
RD)				,	173			0.2	11		
1 2			0.2	1	62	3164 <sup>F</sup>	1				
10:		5 22	0.2	16	424 <sup>F</sup>			25	14 <sup>F</sup>		0.005
RD) 13	0	.3		1	5 <sup>F</sup>			1	0.1 <sup>F</sup>		
				2	5		0.2	0.2			
6				32	23				1		
110		24		308	424	110	140	10	13 <sup>F</sup>	0.04	
110	•	24		10	424	116	148	6	13'	0.04	
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9		3 21		28	127	58 <sup>F</sup>	35	183	16		
								6		3x10 <sup>-5</sup>	
								Ü			
49				1						0.04	0.002
				_		0.7					
12		5	1	7	15	0.3		1			
613		889	)	37184		1635		0.01			
1	U.	05 0.02	0.4	1		1		0.04			





**Figure 1:** Results of acute dietary risk assessment without risk refinement for the highest residues reported by pesticide/crop combination (values are expressed as a percentage of the acute health-based guidance value or ARfD)



### 5.2. Chronic risk assessment

The chronic risk assessment compares the long-term dietary exposure for a pesticide residue (mg of residue/kg bw per day) to that substance's chronic health-based reference value, the acceptable daily intake (ADI in mg of residue/kg bw per day). The ADI values for all the active substances mentioned in this report are found in Annex III – Table 3.5.

# 5.2.1. Methodology for the estimation of chronic exposure

The chronic exposure assessment estimates the dietary exposure to pesticides from food over a long period. Its calculation is based on a deterministic approach developed by JMPR (FAO, 2017). It consists of multiplying the average measured pesticide concentration by the average commodity's daily intake consumption per capita and summing up the results for all commodities within a giving dietary habit.

The assessment deals with samples submitted by the reporting countries for the pesticides covered by the 2020 EU MACP and the MANCP, for unprocessed products covered by Annex I (part A) of Reg. (EC)  $_{\rm No}$  396/2005 for which consumption data are available.

Preference was given to ADI values established by EFSA under regulations (EC) No 1107/2009. Active substances for which EFSA's most recent assessment could not conclude on the establishment of HBGVs were treated according to one of the following two cases:

- a) The substance lacks a demonstrated genotoxic potential *in vivo* (e.g. insufficient data). In such case, a tentative chronic risk assessment was conducted using an ADI based on the current knowledge.
- b) The substance was concluded to be an *in vivo* mutagen. In such cases (e.g. omethoate), is considered not possible to set any HBGV and any residue of the substance needs to be considered as causing a health risk (EFSA, 2017).

For substances that were never reviewed by EFSA, ADIs (in some cases TDIs) established by other bodies were used.

The ADI values used in this assessment for the active substances covered by the 2020 EU-coordinated multiannual programme are reported in Annex  $\overline{\text{III}}$  – Table 3.5, indicating if the assessment is considered tentative.

EFSA calculated three scenarios for chronic exposure assessment and risk assessment: the lower bound, the middle bound and the adjusted upper bound.

- The lower bound scenario assumes that samples with non-quantified residues (i.e. samples with residue levels < LOQ) do not contain any residue. This scenario is the less conservative one, and, as it disregards the contribution of residues eventually present in small amounts below the LOQ, it may result in an underestimation of chronic exposure.
- The adjusted middle-bound scenario assumes that samples with non-quantified residues (i.e. samples with residue levels < LOQ) are present in the sample at level of 1/2 LOQ.<sup>71</sup> This scenario results in a likely chronic exposure overestimate.
- The adjusted upper bound scenario assumes that samples with non-quantified residues (i.e. samples with residue levels < LOQ) are present in the sample at the level of LOQ.<sup>65</sup> This scenario is the most overestimated. Therefore, it represents the most conservative approach.

The lower, adjusted middle- and adjusted upper bound assessments are used by EFSA to frame the boundaries of a more realistic exposure estimate to pesticide residues. The use of LOD to refine the adjusted middle- or upper bound is not used as reporting countries do not systematically report these levels. The aim of the different scenarios is to better address the uncertainties linked to the presence of residues at levels below the LOQ. Further, the adjusted upper bound assessment results are not presented in Table 2 and only adjusted middle-bound in line with CRA.

<sup>&</sup>lt;sup>71</sup> To judge on samples reported without quantifiable residues, SANCO/12574/2015 (rev. 5) (EC, 2018) was applied in those cases of multicomponent residue definitions when resInfo.notSummed=Y. EFSA calculated the sum LOQ based on the individual LOQ reported and the molecular weight factor. This recalculation was used when calculating the mean middle-bound and upper bound scenarios. In case no individual LOQs were reported, EFSA did not recalculate a summed LOQ and disregarded the record.



For these calculated scenarios, the following assumptions were considered:

- The mean residue concentration from the analytical results for any given pesticide/crop combination was used.
- Only results for unprocessed products with available consumption data were used for this exposure calculation.
- Only data on the 186 pesticides listed in 2020 EU MACP and for which the analysis covered their full RD were used. Results of part of a residue definition (i.e. reported as P002A<sup>72</sup>) were not taken into consideration.
- Results from samples analysed with analytical methods for which the LOQ was greater than the corresponding MRL were disregarded.
- If results reported for a given pesticide/crop combination were below the LOQ for all samples analysed, this pesticide/crop combination was excluded from the calculations.
- To be aligned with CRA methodology on the type of samples included in this assessment, only samples obtained through selective or objective sampling were retained (SSD codes ST10A and ST20A). Samples obtained through suspect sampling (ST30A) were considered not representative for this assessment and as such excluded (EFSA, 2021b).
- The estimation of chronic exposure is based on the residue definition for enforcement and not the residue definition for risk assessment.

#### **5.2.2.** Results

In total, 62,850 samples were pooled from the EU MACP and MANCP to be taken in this assessment.

The results of the chronic exposure assessment expressed as percentage of the ADI for each pesticide (lower bound and adjusted middle-bound scenarios) are reported in Table 2. The adjusted middle-bound scenario was considered more relevant than the adjusted upper bound one, in line with cumulative risk assessment methodology and since the upper bound scenario is too overconservative.

For the legal residue of fenvalerate containing esfenvalerate, a compound with a different toxicological profile, the chronic risk assessment was based on the ADI of the authorised active substance esfenvalerate.

For dithiocarbamates, six scenarios were calculated considering that the measured  $CS_2$  concentrations originated exclusively from maneb, mancozeb, metiram, propineb, thiram or ziram, each with a different ADI.

For bromide ion, the chronic risk assessment was conducted using the ADI of 0.1 mg/kg bw per day derived by JMPR/FAO (FAO, 1988). This HBGV has never been formally established at EU level. JMPR assessment is old, and the dossier was incomplete. The ADI is based on human data (NOAEL of 9 mg/kg bw per day, in humans, which is practically the same as NOAEL of 12 mg/kg bw per day, in rats) and only 10 as UF was used. In EFSA's scientific report (EFSA, 2019d), the NOAEL for hypothyroidism was stablished at 12 mg/kg bw per day, based on rat studies in combination with the requirement of an overall threshold for regulatory consideration of 100 (EFSA, 2019d). Therefore, the value finally used was rounded to 0.1. This assessment should be taken as *tentative*.

**Table 2:** Results of the chronic dietary exposure assessment

Pesticide	Chronic exposure (in % of ADI)					
	Lower bound	Adjusted middle bound				
2,4-D (RD)	0.44	0.66				
2-Phenylphenol (RD)	0.14	0.16				
Abamectin (RD)	0.06	7.8				
Acephate (RD)**	0.02	1.4				
Acetamiprid (RD)	0.67	1.2				
Acrinathrin (RD)	0.01	0.54				

<sup>&</sup>lt;sup>72</sup> P002A in accordance with ChemMon Guidance (EFSA, 2021b) means results reported as part of a residue definition for pesticide residues, i.e. individual components of a multicomponent residue definition.



Pesticide	Chronic exposure (in % of ADI)					
	Lower bound	Adjusted middle bound				
Aldicarb (RD)		n.r.				
Ametoctradin (RD)	0.001	0.001				
Azinphos-Methyl (RD)**	0.015	0.79				
Azoxystrobin (RD)	0.23	0.33				
Bifenthrin (RD)	0.153	0.773				
Biphenyl (RD)**	0.0003	0.0056				
Bitertanol (RD)	0.014	1.2				
Boscalid (RD)	1.4	1.8				
Bromide ion (RD)**	22.6	73.1				
Bromopropylate (RD)**	0.005	0.096				
Bupirimate (RD)	0.017	0.19				
Buprofezin (RD)	0.025	1.1				
Captan (RD)	0.784	0.843				
Carbaryl (RD)	0.012	0.856				
Carbendazim (RD)	0.373	0.953				
Carbofuran (RD)	0.201	15.7				
Chlorantraniliprole (RD)	0.005	0.014				
Chlordane (RD)		n.r.				
Chlorfenapyr (RD)**	0.05	0.895				
Chlormequat-Chloride (RD)	1.2	1.3				
Chlorothalonil (RD)	0.102	1.3				
Chlorpropham (RD)	3.5	3.6				
Chlorpyrifos (RD)**	4.0	21.6				
Chlorpyrifos-Methyl (RD)**	0.153	1.5				
Clofentezine (RD)	0.005	0.21				
Clothianidin (RD)	0.0039	0.13				
Cyazofamid (RD)	0.009	0.025				
Cyflufenamid (RD)	0.007	0.199				
Cyfluthrin (RD)	0.017	1.7				
Cymoxanil (RD)	0.013	0.204				
Cypermethrin (RD)	1.3	7.9				
Cyproconazole (RD)	0.013	0.387				
Cyprodinil (RD)	0.723	1.2				
Cyromazine (RD)	0.043	0.122				
DDT (RD)	0.019	4.6				
Deltamethrin (RD)	1.1	3.8				
Diazinon (RD)	0.7	30.5				
Dichlorvos (RD)	0.017	12.0				
Dicloran (RD)	0.0002	0.07				
Dicofol (RD)**	0.002	1.6				
Dieldrin (RD)	0.41	36.5				
Diethofencarb (RD)	0.0001	0.004				
Difenoconazole (RD)	0.0001	2.5				
Diflubenzuron (RD)	0.0009	0.08				
Dimethoate (RD)**	3.8	123				
Dimethomorph (RD)	0.143	0.414				
Diniconazole (RD)	0.143	0.014				



Pesticide	Chronic exposure (in % of ADI)				
	Lower bound	Adjusted middle bound			
Diphenylamine (RD)	0.021	0.180			
Dithianon (RD)	3.2	3.9			
Dithiocarbamates (RD) – maneb sc.	4.9	8.6			
Dithiocarbamates (RD) – mancozeb sc.	11.1	19.5			
Dithiocarbamates (RD) – metiram sc.	35.6	62.5			
Dithiocarbamates (RD) – propineb sc.	10.9	19.2			
Dithiocarbamates (RD) – thiram sc.	14.2	25.0			
Dithiocarbamates (RD) – ziram sc.	47.4	83.3			
Dodine (RD)	0.099	0.189			
Emamectin (RD)	0.225	8.2			
Endosulfan (RD)**	0.013	3.2			
Epoxiconazole (RD)	0.14	1.4			
Ethephon (RD)	1.3	1.7			
Ethion (RD)	0.04	0.197			
Ethirimol (RD)	0.01	0.226			
Etofenprox (RD)	0.282	0.662			
Etoxazole (RD)	0.002	0.14			
Famoxadone (RD)	0.109	0.78			
Fenamidone (RD)**	0.026	0.08			
Fenamiphos (RD)	0.03	5.7			
Fenarimol (RD)	4x10 <sup>-6</sup>	0.0004			
Fenazaquin (RD)	0.013	1.9			
Fenbuconazole (RD)	0.058	1.2			
Fenbutatin Oxide (RD)	0.021	0.126			
Fenhexamid (RD)	0.07	0.129			
Fenitrothion (RD)	0.007	1.3			
Fenoxycarb (RD)	0.007	0.177			
Fenpropathrin (RD)	0.012	0.082			
Fenpropidin (RD)	0.004	0.146			
Fenpropidin (RD)	0.191	1.2			
Fenpyrazamine (RD)	0.003	0.025			
Fenpyroximate (RD)	0.035	1.3			
Fenthion (RD)	0.016	0.056			
Fenvalerate (RD)	0.007	0.691			
Fipronil (RD)	0.13	18.3			
Flonicamid (RD)	0.277	1.3			
. ,					
Fluezifop (RD)	0.053	0.519			
Flubendiamide (RD)	0.002	0.20			
Fludioxonil (RD)	0.289	0.330			
Flurence (RD)	0.009	0.039			
Fluopicolide (RD)	0.015	0.077			
Fluopyram (RD)	1.3	2.6			
Fluquinconazole (RD)**	0.001	0.22			
Flusilazole (RD)	0.006	0.22			
Flutriafol (RD)	0.069	0.914			
Fluxapyroxad (RD)	0.368	1.1			
Folpet (RD)	0.202	0.377			



Pesticide	Chronic exposure (in % of ADI)				
	Lower bound	Adjusted middle bound			
Formetanate (Hydrochloride) (RD)	0.142	1.2			
Fosthiazate (RD)	0.029	1.2			
Glyphosate (RD)	0.03	0.177			
Haloxyfop (RD)	0.600	7.4			
Heptachlor (RD)**	0.03	25.0			
Hexachlorobenzene (RD)**	0.017	62.2			
(α)-Hexachlorocyclohexane (RD)**	0.0015	0.043			
(β)-Hexachlorocyclohexane (RD)**	0.673	287			
Hexaconazole (RD)**	0.015	0.555			
Hexythiazox (RD)	0.015	0.392			
Imazalil (RD)	13.0	13.4			
Imidacloprid (RD)	0.03	0.37			
Indoxacarb (RD)	0.388	3.0			
Iprodione (RD)	0.098	0.590			
Iprovalicarb (RD)	0.016	0.187			
Isocarbophos (RD)*		No ADI			
Isoprothiolane (RD)	0.021	0.027			
Kresoxim-Methyl (RD)	0.0005	0.025			
Lambda-cyhalothrin (RD)	2.0	10.5			
Lindane (RD)**	0.0015	0.309			
Linuron (RD)	0.079	0.890			
Lufenuron (RD)	0.008	0.895			
Malathion (RD)	0.028	0.507			
Mandipropamid (RD)	0.035	0.05			
Mepanipyrim (RD)	0.04	0.187			
Mepiquat chloride (RD)	0.086	0.113			
Metalaxyl and metalaxyl-M (RD)	0.030	0.117			
Methamidophos (RD)	3.4	6.3			
Methidathion (RD)	0.01	2.4			
Methiocarb (RD)	0.144	6.3			
Methomyl (RD)	0.105	2.3			
Methoxychlor (RD)	0.1200	n.r.			
Methoxyfenozide (RD)	0.03	0.143			
Metrafenone (RD)	0.023	0.036			
Monocrotophos (RD)	2.8	9.9			
Myclobutanyl (RD)	0.366	0.91			
Omethoate (RD)*	0.000	No ADI			
Oxadixyl (RD)	0.0003	0.034			
Oxamyl (RD)	0.25	1.7			
Oxydemeton-Methyl (RD)	0.005	0.037			
Paclobutrazol (RD)	0.001	0.325			
Parathion (RD)**	0.0017	0.324			
Parathion-Methyl (RD)	3.002.	n.r.			
Penconazole (RD)	0.031	0.343			
Pencycuron (RD)	0.0002	0.013			
Pendimethalin (RD)	0.0018	0.128			
Permethrin (RD)**	0.03	0.99			



Pesticide	Chronic exposure (in % of ADI)					
	Lower bound	Adjusted middle bound				
Phosmet (RD)	4.1	16.1				
Pirimicarb (RD)	0.09	0.389				
Pirimiphos-Methyl (RD)	4.6	6.9				
Procymidone (RD)**	0.03	0.882				
Profenofos (RD)	0.079	0.150				
Propamocarb (RD)	0.099	0.118				
Propargite (RD)	0.0015	0.253				
Propiconazole (RD)	0.69	1.1				
Propyzamide (RD)	0.001	0.029				
Proquinazid (RD)	0.106	0.771				
Prosulfocarb (RD)	0.099	2.0				
Prothioconazole (RD)	0.006	0.426				
Pyraclostrobin (RD)	0.409	0.883				
Pyridaben (RD)	0.027	0.974				
Pyrimethanil (RD)	1.4	1.4				
Pyriproxyfen (RD)	0.07	0.347				
Quinoxyfen (RD)	0.0003	0.007				
Spinosad (RD)	0.249	0.902				
Spirodiclofen (RD)	0.082	0.990				
Spiromesifen (RD)	0.021	0.140				
Spiroxamine (RD)	0.026	0.292				
Spirotetramat (RD)	0.15	1.1				
Tau-Fluvalinate (RD)	0.127	3.0				
Tebuconazole (RD)	0.326	0.929				
Tebufenozide (RD)	0.04	0.551				
Tebufenpyrad (RD)	0.016	1.3				
Teflubenzuron (RD)	0.008	0.913				
Tefluthrin (RD)	0.005	0.676				
Terbuthylazine (RD)	0.01	1.8				
Tetraconazole (RD)	0.174	3.0				
Tetradifon (RD)**	0.00025	0.124				
Thiabendazole (RD)	1.6	1.7				
Thiacloprid (RD)	0.5	1.9				
Thiamethoxam (RD)	0.141	0.886				
Thiofanate-Methyl (RD)	0.26	0.96				
Tolclofos-Methyl (RD)	0.0007	0.011				
Triadimefon (RD)	0.0002	0.01				
Triadimenol (RD)	0.005	0.221				
Thiodicarb (RD)	0.000	n.r.				
Triazophos (RD)	0.01	0.785				
Tricyclazole (RD)**	0.099	0.603				
Trifloxystrobin (RD)	0.09	0.213				
Triflumuron (RD)	0.376	0.934				
Vinclozolin (RD)	0.570	n.r.				

n.r.: No quantified residues in any of the samples analysed; sc.: scenario.  $\ast$ : Active substance for which no ADI was established.

<sup>\*\*:</sup> Tentative risk assessment.



For heptachlor, hexachlorobenzene, alpha-hexachlorocyclohexane and beta-hexachlorocyclohexane, the chronic risk assessment was performed with TDI reference value. These values have never been formally established at EU level and the toxicological dossiers of these substances are very old. Therefore, these assessments are to be considered tentative.

No chronic consumer intake concerns were identified for any of the European diets incorporated in PRIMo rev. 3.1 when the risk assessment was based on the lower bound scenario. The top three highest chronic risk estimates corresponded to dithiocarbamate (RD) scenarios: ziram 47.4% of the ADI (NL, toddler), metiram 35.6% of the ADI (NL, toddler) and thiram 14.2% of the ADI (NL, toddler), followed by the *tentative* assessment of bromide ion with 22.6% of the ADI (GEMS/Food G08) followed by imazalil (RD) with 13% of the ADI (DE, child).

When chronic risk assessment was based on the adjusted middle-bound scenario, the chronic intake for:

(β)-Hexachlorocyclohexane (RD) highest estimate was 287% (DE, child). The major food contributors to the total chronic exposure were apples (276% of ADI) and chicken eggs (11.5% of ADI). The high contribution of apples is likely to come from high LOQ values of the analytical methods as only one sample out of 1,900 samples was quantified at a level above the MRL. This compound is very persistent in the environment, banned from many years. Its presence in food is very limited occurring occasionally in food of animal commodities. In 2020, it was quantified in 18 of 46,943 samples (0.04%), mainly bovine liver. EFSA recommends analysing liver for this POP substances within the MANCP.

Dimethoate (RD) highest estimate was 123% (DE, child). No processing factors have been used to refine exposure. The major food contributors to the total chronic exposure were apples (56.6% of ADI), oranges (19% of ADI) and potatoes (11.5% of ADI). The total number of samples quantified for dimethoate (RD) were 99 of 52,984 (i.e. 0.19% quantification rate), mainly in oranges (13 samples), Chinese cabbages/pe-tsai (10 samples), sweet cherries (nine samples) and peaches (nine samples). From June 2020, dimethoate should not be applied in the EU. EFSA recommends the analysis of dimethoate on these food products within the MANCP.

Bromide ion highest estimate was 73.1% (GEMS/Food G06). The major food contributors to the total chronic exposure were wheat (38.8% of ADI), tomatoes (8.1% of ADI) and rice (5.8% of ADI). The MRLs<sup>73</sup> established for bromide ion under Regulation (EC) No 396/2005 are based on CXLs and related to the active substance methyl bromide, non-approved in the EU since 2008.<sup>74</sup> EFSA highlights, however, that both substances have different toxicological profiles, and that bromide ion is not specific to methyl bromide, as indeed, it occurs naturally. Moreover, it could be a consequence of the use of other banned bromide-producing fumigants and certain disinfectants (ECHA, 2021). At the time of the MRL review (EFSA, 2013), available data were insufficient to determine whether CXLs specific for bromide ion were derived from the pesticide use or they were based on the natural occurrence. Furthermore, conclusion on acute toxicity was not fully validated by EFSA. Therefore, EFSA recommends reassessing the toxicological reference values for bromide ion, and possibly reviewing the MRLs in place, investigating the degradation of active substances containing bromide ion and the natural sources. Particularly, within the frame of the EU MACP, EFSA recommends extending the scope of analysis of bromide ion to other commodities such as wheat.

Dithiocarbamates (RD) chemical class estimates for the adjusted middle-bound scenario were below 100%. The major food contributors to the total chronic estimates were apples, pears and broccoli at different proportions depending on the precursor.

In 2020, mancozeb, metiram and ziram were approved for use in the EU, pending the renewal of the approval (except mancozeb $^{61}$ ).

In the adjusted middle-bound scenario, the estimated chronic exposure for 176 pesticides (including one dithiocarbamate scenario) was less than 10% of the ADI whereas for 111 of them, the result was lower or equal to 1% of the ADI.

<sup>73</sup> https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/mrls/?event=details&pest\_res\_ids=245&product\_ids=&v=1&e=search.pr

<sup>&</sup>lt;sup>74</sup> Commission Decision 2008/753/EC of 18 September 2008 concerning the non-inclusion of methyl bromide in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. OJ L 258, 26.9.2008.



For aldicarb (RD), chlordane (RD), methoxychlor (RD), parathion-methyl (RD), thiodicarb (RD) and vinclozolin (RD) covered by the 2020 EU MACP, quantifiable residues were not reported for any of the food samples tested, and therefore, they were excluded from the calculation.

The active substances omethoate was quantified in one or more food commodities. As in vivo mutagenicity was demonstrated, no chronic risk was calculated. The exposure estimate using the food consumption in EFSA PRIMo rev. 3.1 is reported in Table 3.

**Table 3:** Results of chronic exposure assessment for omethoate

	Chronic exposure (in mg/kg bw per day)					
Pesticide	Lower bound approach	Adjusted middle-bound approach				
Omethoate	$1 \times 10^{-6}$	$1 \times 10^{-4}$				

In general, the estimated exposure was notably lower in the lower bound scenario compared to the adjusted middle-bound approach. EFSA noted that the high proportion of samples with pesticide residues below the LOQ may result in particularly high middle-bound estimates due to the assumption that even if not quantified, residues are present in all samples at the level of LOQ. This ensures a high level of conservatism within the exposure assessment methodology.

Taking into consideration all food items for which consumption data are provided in PRIMo rev. 3.1, the highest contributors to the overall EU pesticide dietary exposure remain those food items covered by the 3-year cycle of the EU-coordinated programme. This can be seen in Annex II, on the contribution to chronic exposure under 'other products'.

# **5.3.** Accounting for uncertainties

The methodology for quantifying conservatism and uncertainties is described in detail by EFSA in its Guidance on Uncertainty Analysis (EFSA, 2018a). The current assessment, however, relies on a standardised deterministic model that implements internationally agreed equations (i.e. PRIMo revision 3.1), and uncertainties associated with this model should not be discussed in the framework of this assessment. The current section therefore lists the main sources of uncertainties associated with this assessment, indicating how these sources of uncertainty are expected to overestimate or underestimate the exposure estimates.

- Uncertainty related to the consumption data by excluding in the acute assessment the commodities not listed in the 2020 EU MACP. This is expected to underestimate the risk as not all the consumed commodities are considered.
- Uncertainty related to missing occurrence data by excluding substance/commodity combinations for which occurrence data have not been reported. This is expected to underestimate the risk, as for a combination which was not analysed, it cannot be known whether the pesticide was used.
- Uncertainty related to occurrence data based on the assumption that in case of unspecific residue definition for monitoring, the active substance present in or on the commodity is the authorised one (e.g. cypermethrins). This is expected to underestimate the risk.
- Uncertainty related to occurrence data based on the residue definition for enforcement rather than the one set for risk assessment, where normally metabolites considered of risk would contribute. This is expected to underestimate the risk for not accounting for these other contributors.
- Uncertainty related to handling of left-censored data in the chronic middle-bound scenario imputing half the LOQ numerical value (½ LOQ) to results reported as below LOQ, when an active substance is assumed to have been used, i.e. when results for the same pesticide/commodity combination are quantified. This is expected to overestimate the risk as the contribution of the LOQ value is high.
- Uncertainty related to missing processing factors based on the assumption that pesticide residues in the raw primary commodity (RPC) reach the consumer without any loss during household or industrial processing. This is expected to overestimate the risk as the lack of processing factor does not allow to refine the real exposure.
- Uncertainty related to the use of the accuracy of the health-based guidance setting affected by the study design of the critical study (e.g. study duration, route/mode of administration (gavage, diet), analytical methods). This may impact the estimation of the risk in the two directions (i.e. over- and underestimation).



Overall, for most of the samples analysed in the framework of the 2020 pesticide monitoring programmes (EU MACP and MANCP), the dietary exposure to pesticides for which health-based guidance values (HBGV) were available, a risk to EU consumer health is unlikely. In the rare cases where the dietary exposure for a specific pesticide/product combination was calculated to exceed the health-based guidance value assuming the conservative assumptions described, and for those pesticides for which no HBGV could be established, the competent authorities took appropriate and proportionate corrective measures to address potential consumer risks. Information on the measures taken can be found at the National Summary Reports (EFSA, 2022b).

Nevertheless, in future reports on pesticide residues in food, the deterministic exposure assessments will be accompanied by probabilistic assessments to single substances allowing to quantify better the possible risk encountered, and the uncertainties associated.

# 6. Conclusions and recommendations

The 2020 EU report on pesticide residues in food, prepared by EFSA in accordance with Article 32 of Regulation (EC) No 396/2005, provides an overview of the official control activities on pesticide residues carried out in the EU Member States,  $^1$  Iceland and Norway. Results are presented in Annex  $I^2$  allowing stakeholders to scroll through.

A total of 88,141 samples were analysed. Compared to 2019 (96,302 samples), this constitutes a decrease by 9.3% in the total number of samples that reporting countries were able to submit mainly due to the COVID-19 pandemic situation. 94.9% of the total number of samples fell within the legal limits (83,666 samples) (96.1% in 2019); of these, 48,181 samples (54.6%) did not contain quantifiable residues (results below the LOQ for all pesticides analysed), while 40.3% of the samples analysed contained quantified residues not exceeding the legal limits (35,485 samples). In total, MRLs were exceeded in 5.1% of the samples (4,475 samples), an increase compared with 2019 (3.9%). When taking into account the measurement uncertainty, it was found that 3.6% (3,156 samples) of all the samples triggered legal sanctions or enforcement actions.

Out of the 59,026 samples (67%) originating from any reporting countries, 41.3% were found to be below the LOQ, 24.1% contained residues at or above the LOQ but below or equal to the MRL; 1.6% of the samples exceeded the MRL and 0.9% were non-compliant with the MRL. Samples imported from third countries were 25,014. The percentage without quantifiable residues was 10.8%, while the percentage of samples containing quantifiable residues within the legal limits was 14.2%. Samples imported from third countries were found to have a higher MRL exceedance rate (3.3%) and a higher non-compliance level (2.6%) compared to food produced within the EU. The remaining 4.7% (4,101 samples) were reported as origin unknown, a significant decreased compared to previous years (11.3% in 2019 and 10.1% in 2018).

The random sampling on the EU MACP (Regulation (EU) No 2019/533) commodities consumed by EU citizens (i.e. carrots, cauliflowers, kiwi fruits (green, red, yellow), onions, oranges, pears, potatoes, dried beans, brown rice, rye grain, bovine liver and poultry fat) provides a snapshot of the level of pesticide residues in those food products. These were compared with the same food products as sampled in 2017 and 2014 EU monitoring programmes. One hundred and eighty-six pesticide residues were included the 2020 EU MACP.

Overall, in 68.5% of samples (8,278 out of the 12,077 samples analysed), no quantifiable levels of residues were reported (residues were below the LOQ). The number of samples with pesticide residues within the legal limits (at or above the LOQ but below or at the MRL) was 3,590 (29.7%). MRLs were exceeded in 1.7% of samples (209 samples), 0.9% of which (113 samples) were found to be noncompliant taking due account of measurement uncertainty.

Direct comparison on the overall MRL exceedance rate between 2020 and 2017 was possible as the food products were common to both years, resulting on an average increase from 1.7% in 2017 to 2.1% 2020. A comparison by food commodities between the individual MRL exceedance rates showed an increase trend from 2014 to 2017 and to 2020 in rice (from 2.1% to 5.1% and to 6.7%), oranges (from 1.5% to 1.1% and to 2.9%), pears (from 1.6% to 2.3% and to 2.3%) and fat poultry (from 0% in 2014 and 2017 to 0.06%). An upward trend from 2017 to 2020, as it was not request in 2014 EU MACP, was also observed in dried beans (from 2.3% in 2017 to 4.9% in 2020), kiwi fruits (green, red, yellow) (from 1.3% in 2017 to 1.96% in 2020) and cauliflower (from 0.8% in 2017 to 1.0% in 2020). A downward trend was showed in carrots (from 2.1% in 2014, to 1.9% in 2017 and 1.2% in 2020), potatoes (from 1.1% in 2014 to 1.2% in 2017 and to 0.8% in 2020), rye (from 1.9% in 2017 to 1.1%



in 2020) and onions (from 0.3% in 2017 to 0.2% in 2020). Bovine liver remains steady with no MRL exceedances in 2014 and 2020 programmes.

The results from the monitoring programmes are a valuable source of information for estimating the dietary exposure of EU consumers. In the context of this report, the analysis on the health risk to consumers has been performed using a deterministic model to single pesticide residues that bases its calculations on conservative model assumptions. PRIMo rev. 3.1 model is used to perform acute risk assessment to the pesticide/food product combinations covered by the 2020 EU MACP, and chronic risk assessment to the pesticides covered by the 2020 EU MACP reported in those raw commodities for which consumption data are available.

The acute exposure assessment was carried out in 186 pesticides on 17,494 samples. The health-based guidance value (ARfD) was found to be exceeded in 1.0% of these samples. The pesticides found to be most responsible (more than 10 samples) included phosmet (RD) (57 samples), cypermethrin (RD) (24 samples), dimethoate (RD) (17 samples) and chlorpyrifos (RD) (11 samples).

The chronic exposure assessment was conducted on 62,850 samples. The estimated exposure was below the 100% of ADI for all the pesticides assessed for both lower and adjusted middle-bound scenarios.

Overall, for most of the samples analysed in the framework of the 2020 pesticide monitoring programmes (EU MACP and MANCP), the dietary exposure to pesticides for which health-based guidance values (HBGV) are available, is unlikely to pose a risk to EU consumer health. In the rare cases where the dietary exposure for a specific pesticide/product combination was calculated to exceed the health-based guidance value assuming conservative assumptions, and for those pesticides for which no HBGV could be established, the competent authorities took appropriate and proportionate corrective measures to address potential consumer risks.

When a probabilistic exposure assessment will be implemented in the future reports on pesticide residues in food, a more detailed and refined analysis of the uncertainties would be possible allowing to better quantify the possible risk encountered.

Based on the 2020 pesticide monitoring findings, EFSA recommends the following:

- Several EU non-approved pesticides were found repeatedly in randomly sampled food grown in the EU territory at levels exceeding the legal limits, namely:
  - oranges: dimethoate (RD), linuron (RD),
  - dried beans: triadimenol (RD),
  - o carrots: iprodione (RD), linuron (RD), dieldrin (RD), chlorpyrifos-methyl (RD)
  - o pears: chlorpyrifos (RD), iprodione (RD), diphenylamine (RD),
  - potatoes: chlorpyrifos (RD), fipronil (RD),
  - kiwi: dimethoate (RD),
  - rye grain: chlorpyrifos (RD), thiacloprid (RD),
  - rice: thiamethoxam (RD),
  - poultry fat: hexachlorobenzene (RD)

Despite Member States were able to follow-up on these findings, investigating the reasons for these exceedances and/or use and taking corrective measures where appropriate, EFSA recommends keep analysing for it to account for its lowering frequency.

- Chlorpropham, for which a decision for non-renewal of approval was taken in 2020, with a
  maximum grace period granted until 8 October 2020, was reported in two carrot samples, one
  orange sample and one dry bean sample grown in the EU. Its authorised uses included
  fumigation of potatoes in storage facilities. Due to chlorpropham properties, remaining residues
  cannot be fully avoided with the current cleaning operations of these storage facilities.
  Consequently, EFSA suggests that MS should continue monitoring potatoes<sup>33</sup> and other food
  products having been placed in the same storage facilities as chlorpropham was used, as
  possible cross-contamination may take place.
- Several EU non-approved pesticides were found in concentrations exceeding the legal limit in randomly sampled food grown in third countries:
  - dried beans: carbaryl (RD), chlorpyrifos (RD), fenitrothion (RD), hexaconazole (RD),
  - carrots: iprodione (RD),
  - kiwi: spirodiclofen (RD),



- oranges: bromopropylate (RD), carbendazim (RD), fenbutatin oxide (RD), profenofos (RD),
- pears: chlorpyrifos (RD),
- rice: carbendazim (RD), chlorpyrifos (RD), hexaconazole (RD), profenofos (RD), thiamethoxam (RD), triazophos (RD), tricyclazole (RD)

EFSA recommends follow-up by Member States on import controls for these pesticides/crop combinations.

- Due to the high MRL exceedance rate observed in rice (6.7%) and dried beans (4.9%), the upward trend showed from 2017 to 2020 (from 5.1 to 6.7% in rice; from 2.3 to 4.9% in dried beans) and the presence of up to seven (in rice) and six (in dried beans) non-approved pesticides, it is recommended to keep monitoring these two matrices within the EU-coordinated programme. Fat soluble-persistent organic pollutants (POPs) used as pesticides in the past were the substances most frequently quantified in animal products samples under the EU MACP. Continuous monitoring of animal fat products is again recommended to assess the evolution of levels of POPs.
- Bromide ion (RD), dithianon (RD), haloxyfop (RD), 2,4-D (RD), 2-phenylphenol (RD), glyphosate (RD), mepiquat chloride (RD), cyflufenamid (RD), ethephon (RD), dithiocarbamates (RD) and fenbuconazole (RD) were the pesticides analysed the least, probably due to analytical single residue methods being required for its quantification in food. Thus, EFSA recommends MS taking necessary measures to be able to enforce properly these substances.
- EFSA recommends reassessing the toxicological reference values for bromide ion, and possibly reviewing the MRLs in place, investigating the degradation of active substances containing bromide ion and the natural sources. Particularly, within the frame of the EU MACP, EFSA recommends extending the scope of analysis of bromide ion to other commodities such as wheat.
- An improvement in 2020 is noted in comparison with 2019 and 2018, on a decreasing rate on samples reported as unknown origin (4.7% in 2020 vs. 11.3% in 2019 and 10% in 2018). However, still some MSs reported more than 10% of their samples as origin not known and notably in rice, up to 20 samples under EU MACP. EFSA reiterates that the country of origin of a sample remains a valuable piece of information for traceability of non-compliant samples and gives relevant information on potential problems in third countries. Member States' competent authorities should make sure that this information is provided when reporting the sample results to EFSA.
- The rate of MRL exceedances (5.1%) increased compared with 2019 (3.9%) and 2018 (4.5%). It remained high for specific crops (e.g. unprocessed and processed grape leaves and similar species, unprocessed cumin seed and processed Brazil nuts) that are not covered in the EU MACP. Thus, it is recommended to continue monitoring these food items in the various national control programmes throughout the EU.
- Higher MRL exceedances (3.3%) and non-compliance (2.6%) rates were exhibited by samples imported from third countries compared with food produced within EU (1.6% MRL exceedances and 0.9% non-compliance). MS National authorities are recommended to keep monitoring pesticides residues in samples imported from third countries with a wide analytical scope.
- The EU non-approved active substances with the highest MRL exceedance rate (%) were found to be ethylene oxide (RD) (21.3%), chlorates (RD) (2.9%), chlordecone (RD) (0.9%), chlorpyrifos (RD) (0.4%) and anthraquinone (RD) (0.2%). Remarkably, the MRL exceedance rate reported for chlorate decreased compared with previous year (7.2%). National authorities should consider the following pesticide/sample groupings when planning their monitoring programmes:
  - ethylene oxide (RD) in sesame seeds, peppercorn and buckwheat,
  - chlorates (RD) in leafy crops (lettuce, lamb's lettuce/corn salads), tomatoes and beans with pods
  - chlordecone (RD) in cassava roots and chicken eggs,
  - chlorpyrifos (RD) sweet peppers/bell peppers, grape leaves, dried beans, pomegranates, potatoes and teas,
  - o anthraquinone (RD) in tea.



- The number of samples with multiple pesticide residues remained steady in 2020 compared with the previous year (27%). Unprocessed oranges and pears grown in the EU and flagged as EU MACP samples presented up to 13 and 14 different pesticides, respectively. Regarding samples analysed under national programmes, unprocessed sweet peppers/bell peppers and wine (processed commodity) represented the commodities with the highest frequency (4.6% and 2.7%, respectively) of multiple quantified residues. EFSA thus recommends Member States to continue monitoring these foodstuffs under their national programmes and to keep oranges and pears in the respective three-year cycle of the EU coordinated programme.
- The following pesticides not authorised in organic farming were sporadically found in crops labelled as such: chlorpyrifos, anthraquinone and lambda-cyhalothrin. Member States should investigate the reason for their presence. As in 2019, animal product samples flagged as being grown under organic production presented a higher quantified sample rate (16%) than conventional production samples (7%), whereas MRL exceedances rates were practically in the same range (1.2% conventional vs 1.9% organic). Most of the exceedances in organic production were coming from POPs (hexachlorobenzene (RD) and DDT (RD). While as per Directive 2002/32/EC, legal limits are set for POPs in feed, Member States should try to elucidate the reasons for these exceedances.
- Organic pollutants persistent in the environment (POPs) used as pesticides in the past (e.g. DDT (RD) and hexachlorobenzene (RD)), constituted the main findings in animal products, together with substances with uses other than as a pesticide (e.g. copper compounds (RD)), naturally occurring (bromide ion (RD)), or globally distributed contaminants (mercury (RD)). EFSA recommends continuing to monitor these substances in animal products. Noticeably, for the calculated adjusted middle-bound scenario, a chronic risk was identified for the POP ( $\beta$ )-hexachlorocyclohexane (RD), which was quantified mainly in bovine liver. EFSA recommends continuous monitoring of this pesticide/crop combination under national programmes.
- In honey, up to 30 different pesticides were found. Substances with non-approved uses as pesticide such as amitraz (RD), chlorfenvinphos (RD) and coumaphos (RD), were detected in honey and other apicultural products. Thiacloprid, for which a decision for non-renewal of approval was taken in January 2020 with a maximum grace period for use until 3 February 2021, was the most frequently quantified.
  - EFSA recommends Member States investigating the reasons for the presence of these active substances in honey and other apicultural products.
- The following active substances exceeded their respective MRLs in honey and other apicultural products in five or more samples: copper compounds (RD), bromide ion (RD), chlorfenvinphos (RD), tau-fluvalinate (RD) and acetamiprid (RD). EFSA recommends that Member States keep monitoring honey in their national programmes, with an analytical scope as wide as possible.
- Considering that the EU MACP sampling is not only used for evaluating MRL compliance but also for performing deterministic and probabilistic exposure assessments to individual and multiple pesticides, EFSA recommends revisiting the commodities included based on newest consumption diets.
- Acute risk was identified for the different dithiocarbamates scenarios, except for metiram for which the ARfD was not deemed necessary. EFSA will perform a comprehensive MRL review (foreseen in 2022) of all authorised uses of dithiocarbamates, taking into account their different approval status and the natural occurring background levels of CS<sub>2</sub>. EFSA recommends deriving processing factors to refine exposure assessments in cases where any dithiocarbamate remains approved for use to allow refining exposure, if needed.
- Based on the ARfD exceedances observed for cypermethrin (RD), mostly in oranges, and to the low toxicological reference values, it is recommended requiring the authorisation holder to produce processing factors for oranges.
- Exceedances of the ADI for the adjusted middle-bound scenario and of the ARfD were calculated for dimethoate (RD). Considering that this is an active substance no longer approved in the EU, but for which a grace period still applied until 30 June 2020, EFSA recommends reporting countries continuing monitoring the presence of dimethoate in fruits (mostly oranges), potatoes and Chinese cabbage under their national programmes.
- EFSA reiterates its recommendation to build and regularly update the EFSA European database on processing factors that will allow Member States and EFSA to refine exposure assessments as needed. Moreover, FBO are recommended conducting processing studies



leading to the derivation of PF for their own processes and share them later with EU MSs competent authorities for enforcement purposes and ultimately with EFSA.

This report is intended to provide information to the general and informed public and stakeholders with an interest and responsibilities in the food chain, in particular food supply chain operators. Its aim is to present a comprehensive overview of residue findings in food placed on the EU market, including possible non-compliances with legal limits, and to assess the potential exposure of consumers to pesticide residues. Furthermore, it gives recommendations on various possible risk management options where appropriate. The report's findings are systematically used by the Commission and the Member States to establish priorities for controls on food on the market, including the most relevant substance/commodity combinations to be included in the EU MACP regulation or in the national control programmes of Member States.

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#### **Abbreviations**

# EU/EEA country codes

AT	Austria	IS	Iceland
BE	Belgium	IT	Italy
BG	Bulgaria	LT	Lithuania
CY	Cyprus	LU	Luxembourg
CZ	Czechia	LV	Latvia
DE	Germany	MT	Malta
DK	Denmark	NL	The Netherlands
EE	Estonia	NO	Norway
EL	Greece	PL	Poland
ES	Spain	PT	Portugal
FI	Finland	RO	Romania
FR	France	SE	Sweden
HR	Croatia	SI	Slovenia
HU	Hungary	SK	Slovak Republic
ΙΕ	Ireland	UK	The United Kingdom



#### Other abbreviations

ADI Acceptable Daily Intake
ARfD Acute Reference Dose
BAC Benzalkonium Chloride
BCP Border Control Posts

CAG Cumulative Assessment Group

CP Control Point CS<sub>2</sub> Carbon disulfide

DDĀC Didecyldimethylammonium chloride DWH EFSA's scientific Data Warehouse

EEA European Economic Area
EFTA European Free Trade Association

EU MACP EU-coordinated multiannual control programme

EUPT European Proficiency Test

EURL European Union Reference Laboratory

FAO Food and Agriculture Organization of the United Nations

GAP Good Agricultural Practice
HBGV Health-based guidance value
HCH Hexachlorocyclohexane
HRM Highest Residue Measured

LOD Limit of Detection
LOQ Limit of Quantification

MANCP Multiannual National Control Programme

MRL Maximum Residue Level
POP Persistent Organic Pollutants
PRIMo Pesticide Residue Intake Model

RD Residue Definition

SSD Standard Sample Description

VMPR Veterinary medicinal product residues

WHO World Health Organization



# Appendix A - Authorities responsible for reporting monitoring of pesticide residues by country

Country	National competent authority	Web address for published national monitoring reports	
Austria	Federal Ministry of Social Affairs, Health, Care and Consumer Protection	https://www.verbrauchergesundheit.gv.at/ lebensmittel/lebensmittelkontrolle/monitoring/ pestizid.html	
	Austrian Agency for Health and Food Safety	http://www.ages.at/themen/rueckstaende- kontaminanten/pflanzenschutzmittel- rueckstaende/pestizidmonitoringberichte/	
Belgium	Federal Agency for the Safety of the food Chain (FASFC)	http://www.favv-afsca.fgov.be/ publicationsthematiques/pesticide-residue- monitoring-food-plant-origin.asp	
Bulgaria	Risk Assessment Centre on Food Chain	http://www.babh.government.bg/en/	
Croatia	Ministry of Agriculture	http://www.mps.hr/	
Cyprus	Ministry of Health, Pesticides Residues Laboratory of the State General Laboratory	http://www.moh.gov.cy/sgl	
	Ministry of Health, Department of Medical and Public Health Services (MPHS)		
Czech Republic	Czech Agriculture and Food Inspection Authority	http://www.szpi.gov.cz	
	State Veterinary Administration	http://www.svscr.cz	
Denmark	Danish Veterinary and Food Administration	https://www.foedevarestyrelsen.dk/Kontrol/ Kontrolresultater/Sider/Pesticidrester.aspx	
	National Food Institute, Technical University of Denmark	http://www.food.dtu.dk/publikationer/ kemikaliepaavirkninger/pesticider-i-kosten	
Estonia	Veterinary and Food Board	http://www.vet.agri.ee	
Finland	Finnish Food Authority, Finnish Customs and National Supervisory Authority for Welfare and Health	https://www.ruokavirasto.fi/en/companies/food-sector/production/common-requirements-for-composition/residues-of-plant-protection-products/control-of-plant-protection-product-residues-in-food/	
France	Ministère de l'économie et des finances / Direction générale de la concurrence, de la consommation et de la répression des fraudes (DGCCRF)	http://www.economie.gouv.fr/dgccrf/securite/ produits-alimentaires	
	Ministère de l'Agriculture et de l'Alimentation, Direction générale de l'alimentation (DGAL)	http://agriculture.gouv.fr/plans-de-surveillance-et-de-controle	
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	www.bvl.bund.de/berichtpsm	
Greece	Ministry of Rural Development and Food	http://www.minagric.gr/index.php/en/citizen- menu/foodsafety-menu	
		http://www.minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostasiamenu/ypoleimatafyto	
Hungary	National Food Chain Safety Office	https://www.nebih.gov.hu	
Iceland	MAST – The Icelandic Food and Veterinary Authority	http://www.mast.is	
Ireland	Department of Agriculture Food and the Marine	www.pcs.agriculture.gov.ie	
Italy	Ministero della Salute – Direzione Generale per l'Igiene e la Sicurezza degli Alimenti e la Nutrizione – Ufficio 7	http://www.salute.gov.it/portale/temi/p2_6.jsp? lingua=italiano&id=1105&area=fitosanitari&menu= vegetali	



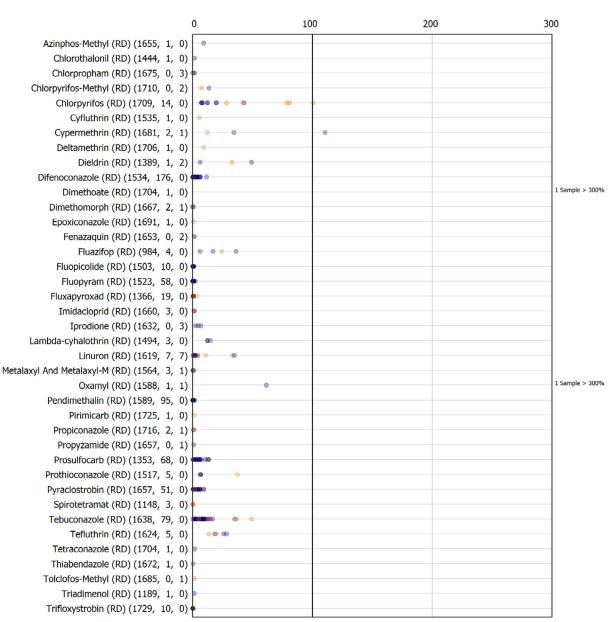
Country	National competent authority	Web address for published national monitoring reports
Latvia	Ministry of Agriculture	www.zm.gov.lv
	Food and Veterinary Service of Latvia	
Lithuania	National Food and Veterinary Service (SFVS)	http://www.nmvrvi.lt
Luxembourg	Ministry of Health, Directorate for public health, Division of Food Safety (Secualim)	http://www.securite-alimentaire.public.lu
	Ministry of Health, Administration of Veterinary Services (ASV)	
Malta	Malta Competition and Consumer Affairs Authority	www.mccaa.org.mt
Netherlands	Netherlands Food and Consumer Product Safety Authority (NVWA)	www.nvwa.nl
Norway	Norwegian Food Safety Authority	www.mattilsynet.no
		https://www.mattilsynet.no/mat_og_vann/ uonskede_stofferimaten/rester_av_ plantevernmidler_i_mat/#overvakings_og_ kartleggingsprogrammer
Poland	The State Sanitary Inspection	http://www.gis.gov.pl
Portugal	Direção-Geral de Alimentação e Veterinária (DGAV)	http://www.dgv.min-agricultura.pt/portal/page/ portal/DGV/genericos?generico=4217393&cboui= 4217393 t
Romania	National Sanitary Veterinary and Food Safety Authority	http://www.ansvsa.ro
	Ministry of Agriculture and Rural Development	http://www.madr.ro
	Ministry of Health	
Slovakia	State Veterinary and Food Administration of the Slovakian Republic	http://www.svps.sk/
	Public Health Authority of the Slovakian Republic	
Slovenia	Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection	http://www.uvhvvr.gov.si/si/delovna_podrocja/ostanki_pesticidov
Spain	Spanish Agency for Food Safety and Nutrition (AESAN)	http://www.aecosan.msssi.gob.es/AECOSAN/web/seguridad_alimentaria/subseccion/programa_control_residuos.htm
Sweden	National Food Agency	www.livsmedelsverket.se
United Kingdom	Health and Safety Executive, Chemicals Regulation Division	https://www.gov.uk/government/publications/ expert-committee-on-pesticide-residues-in-food- prif-annual-report



# Appendix B – Detailed results on risk assessment

Results of acute risk assessment for food products in focus of the EU MACP expressed as percentage of the ARfD.

In the following figures,<sup>75</sup> the acute exposure calculated for each sample with residues above the LOQ is presented individually, expressing the result as a percentage of the ARfD. The blue dots refer to results reported under the EU-coordinated programme, whereas the orange dots refer to findings in samples that were analysed in the framework of the national control programmes. The figures in brackets next to the name of the pesticides represent the number of samples with residues below the LOQ, the number of samples with quantified residues below or at the MRL and the number of samples with residues above the MRL.<sup>76</sup>



Carrots - Residue concentration in % of the Acute Reference Dose

Figure B.1: Acute dietary exposure assessment – carrots

<sup>&</sup>lt;sup>75</sup> In the following figures, there are some cases where the ARfD was exceeded due to recent lowering in the ARfD value, while the samples were still within the MRL. In other cases, the exceedance of the ARfD is due to the IESTI equation and the gap between the highest residue derived under residue trials and the calculation of the MRL.

<sup>&</sup>lt;sup>76</sup> Samples with residues above the MRL in the context of this report refers to samples with one or several pesticides exceeding the legal limit, as reported by the Member States including compliant and non-compliant samples.





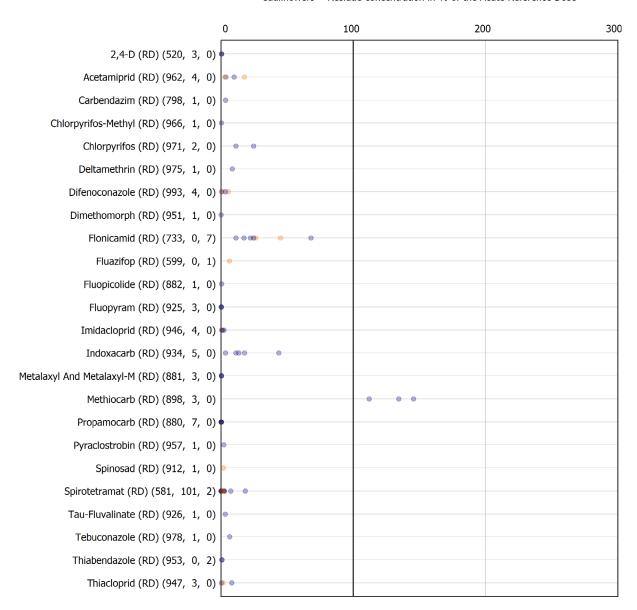


Figure B.2: Acute dietary exposure assessment – cauliflower



Kiwi fruits (green, red, yellow) - Residue concentration in % of the Acute Reference Dose

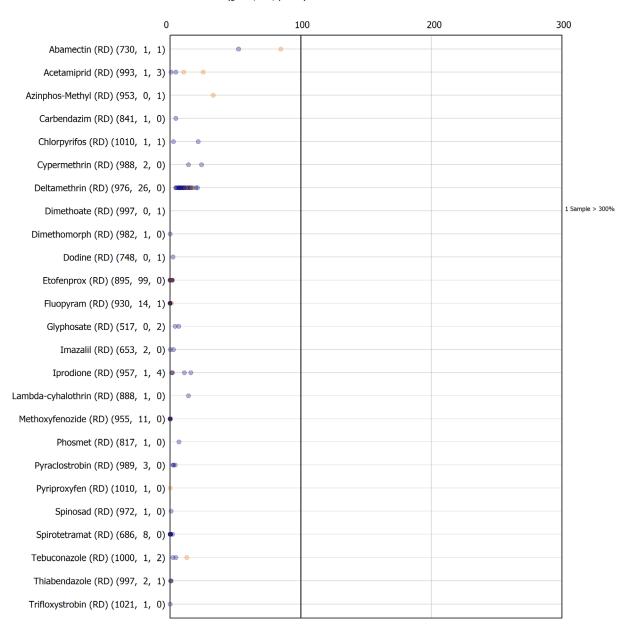
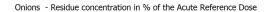


Figure B.3: Acute dietary exposure assessment – kiwi fruit





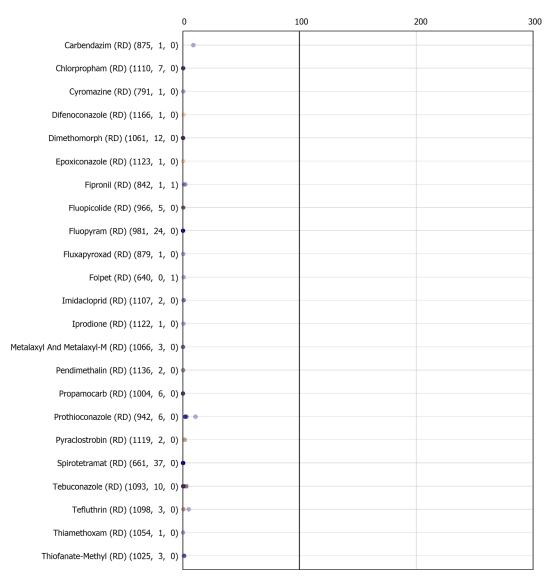
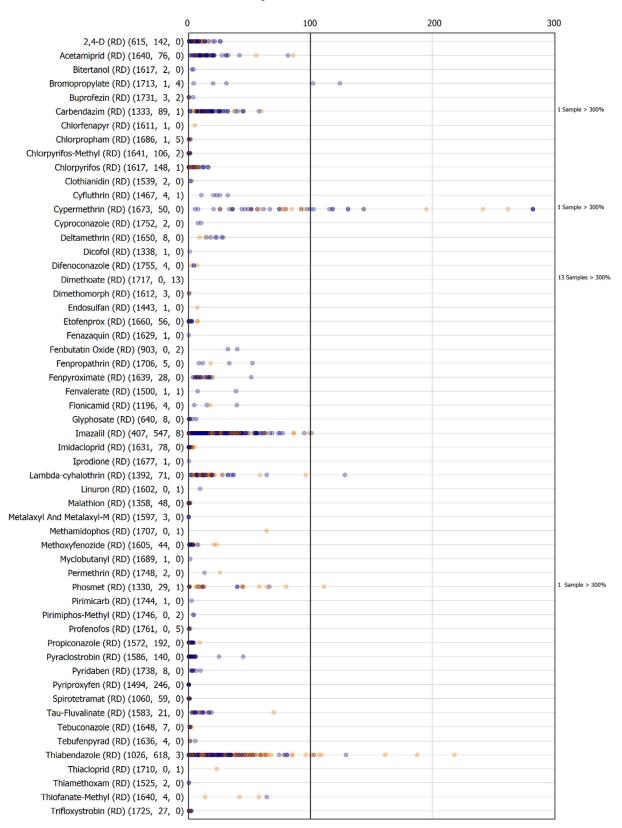


Figure B.4: Acute dietary exposure assessment – onion







**Figure B.5:** Acute dietary exposure assessment – oranges



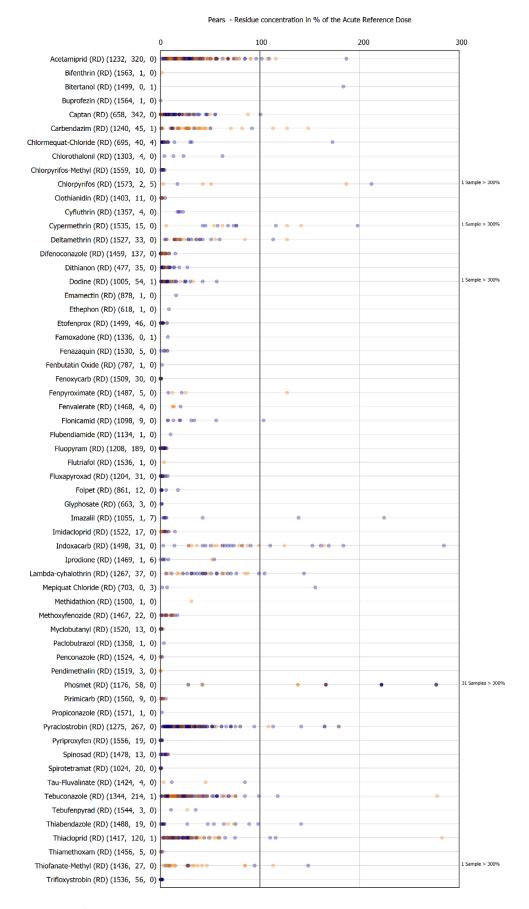
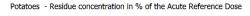
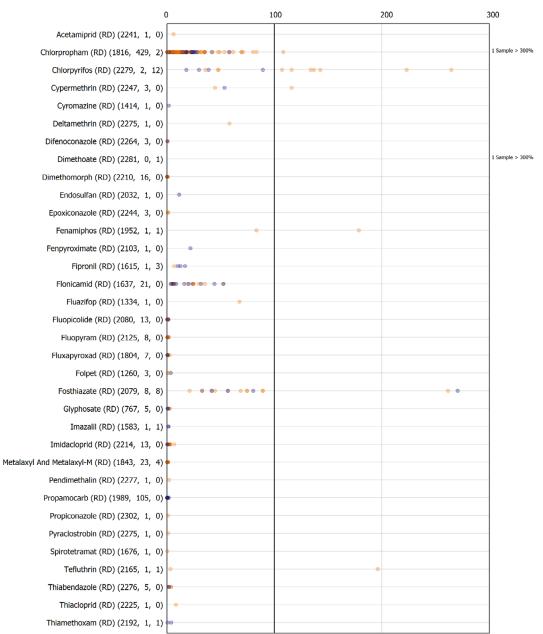


Figure B.6: Acute dietary exposure assessment – pears







**Figure B.7:** Acute dietary exposure assessment – potatoes





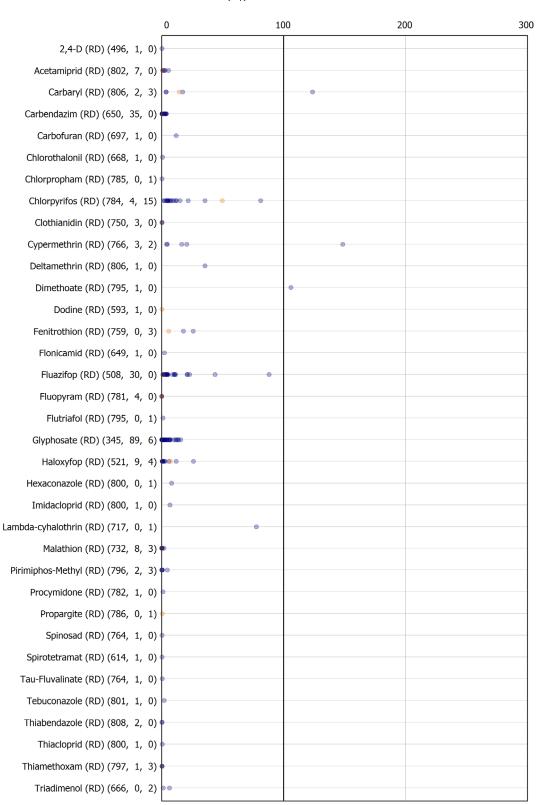
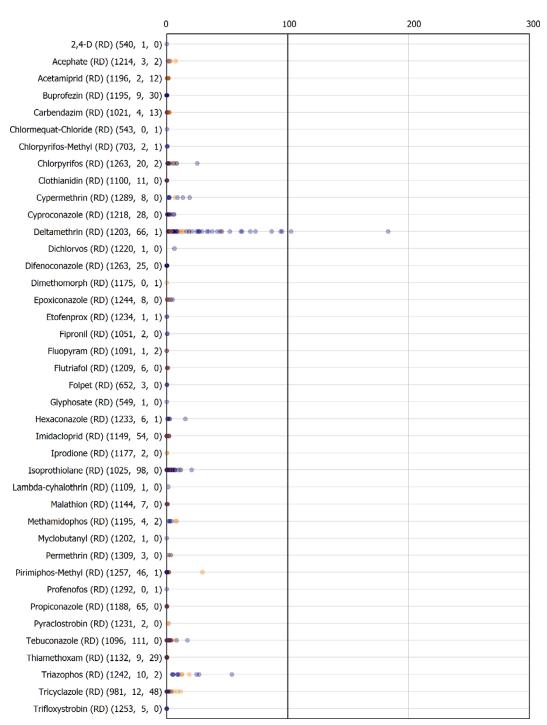


Figure B.8: Acute dietary exposure assessment – dried beans







**Figure B.9:** Acute dietary exposure assessment – rice

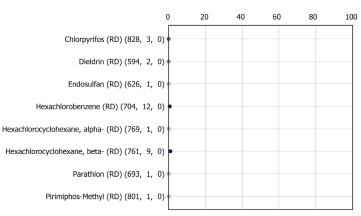




Rye - Residue concentration in % of the Acute Reference Dose

Figure B.10: Acute dietary exposure assessment – rye grain

Triadimenol (RD) (513, 1, 0)



**Figure B.11:** Acute dietary exposure assessment – bovine liver





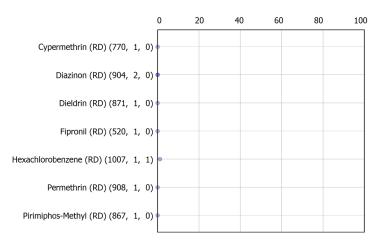


Figure B.12: Acute dietary exposure assessment – poultry fat



# **Annexes**

- Annex I: The data visualisation (EU MACP and MANCP)
- Annex II: The PRIMo exposure model on the 2020 annual report on pesticide residue results
- Annex III: Input and output data of the 2020 EU pesticide residues report on food
  - Table 3.1 The 2020 EU coordinated multiannual programme of the Union
  - Table 3.2 List of samples exceeding the MRLs, including information on the measured residue concentrations and the origin of the samples
  - Table 3.3 Scope of analysis of pesticides reported
  - Table 3.4 Regulation (EU) 2019/1793 on the temporary increase of official controls extract of the controls to be performed of pesticides in food
  - Table 3.5 Health-based guidance values (HBGV)
  - Table 3.6 Processing factors used to refine acute exposure assessment