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The 2021 European Union report on pesticide residues in food

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Abstract

Under European Union legislation (Article 32, Regulation (EC) No 396/2005), EFSA is to provide an annual report assessing the pesticide residue levels in foods on the European market. In 2021, 96.1% of the overall 87,863 samples analysed fell below the maximum residue level (MRL), 3.9% exceeded this level, of which 2.5% were non-compliant, i.e. samples exceeding the MRL after accounting for the measurement uncertainty. For the EU-coordinated multiannual control programme subset, 13,845 samples were analysed of which 2.1% exceeded the MRL and 1.3% were non-compliant. To assess acute and chronic risk to consumer health, dietary exposure to pesticide residues was estimated and compared with available health-based guidance values (HBGVs). A new pilot methodology based on probabilistic assessment was introduced to provide the probability of subjects being expose to an exceedance of the HBGV. Recommendations to risk manager are given to increase the effectiveness of European control systems and to ensure a high level of consumer protection throughout the EU.

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Summary

The 2021 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,[1*] Iceland and Norway. It summarises the results of both the EU-coordinated multiannual control programme (EU MACP) and the national control programmes (MANCP).

The analysis of the results from all reporting countries is presented in a data visualisation format,[2] 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.

The report also includes the outcome of the risk deterministic assessment both acute and chronic to single substances. For the first time, a pilot methodology has been introduced to address the probabilistic exposure assessment to single substances, where probabilities of exceedance of the health-based guidance value (HBGV) of pesticides has been calculated in different subpopulation of European consumers. The purpose of these calculation is to provide readers with a new insight into the risk of dietary exposure to pesticides.

EU-coordinated multiannual control programme (EU MACP)

The EU MACP randomly sampled covers the most consumed food products by EU citizens as indicated in the EU MACP Regulation (EU) No 2020/585. The control of these products is distributed across a three-year cycle, so that every 3 years the same products are analysed. A snapshot of the situation in 2021 of the pesticide residues present in those food products is provided and compared with 2018 and 2015.

In 2021, the 12 food products selected in the EU MACP were: aubergines (egg plants), bananas, broccoli, cultivated fungi, grapefruit, melons, sweet peppers, table grapes, virgin olive oil, wheat, bovine fat and chicken eggs. A total of 13,845 samples were analysed.[3] Overall, 13,550 samples (97.9%) were found to be within the legal limits. MRLs[4] were exceeded in 295 samples (2.1%), of which 184 samples (1.3%) were found to be non-compliant based on the measurement uncertainty. On average, 53.3% of the samples analysed were domestic, 22.8% were from other EU countries, 19.6% from third countries and 4.3% were of unknown origin. Similar rates were observed in 2020 except for the imports from third countries that raised from 14% in 2020 to 19.6% in 2021.

National programmes (EU MACP + MANCP)

The 2021 programmes (both EU MACP and MANCP) amounted a total of 87,863 samples. Of the total number of samples analysed, 84,399 samples (96.1%) fell within the legal limits. In total, MRLs were exceeded in 3,464 samples (3.9%). When accounting for the measurement uncertainty, 2,207 samples (2.5%) triggered legal sanctions or enforcement actions. The MRL exceedance rate decreased from 5.1% in 2020 to 3.9% in 2021.

Dietary exposure and risk assessment

An analysis of the acute and chronic health risk to consumers was performed using the deterministic Pesticide Residues Intake Model (PRIMo rev. 3.1), to the 190 individual pesticides listed in the EU MACP Regulation.

Out of 19,499 samples analysed under the acute assessment, 220 samples (1.1%) exceeded the HBGVs in 29 different pesticides out of the 190 analysed. In the chronic deterministic assessment, no consumer intake concern was identified.

[1*] Pursuant to Article 5(4) and Section 24 of Annex 2 of the Protocol on Ireland/Northern Ireland, which is an integral part of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, the EU requirements on data sampling are also applicable to Northern Ireland and, for the purpose of this report, references to Member States are read as including the United Kingdom in respect of Northern Ireland.

[2] A dedicated website where EU MACP and MANCP results are presented: https://multimedia.efsa.europa.eu/pesticides-report-2021/.

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

[4] 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.

The pilot probabilistic risk assessment performed to the 29 pesticides revealed that for most of them, the probability for a consumer to exceed the HBGV is expected to be very low. The assessments (both for acute and chronic) still need to account for additional uncertainties that may overestimate or underestimate the risk.

Overall, for most of the samples analysed in the framework of the 2021 pesticide monitoring programmes the dietary exposure to pesticides for which HBGVs are available is very low 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 HBGV, 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 such as withdrawing the sample from the market or recalling it before even being placed on it. Probabilistic methodologies will allow in future better quantification of the real risk.

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1. Background

1.1. Legal Basis

Pesticide residues,[5] resulting from the use of 'plant protection products' (PPP)[6] 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, their uses in PPP[7] and their permissible residues in food. To ensure a high level of consumer protection, legal limits, or so called 'maximum residue levels' (MRLs),[4] providing a wide margin of safety being based on the most critical Good Agricultural Practice (GAP) for an intended crop and apply to a residue definition for monitoring/enforcement, i.e. to ensure GAP-compliant uses of PPP. These MRLs are established in Regulation (EC) No 396/2005.[8] EU-harmonised MRLs are set for more than 1,300 pesticides covering 378 food products/food groups. The MRLs apply to the pesticide residue, compounds and/or degradation products found after applying a PPP. The description of what the MRL covers is known as 'residue definition for enforcement' or 'RD'. However, there are other residue definition for risk assessment, which includes all relevant metabolites with toxicological relevance. These risk assessment residue definitions are not used in the remit of this report. Furthermore, 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. The exceedance of a MRL accounting for the measurement uncertainty (Codex, 2006; Ellison and Williams, 2012) constitutes a non-compliant sample. 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 multiannual control programme: this programme defines the food products and pesticides that should be monitored by all Member States as well as the number of samples per Member States that are to be taken in respect of their population size (EFSA, 2015a) to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues. The EU-coordinated multiannual control programme (EU MACP) relevant for the calendar year 2021 was set up in Regulation (EU) No 2020/585[9] hereafter referred to as '2021 EU MACP Regulation' or '2021 monitoring programme'. This Regulation was later amended by Regulation (EU) No 2020/2041[10] in respect to the number of samples to be taken by Member States in view of the United Kingdom withdrawal from the European Union.
- 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 of Regulation (EC) No 396/2005). This Article was superseded on

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[5] 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 origin.

[6] 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.

[7] 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, p. 1–50.

[8] 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.

[9] Commission Implementing Regulation (EU) 2020/585 of 27 April 2020 concerning a coordinated multiannual control programme of the Union for 2021, 2022 and 2023 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 135, 29.4.2020, p. 1–12.

[10] Commission Implementing Regulation (EU) 2020/2041 of 11 December 2020 amending Implementing Regulation (EU) 2020/585 as regards the number of samples to be taken and analysed by each Member States in view of the withdrawal of the United Kingdom from the European Union and the European Atomic Energy Community. OJ L 420, 14.12.2020, p. 6–8.

14 December 2022 by Regulation (EU) No 2017/625, Article 155[11]). From 15/12/2022, the national control programmes were to be established by Member States in accordance with Regulation (EU) No 2021/1355[12], hereafter referred to as 'MANCP'.

- Temporary increase of official controls and emergency measures control programmes: in accordance with Regulation (EU) No 2019/1793[13] and its annual revisions,[14,15,16,17,18] certain goods listed in its annexes are subject to requiring a temporary increase of official controls or emergency measures. These official controls are done at border control posts (BCPs) or at control points (CPs) at their entry into the Union, for a given hazard (e.g. pesticides residues, not approved food additives, mycotoxins, pentachlorophenol, dioxins and microbiological contamination) and for non-animal origin good and feed coming from a given third country. The outcome of these controls is to be reported through the information management system for official controls (IMSOC). On a voluntary basis, Member States provide them also to EFSA. The analysis of these controls is presented in Section 4.2.3 and are not considered on the exposure/risk assessments (Section 5).

According to Article 31 of Regulation (EC) No 396/2005, Member States are requested to submit[19] the results of the official controls and other relevant information with the European Commission, EFSA and other Member States by 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.

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[11] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation). OJ L 95, 7.4.2017, p. 1–142.

[12] Commission Implementing Regulation (EU) 2021/1355 of 12 August 2021 on multiannual national control programmes for pesticides residues to be established by Member States. OJ L 291, 13.8.2021, p. 120–121.

[13] 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.

[14] 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.

[15] Commission Implementing Regulation (EU) 2020/1540 of 22 October 2020 amending Implementing Regulation (EU) 2019/1793 as regards sesamum seeds originating in India. OJ L 353, 23.10.2020, p. 4–7.

[16] Commission Implementing Regulation (EU) 2021/608 of 14 April 2021 amending 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. OJ L 129, 15.4.2021, p. 119–149.

[17] Commission Implementing Regulation (EU) 2021/1900 of 27 October 2021 amending 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. OJ L 387, 3.11.2021, p. 78–109.

[18] Commission Implementing Regulation (EU) 2021/2246 of 15 December 2021 amending 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. OJ L 453, 17.12.2021, p. 5–34.

[19] Within EFSA terminology the term submit refers to fully accept the data in EFSA's sDWH.

Specific MRLs were set in Directives 2006/125/EC[20] and 2006/141/EC[21] 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 applicable unless lower legal limits for the residue levels are defined in the above-mentioned Directives. Regulation (EU) No 2016/127[22] repeals the aforementioned Directives on the 22 February 2021. Thus, during 2021 the three legislative pieces have coexisted. The residue definitions applicable for this type of food are those given by Regulation (EC) No 396/2005.

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.[23] For these so-called dual use substances, Member States perform controls in accordance with Council Directive 96/23/EC[24] for veterinary medicinal products (VMPRs). Results of the controls for dual use substances are reported within this report if Member States Competent Authority has flagged as so in the remit of the ChemMon data collection (EFSA, 2022a). Otherwise, results are reported in another EFSA output on VMPR residues (EFSA, 2023b).

Under Article 5 of Regulation (EC) No 889/2008[25] on organic production of agricultural products is define the restrictions in place for the use of PPP. However, The MRLs set in Regulation (EC) No 396/2005 apply equally to organic food and to conventional food.

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 2021.

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,
- 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[26].

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[1], including Iceland and Norway as members of the European Free Trade Association (EFTA) and of the European Economic Area (EEA).[27] The main purpose of the data analysis presented in this report is to give risk managers the

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[20] 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.

[21] 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.

[22] 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.

[23] 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.

[24] 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.

[25] 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.

[26] 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.

[27] Iceland and Norway are considered as second countries in respect to EU Member States considered first countries and other world-wide country that is considered third country within this report.

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 what 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 non-compliant 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 at answering 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 2021 EU-coordinated programme results, as defined by Commission Implementing Regulation (EU) No 2020/585[9] and Regulation (EU) No 2020/2041, and the national programme results as defined in Article 30 of Regulation (EC) No 396/2005[8] and Regulation (EU) No 2021/1355 are presented in Appendix D – Annex I.[2] 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 rev. 3.1 tool deterministic risk assessments to single substance are presented in Appendix D – 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[28] by typing: 'Member-State-Name results from the monitoring of pesticide residues in food'.

Furthermore, complementary data to this report are published in Zenodo[29] as Appendix D – Annex III to Annex VII. Information on the content of these annexes can be checked in Appendix D.

In addition, EFSA compiled a technical report (EFSA, 2023c) 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.

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

In compliance with Appendix D – Annex I of Regulation (EU) No 2020/585[9], reporting countries sampled and analysed a given number of pesticide/food product combinations.

The EU MACP covered the most consumed food products in Europe. The listed products are distributed across a 3-year cycle, so that every 3 years the same products are analysed. This year food products included were aubergines (egg plants), bananas, broccoli, cultivated fungi, grapefruit, melons, sweet peppers, table grapes, virgin olive oil, wheat, bovine fat and chicken eggs.

In 2021, a total of 13,845 samples were reported under the EU MACP. In 8,043 of those samples (58.1%), no quantifiable residues were reported (residues were below the limit of quantification (LOQ)). The number of samples with pesticide residues within legally permitted levels (at or above the LOQ but below or at the MRL) was 5,507 (39.8%). MRLs were exceeded in 2.1% (295) of samples, of which 1.3% (184) were found to be non-compliant after taking into consideration the measurement uncertainty.

The overall MRL exceedance rate rose from 1.4% in 2018 to 2.1% in 2021. However, 2021 rate was distorted by the high exceedance rate from grapefruits coming from Türkiye.[30] The data resulting from Rapid Alert System for Food and Feed (RASFF) notifications and the information regarding official controls performed by Member States and provided to SANTE during the 2021, indicate the emergence of a concern of this commodity coming from this country. Therefore, the level of official controls on entries of such consignments was increased to 10% as set in Regulation (EU) No 2021/2246[18] already published on the 15 December 2021 (Appendix D – Annex III – Table 3.4). If grapefruits would have

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[28] https://zenodo.org/
[29] https://doi.org/10.5281/zenodo.7767236
[30] The overall exceedance rate for grapefruits in 2021 was 9.9% compared to 1.7% in 2018.

been taken out from the average calculation, the MRL exceedance rate for 2021 would have been 1.4% as in 2018.

Results on 2021 findings were compared with 2018 and 2015 EU monitoring programmes.[31] Among individual food commodities, MRL exceedance rates from 2015 to 2018 and to 2021 rose in aubergines (from 0.4% to 1.6% and to 2.1%), bananas (from 0.3% to 1.7% and to 2.3%), sweet/bell peppers (from 0.8% to 2.4% and to 3.4%) and wheat (from 0.6% to 0.6% and to 1.5%). An increased trend for those food products to be sampled only in 2018 and 2021, was also observed in cultivated fungi (from 1.2% to 2.2%). Decreases were noticed on the exceedance rates from 2015 to 2018 and 2021 for broccoli (from 3.4% to 2.0% and to 1.7%), chicken eggs (from 0.2% to 0.1% and to 0%), melons (although not included in 2015 programme, decreased from 2.2% to 1.3%) and virgin olive oil (from 0.9% to 0.6% and to 0.3%). The tendency for table grapes was an increase compared to 2015 (1.7%) although in 2021 (2.1%) the rate decreased compared to 2018 (2.6%).

In all 12 commodities, the minimum number of 683 samples set in the EU MACP Regulation and required to estimate a minimum of 1% MRL exceedances with a margin of error of 0.75% was reached (for virgin olive oil 682 samples were reported).

The countries sampling the most were France (15.1%), Germany (14.9%) and Italy (10.8%). However, the Regulation set a minimum number based on the population size of each country. Therefore, those countries sampling the most in respect of the legal requirement were The Netherlands (4 times more), Romania (3 times more) and Bulgaria (2.9 times more). Instead, those sampling the least in respect to the minimum number given on the Regulation were Lithuania (44%), Malta (68%) and Greece (77%).

On average, out of the 13,845 samples collected, 53.3% were domestic samples, 22.8% were from other EU countries, 19.6% from third countries (an increase compared to 14% in 2020) and 4.3% were of unknown origin. The increase on samples from third countries explains the high non-compliant rate in some commodities compared to previous years (e.g. grapefruits) but also allowed to highlight the issue.

Reporting countries do not have a common approach to take the same rate of domestic, EU or third country samples. However, it is aimed to reflect the market share present in their country. Thus, countries where more than 80% of samples were domestic were Lithuania (100%), Spain (90.4%), Italy (84.18%) and Greece (82.01%). Those sampling the most from third countries were Romania (47.6%), Iceland (43.5%), Austria (37%) and Ireland (35.6%). The Netherlands (27.5%) and Germany (11.7%) had more than 10% of samples with origin unknown. The highest non-compliant rate by reporting country were Estonia (8.8%), Czechia (5.5%) and Slovakia (4.7%).

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 one sample per commodity listed. In total, 957 organic samples[32] were analysed. EFSA recommends Member States to fulfil the requirement on sampling at least one sample per given commodity.

In addition, 10 samples of processed cereal-based baby food were to be sampled. The total number of samples reported under baby food categories amounted to 484 samples.[33] EFSA recommends Member States to fulfil the requirement on sampling of at least 10 samples per given type of commodities. A comprehensive analysis of these results is reported in Section 4.3.3 where the data for all baby food samples are pooled. This category of samples has not been included in Appendix D – Annex I.[2]

Annex I of Regulation (EU) No 2020/585[9] also provides the list of pesticides to be analysed on each EU MACP sample taken by the EU official laboratories. In total, 190 pesticides were listed, of which, 165 pesticides were to be analysed in plant origin commodities, 9 pesticides in animal origin commodities and 16 both in plant and animal commodities.

Among the EU MACP samples reported and grown outside the internal EU market, 22 non-EU approved active substances were found to be non-compliant in 97 samples. The combinations reported in more than 5 samples were: grapefruits/chlorpyrifos-methyl (RD) (44 samples, all coming from Türkiye), grapefruits/chlorpyrifos (RD) (27 samples, all coming from Türkiye) and sweet/bell peppers/chlorfenapyr (RD) (4 samples from Cambodia and 1 sample from Albania). Moreover, in 53 samples

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[31] Cultivated fungi, melons and bovine fat were only compared to 2018 findings as were not requested in 2015.

[32] The minimum number of 12 samples mentioned in the EU MACP on organic were not reported by Czechia (2 commodities), Hungary (2 commodities), Greece (3 commodities), Estonia (3 commodities), Slovakia (5 commodities), Latvia (5 commodities), Finland (6 commodities), Croatia (6 commodities), Sweden (7 commodities), the Netherlands (7 commodities), Northern Ireland (7 commodities), Luxembourg (8 commodities), Slovenia (8 commodities).

[33] The minimum number of 10 samples of baby food category mentioned in the EU MACP were not reached by France (9 samples), Finland (8 samples), Portugal (4 samples) and no samples were reported by Bulgaria, Denmark, Ireland, Northern Ireland, Lithuania and Hungary.

from third countries, non-compliant results were reported on 15 approved active substances. The combinations reported in more than 5 samples were: grapefruits/buprofezin (RD) (16 samples from Türkiye and 1 sample from USA), grapefruits/prochloraz (RD) (7 samples from Türkiye) and bananas/imazalil (RD) (8 samples from Ecuador).

For those samples with origin the EU, 28 samples were reported as non-compliant for 14 pesticides non-approved at EU level. The combinations reported in more than 5 samples were: wheat/chlorpyrifos (RD) (6 samples from Bulgaria and 1 sample from Slovakia). In 39 samples grown in the EU, non-compliant results were reported in 23 approved substances. The combinations reported in more than 5 samples were: sweet/bell peppers/ethephon (RD) (3 samples from Poland, 2 samples from Spain and 1 sample from The Netherlands) and cultivated fungi/dithiocarbamates (RD)[34] (2 samples from Croatia, 2 samples from Spain and 1 sample from Portugal).

EFSA recommends reporting countries to keep monitoring these combinations in their scope of analysis.

Member States were to analyse 190 pesticides listed in the EU MACP. Therefore, a target number of analysis was calculated considering the minimum number of samples (683 samples per commodity) to be reported by each country and comparing it against the total number of reported results. Nineteen pesticides did not reach this minimum number of results: pencycuron (RD), dithianon (RD), 2-phenylphenol (RD), glufosinate (RD), fosetyl (RD), bromide ion (RD), 2,4-D (RD), prochloraz (RD), chlordane (RD), spirotetramat (RD), haloxyfop (RD), fluazifop (RD), ethephon (RD), mepiquat chloride (RD), formetanate hydrochloride (RD), pyridalyl (RD), dithiocarbamates (RD), cyflufenamid (RD), fenbutatin oxide (RD). Most of these substances require a single residue method (SRM) to be quantified. Thus, EFSA recommends again to encourage Member States taking the necessary measures to be able to enforce properly these substances.

Of the 13,845 samples, 5,802 had quantified results (41.9%) and in 3,734 samples (27%) more than one pesticide was quantified. The food products where the rate of multiple residues was higher than 10% were table grapes (22.2%), bananas (18.5%), grapefruits (18.4%) and sweet/bell peppers (12.8%).

The highest frequency of multiple residues was found in sweet peppers/bell peppers in a sample with origin Cambodia where 28 different pesticides were quantified followed by table grapes from Türkiye where 19 pesticides were quantified.

Detailed analyses are presented in Appendix D – Annex I.[2]

4.   Overall monitoring programmes (EU MACP and MANCP)

The MANCP are risk-based sampling programmes in accordance with Article 30 of Regulation (EC) No 396/2005 (supersede by Regulation (EU) No 2021/1355[12]). The focus is 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 used to compare countries directly as there are specific needs in each country and their dietary habits and access to local products 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.

The data analysis of this section is also presented in Appendix D – Annex I.[2] The data is 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. The section on reasons for MRL exceedance remain in this report (Section 4.4). More information on the national control programmes can be found in a separate EFSA technical report that summarises the national results (EFSA, 2023c).

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[34] As long as all the dithiocarbamates assessment for each single precursor have not been assessed individually, within the remit of this report 'dithiocarbamates' will be considered as an approved substance.

4.1.   Geospatial findings

In 2021, the EU Member States,[1]* Iceland and Norway, analysed a total of 87,863 samples for pesticide residues on/in food products covered by Regulation (EC) No 396/2005, very similar to 2020 (88,141 samples).

Additionally, 11 countries reported 1,523 feed samples and 14 countries reported 2,382 fish samples. Although under Regulation (EC) No 396/2005, no MRLs are established in/on fish in view of the mandate received,[35] a short summary of the pesticide findings in fish has been included in Appendix D – Annex I.[2]

Of the total number of 87,863 samples analysed, 56% of the samples were domestic samples, 16.6% were originated from another EU country, 21.7% were imported from third countries and 5.7% had unknown origin.

The countries with the highest sampling rates of imported products from third countries were Finland (46%) and Sweden (41%). Lithuania, Italy and Spain focussed mainly on domestic sampling (more than 80% of the samples analysed). Further, Germany and the Netherlands, reported the highest rate of samples with origin unknown (15% and 14%, respectively).

Of the total 87,863 samples, 63,803 were reported as originating from one of the reporting countries. Of these 38% were found not to contain any residue above the LOQ, while 24% contained residues at or above the LOQ but below or equal to the MRL. A 2% of the samples exceeded the MRL and of these, 1.3% were non-compliant with the MRL. A remaining 19,053 samples were imported from third countries, of which 42% were reported as without quantifiable residues, while in 47.7% of samples contained quantifiable residues within the legal limits. The MRL exceedance rate (10.3%) was five times higher than in those samples grown in one of the reporting countries, as well as the non-compliant rate (6.4%). The remaining 5,007 samples (5.7%) were reported as origin unknown of which 225 samples (4.5%) exceeded the MRL.

4.2.   Results by pesticide residues

In 2021, a total of 87,863 samples were analysed. Of these, 48,916 samples (55.7%) did not contain quantifiable residues (results below the LOQ for each pesticide analysed) while 40.4% of the samples analysed contained quantified residues not exceeding the legal limits (35,483 samples). In total, 96.1% of the samples fell within the legal limit. This tendency seems to be constant for the last years (94.9% in 2020; 96.1% in 2019). The MRL exceedance rate decreased from 5.1% in 2020 to 3.9% in 2021 (3,464 samples). When measurement uncertainty is considered, the non-compliance rate also decreased from 3.6% in 2020 to 2.5% in 2021 (2,207 samples).

Close to 21 million analytical determinations (individual results) were submitted to EFSA (see Appendix D – Annex III – Table 3.3). The number of determinations for which residue levels were quantified at or above the LOQ amounted for 103,229 (i.e. 0.5% of the total determinations) in relation to the overall number of 87,863 samples.

The reporting countries analysed in total 854 different pesticides. An analytical scope higher than 600 pesticides at country level, was noted for Luxembourg (656 pesticides), Germany (636 pesticides), Portugal (630 pesticides), Malta (623 pesticides), France (620 pesticides) and Belgium (614 pesticides). On average, 271 different pesticides were analysed per sample.

The pesticides quantified in more than 100 samples and where a quantification rate higher than 10% was reported were: copper compounds (RD) (78.3%), mercury (RD) (20.4%), bromide ion (RD) (20.2%), fosetyl (RD)[36] (17.2%), chlorate (RD) (12.0%), chlordecone (RD) (11.2%), dithiocarbamates (RD) (10.8%) and ethylene oxide (RD) (10.2%). The pesticides where the MRL exceedance rate was higher than 1% were: ethylene oxide (RD) (6.6%), dithiocarbamates (RD) (1.2%) and copper compounds (RD) (1.0%).

- Ethylene oxide. Out of 2,011 samples where ethylene oxide was analysed, in 133 samples the MRL was exceeded (6.6%). Of those, 25 samples were of sesame seeds coming from India, 13 samples were of curcuma from India, 9 samples of rice from India and 6 samples of chilli

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[35] Exposure assessment concerning the risks for public health related to the presence of benzalkonium chloride (BAC), didecyldimethyl ammonium chloride (DDAC) and chlorates in/on fish and fish-products. M-2022-00181.

[36] 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 residue definition for enforcement common to all was derived 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)' (EFSA, 2021a).

peppers from India. In the autumn of 2020, Member States[37] notified in the RASFF[38] 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, Regulation (EU) 2020/1540[15] increased the frequency of controls at borders to 50%. EFSA recommends Member States to monitor this substance in curcuma, rice or chilli peppers coming from India.

- Dithiocarbamates (RD) was analysed in 13,049 samples, of which 157 samples exceeded the MRL (1.2%), mainly in grape leaves and similar species. Dithiocarbamates precursor are six active substances. All share a common residue definition for enforcement (determined and expressed as carbon disulfide (CS_2)). In view of the different approval status in place in 2021, ziram and metiram would be the most likelihood precursors for the above exceedances on domestic (or EU) samples.[39] As

  - Maneb's approval expired in June 2016. EFSA's conclusion on mancozeb on the renewal of the approval concluded that the new criteria to identify endocrine disrupting properties were met and thus the approval of mancozeb was not renewed.[40]
  - In EFSA's peer review on propineb, a critical area of concern was underlined related to the endocrine-disrupting properties of the relevant metabolite 4-methylimidazolidine-2-thione (PTU). Moreover, a high risk to honeybee brood development could not be excluded. Consequently, the approval of propineb was not renewed by Regulation (EU) 2018/309[41].
  - EFSA's conclusion on the peer review of thiram identified a high acute risk to consumers and to workers from application of thiram by foliar spraying. Furthermore, EFSA could not conclude on the endocrine disrupting potential of thiram. Consequently, in 2018, a decision of non-renewal of thiram was taken by Regulation (EU) 2018/1500[42].
  - Ziram approval was restricted to uses as fungicide and as repellent. In 2018, EFSA initiated the peer review process for the renewal of the approval. The evaluation is currently suspended to provide the time necessary to carry out an assessment relating to endocrine disrupting properties. Consequently, the approval of ziram has been extended until 30 April 2023 by Regulation (EU) 2022/378[43].
  - Metiram approval was restricted to fungicide uses. In 2019, EFSA initiated the peer review process for the renewal of the approval of metiram which is still on-going while this report is being finalised. EFSA is performing a combined review on the existing MRLs. In certain crops, naturally occurring compounds mimic the presence of residues resulting from the use of dithiocarbamates. Therefore, monitoring data from organic samples compiled by EURLs, from control samples and Ruedis database (RUEDIS, 2020), reflecting CS_2 levels in these crops not related to the uses of the dithiocarbamates are being considered in the

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[37] https://ec.europa.eu/food/safety/rasff-food-and-feed-safety-alerts/ethylene-oxide-incident-food-additive_en

[38] https://food.ec.europa.eu/safety/rasff_en

[39] Samples coming from third countries, could potentially contain any of the six precursors since no differentiation is made in the analysis.

[40] 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.

[41] Commission Implementing Regulation (EU) 2018/309 of 1 March 2018 concerning the non-renewal of approval of the active substance propineb, 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 60, 2.3.2018, p. 16–18.

[42] Commission Implementing Regulation (EU) 2018/1500 of 9 October 2018 concerning the non-renewal of approval of the active substance thiram and prohibiting the use and sale of seeds treated with plant protection products containing thiram, 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 Commission Implementing Regulation (EU) No 540/2011. OJ L 254, 10.10.2018, p. 1–3.

[43] Commission Implementing Regulation (EU) 2022/378 of 4 March 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, Bacillus subtilis (Cohn 1872) strain QST 713, Bacillus thuringiensis subsp. Aizawai strains ABTS-1857 and GC-91, Bacillus thuringiensis subsp. Israeliensis (serotype H-14) strain AM65-52, Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, Beauveria bassiana strains ATCC 74040 and GHA, clodinafop, Cydia pomonella Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, Pseudomonas chlororaphis strain MA342, pyrimethanil, Pythium oligandrum M1, rimsulfuron, spinosad, Trichoderma asperellum (formerly T. harzianum) strains ICC012, T25 and TV1, Trichoderma atroviride (formerly T. harzianum) strain T11, Trichoderma gamsii (formerly T. viride) strain ICC080, Trichoderma harzianum strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram OJ L 72, 7.3.2022, p. 2–6.

review. During 2023, risk managers are expected to discuss the recommendations derived by EFSA MRL review and decide whether actions towards a modification on the current MRLs need to be taken.

- Copper compounds (RD) was reported to have been analysed in 3,647 samples. Of which, in 38 samples the MRL was exceeded (1.0%). Copper findings tend to be linked to different sources rather than uniquely as a pesticide use. Is a naturally occurring substance that can be present in the diet as food additives or in feed giving to livestock. According to EFSA's recent publication estimating the contribution of copper to the total dietary and non-dietary sources, the exposure to copper coming from pesticide uses in negligible (EFSA Scientific Committee, 2023).

Details on the samples exceeding the MRL can be consulted in Appendix D – 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.

Of the 87,863 samples analysed, 38,947 samples (44.3%) contained one or several pesticides in quantifiable concentrations. Multiple residues were reported in 23,177 samples (26.4%); in an individual sample of raisins of unknown origin, up to 39 different pesticides were reported.

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

The highest frequency of multiple residues in processed food samples was found in wine grapes, raisins, dried celery leaves, marjoram, grape leaves and similar species (salted and canned).

4.2.2. Results on glyphosate

Glyphosate is approved for use in the EU until 15 December 2022.[44] Article 17 of Regulation (EC) No 1107/2009[7] sets the legal obligation of the European Commission to take account of EFSA adopted conclusion to complete a renewal assessment. EFSA has not yet finalised its output. Thus, the approval of glyphosate active substance has been prolonged for a period sufficient to allow EFSA to finish its work. The glyphosate assessment is on-going.[45] The expected date for EFSA's peer review conclusion to be finalised is July 2023.[46]

EFSA considers an analysis on the occurrence data received on glyphosate of interest. In 2021, glyphosate was reported by 26 countries analysing 15,136 samples of different food products and by 7 countries analysing 459 samples of animal feed (on which no MRL is set).

Regarding food samples, in 14,904 of the samples (98.5%) glyphosate was not quantified. In 209 samples (1.4%), glyphosate was quantified at levels above the LOQ but below the MRL and in 23 samples (0.15%) the residue levels exceeded the MRL, mainly in common millet, buckwheat and other pseudo-cereals. The exceedance rate was lower than in 2020 (0.6%). Of these, considering the measurement uncertainty, 12 samples (0.07%) were non-compliant. Glyphosate residues were analysed in 537 baby food samples all below the LOQ.

Glyphosate metabolites were analysed in different volume of food samples: AMPA (3,875 samples), AMPA-*N*-acetyl (954 samples) and *N*-acetyl glyphosate (2,669 samples), being only AMPA quantified in 44 samples (1.2%), mainly in cultivated fungi.

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[44] https://food.ec.europa.eu/plants/pesticides/approval-active-substances/renewal-approval/glyphosate_en
[45] https://www.efsa.europa.eu/en/topics/topic/glyphosate
[46] https://www.efsa.europa.eu/en/news/glyphosate-efsa-and-echa-update-timelines-assessments

4.2.3. Results on temporary increase on import controls

According to the provisions of Regulation (EU) 2019/1793[13] on temporary increase on import controls, certain foods were subject to an increased frequency of official controls for certain pesticides at BCPs into the EU territory. The data presented in this section, is a subset of the one sent by reporting countries through the IMSOC[47] platform. Some of these controls may enter the RASFF[38] of the European Commission. More information can be found in 2021 RASFF report (European Union, 2022).

The total number of samples reported to EFSA were 1,111 samples. Of those, 77 samples (7%) were considered non-compliant with EU legislation on pesticide residues.

The results presented in this section are based on the data reported directly to EFSA for the sampling year 2021. Other data might have been reported directly to DG SANTE. Therefore, this section may not give the whole picture of the situation.[48]

A description of the required controls regarding hazard analysis, type of food products and countries of origin, relevant for the calendar year 2021 can be found in Appendix D – Annex III – Table 3.4.

4.3. Results by food products

4.3.1. Results by processed versus unprocessed food products

Of the 87,863 total samples reported in 2021, 8,871 samples (10.1%) were of processed food, excluding baby food. The compliance of these samples is checked against the maximum residue levels in the respective raw agricultural commodity after applying a processing factor (PF) derived for the given processed technique as per Article 20 of Regulation (EC) No 396/2005[49]. In 397 samples (4.5%), residues exceeding the corresponding MRL were found. Of these, 275 samples (3.1%) were non-compliant taking into account the measurement uncertainty. Both rates are higher than in 2020, where the MRL exceedance rate was 2.6% and the non-compliance rate was 1.2%.

Food products where more than 10 samples were reported and the non-compliance rate was higher than 10% were: grape leaves and similar species 56.6% (involved processes were canned/jarred, pickled/marinated and salted vegetables processed), dried chilli peppers (19.1%), dried laver (13.9%) and dried dill leaves (11.9%).

On the contrary, 77,422 samples were reported as unprocessed food products.[50] Of these, 3,038 samples (3.9%) had residues exceeding the MRL, 1,766 samples (2.3%) were non-compliant due to measurement uncertainty. Those unprocessed food products for which more than 100 samples were reported and the non-compliance rate was higher than 10% were: passionfruit/maracujas (14.9%), granate apples/pomegranates (12.8%) and chilli peppers (13.9%).

4.3.2. Results on organic products

No specific MRLs are established for organic products. 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[25] on organic production of agricultural products defines restrictions in place for the use of PPP. Compared to conventionally produced food (non-organic), in 2021 the MRL exceedance and quantification rates were lower in organic food for all food product categories.

In 2021, 6,530 samples labelled as organic (excluding baby food) were reported, corresponding to 7.4% of the total samples and being an increase respect to 2020 (6.5%). Of those, 957 samples were reported under the EU MACP.

Overall, 5,408 samples flagged as organic did not contain quantifiable residues (82.8% of the analysed samples vs 80.1% in 2020); 1,005 samples contained quantified residues below or at the MRL level (15.4% vs 18.4% in 2020) and 117 samples were reported with residue levels above their corresponding MRLs (1.8% vs 1.5% in 2020), of which 1% (68 samples) were non-compliant.

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[47] https://ec.europa.eu/dpo-register/detail/DPR-EC-02027.2

[48] 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.

[49] 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.

[50] In the framework of this report, unprocessed food products are considered those to which a 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.

The pesticides with higher quantification rate (i.e. at levels above the LOQ but below the MRL) were copper compounds (RD) (430 samples, 79%), bromide ion (RD) (98 samples, 15%), chlorate (RD) (59 samples; 7%), fosetyl (RD)[36] (6.5%), mercury (RD) (5.9%) and dithiocarbamates (RD) (5.6%). The pesticides exceeding the MRL the most was ethylene oxide (RD) (6.4%).

Most of the quantified substances are often present in samples flagged as organic, either because they are authorised for use (e.g. copper compounds), they naturally occur (e.g. bromide ion), they occur as degradation product of a sanitisation processed (e.g. chlorate) or are persistent contaminants of already banned substances (e.g. DDT (RD)). In the case of ethylene oxide (RD),[37] misuses of this substance were known since 2020 and monitored by Member States on samples imported in the EU.[15] MRL exceedances in ethylene oxide were reported in 18 samples, of which 5 were turmeric/curcuma samples from India.

The following pesticides not authorised in organic farming were sporadically found in crops labelled as such: imazalil (RD) in 15 samples (of which, 12 samples were from 'other miscellaneous large fruits with inedible peel' coming from Ecuador') and chlorpyrifos (RD) in 13 samples (of which, 4 samples were from 'buckwheat and other pseudo-cereals' coming from Bolivia).

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, EFSA recommends Member States to try to elucidate the reasons when pesticides found occasionally in organic food are quantified and which are not permitted in these types of products. EFSA also recommends widening the analytical scope on organic samples as much as possible.

4.3.3. Results on baby food

Reporting countries analysed 1,686 samples of foods for infants and young children as defined in Regulation (EU) No 2016/127[22] and Directive 2006/141/EC[21] of herein referred to as foods for infants and young children or baby food. The types of baby food products reported were infant formulae (124 samples), follow-on formulae (138 samples), food for infants and young children (108 samples), processed cereal-based foods for infants and young children (702 samples) and baby foods other than processed cereal-based foods (614 samples).

From the overall number of baby food samples analysed, 497 samples were flagged as organic samples. Of the total, 484 baby food samples were flagged as EU MACP.

The MRLs in baby food are stablished at the default MRL of 0.01 mg/kg, except for a given number of substances which are set much lower[21] (EFSA, 2018d). Overall, 799 different pesticides were analysed. In 1,475 samples (87.5%) no residues were quantified (a rate lower than in 2020–91.7%). Quantified samples with residues at or above the LOQ but below the MRL, were found in 182 samples (10.8%). In 94.9% of the samples copper compound was quantified. Copper compound is a naturally occurring substance but can also be present in the diet being a food additive or intake by livestock through feeding stuff. Moreover, when reporting pesticide residue in infant food, in accordance with Article 2(3) of Regulation (EU) No 2020/585, the results shall be reported based on the reconstituted product. This process mainly adds water being a possible significant contributor of copper. According to EFSA's recent publication (EFSA Scientific Committee, 2023), infant formula and follow-on formula[51] are important contributors to the dietary exposure of copper in infants and toddlers. However, adverse effects from exposure to it in children, are not expected due to children's higher nutrient requirements for growth.

In 29 samples (1.7% of samples), the MRL was exceeded. Of these, when measurement uncertainty was considered 10 samples led to non-compliant results (0.6% of samples), a lower rate than in the last years (1.7% in 2020, 1.3% in 2019 and 2018). The most frequent pesticides found to exceed the MRL were bromide ion (RD) (7.8% of samples) and chlorate (RD) (2.7% of samples). Bromide ion is a naturally occurring substance. The active substance leading to bromide ion residues (i.e. methyl-bromide) was banned from the market many years ago. Chlorate findings are explained as occurring after sanitisation practice in the food change, thus its presence is not due to a pesticide use.

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[51] Copper is a microelement authorised in the formulae's manufactured from cows' milk proteins or protein hydrolysates (EFSA, 2014a).

4.3.4. Results on animal products

A total of 14,439 samples of animal products were reported. The results showed that 12,400 samples were free of quantifiable residues (85.9% vs 92.0% in 2020) while 1,850 samples (12.8% vs 6.8% in 2020) contained quantifiable concentrations at or below the MRL.

The pesticides with a higher quantification rate were copper compounds (RD) (78.4% in 1,441 samples), chlordecone (RD) (42.7% in 2,927 samples), DDT (RD) (15.6% in 554 samples) and hexachlorobenzene (RD) (5.3% in 365 samples).

MRL exceedances were identified in 189 samples (1.3% vs 1.2% in 2020), of which 126 (0.9% vs 0.8% in 2020) were deemed non-compliant when measurement uncertainty was taken into account. Among the pesticide findings leading to MRL exceedances in more than 10 samples were: bromide ion (RD) (17 chicken eggs samples and 19 bovine fat samples), BAC (RD) (25 cattle milk samples), copper compounds (RD) (12 honey and other apicultural products samples, 10 bovine liver samples and 8 wild terrestrial vertebrate animal samples), chlordecone (RD) (22 chicken eggs samples[52] and 5 bovine fat samples), DDAC (RD) (10 cattle milk samples) and chlorate (RD) (10 quail egg samples).

Bromide ion is a naturally occurring substance in some feed commodities. Copper compound findings tend to be linked not only to a pesticide use but as feed supplement taken up by livestock. BAC/DDAC/chlorate are degradation products generated under industrial practice, found mostly inn products derived from milk such as cream. EFSA recommends food business operators to review their food handling practice aiming at reducing the MRL exceedances of chlorinated derived substances. The presence of chlordecone (RD) in chicken eggs relates to its persistence on/in the soil, as a contamination may occurred in chicken grown in open-cage farms when feed is placed in contact with the soil in areas where this active substance was used in the past. EFSA recommends putting measures in place to avoid intake contamination.

In honey, 1,035 samples were reported. In 894 samples (86.4%) 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) was 119 (11.5%). MRLs were exceeded in 22 samples (2.1% vs 5.5.% in 2020), of which 17 samples (1.6% vs 3.5% in 2020) were found to be non-compliant taking the measurement uncertainty into account. A decrease on the quantified rates is noted for honey. In total 28 different pesticides were found. The most frequent quantified pesticides were thiacloprid (46 samples, leading to 1 MRL exceeding sample) and acetamiprid (39 samples, leading to 2 samples exceeding the MRL). A decrease on thiacloprid findings is noted due to the stop at EU level of its use. EFSA recommends that reporting countries keep analysing animal products for these substances.

Despite no MRLs are applicable to fish under Regulation (EC) No 396/2005, 2,382 fish samples were reported covering an analytical scope of 509 pesticides. In 133 samples (5.6%) pesticide residues at levels quantified at or above the limit of quantification were reported. In total, 11 different pesticides were reported. The most frequent ones were chlorate (RD) (39 results in pangas catfishes), DDT (RD) (5 results in sea bass), benzalkonium chloride (RD) (8 results in cod), mercury (RD) (10 results in Atlantic salmon), copper compounds (RD) (10 results in Atlantic salmon) and DDAC (RD) (7 results of which 2 in sea bass, 2 in tilapias and 1 in cod).

4.4. Reasons for MRL exceedances/non-compliances

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 (OECD, 2011). Therefore, a percentage of approximately 1% of MRL exceedances are expected even if GAPs are fully respected. A sample is considered to be non-compliant when at least one pesticide is quantified at a level that after taking into account the expanded measurement uncertainty, the lower tail of the distribution is above the MRL value (European Commission, 2021). When a non-compliant sample is identified, a call for action at Member States level in line with Article 50 of Regulation (EC) No 178/2002 is required. Generally,

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[52] All samples reported as MRL exceedance on chlordecone in eggs came from chickens grown under cage-free conditions. The likelihood of contaminated soil could be the reason for uptake of the pesticide through the diet.

Member States reply with appropriate measures to non-compliances (e.g. administrative fines, RASFF notifications[38,53] and follow up actions, etc.).

In 2021, out of 87,863 samples reported, 3,464 samples contained pesticide residues exceeding their respective MRLs (3.9%). The MRL exceedance rate in 2020 was 5.1%. When taking into account the measurement uncertainty, 2,207 samples resulted into non-compliant (2.5%), less than in 2020 (3.6%).

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 oranges from Egypt, in grapefruits from Türkiye, in tea leaves from China, in sesame seeds from India and in grape leaves from Egypt; *chlorpyrifos-methyl* in grapefruits, sweet peppers/bell peppers, mandarins and lemons coming from Türkiye; *propiconazole* in oranges from South Africa).
    - GAP not respected or registered use follows different treatment pattern: use of approved pesticide deviating from the application rates, pre-harvest intervals, number or method of applications (e.g. *acetamiprid* in pomegranate from Türkiye, tea leaves from China, in rice from Pakistan, grape leaves from Egypt).
    - Processing techniques used in third countries mainly with the view of reducing microbiological contamination (i.e. *Salmonella sp*. in sesame seeds), found to lead to not approved residues (e.g. ethylene oxide in sesame seeds and curcuma from India).

- For samples originating from the internal market (reporting countries):

    - Use of approved pesticides but not in the crop for which the GAP is authorised (e.g. *fluazifop* in melons, *oxamyl* in cucumbers, *azadirachtin* in parsley)
    - GAP not respected in accordance with application rates, pre-harvest intervals, number or method of applications of the pesticide product (e.g. *dithiocarbamates* in spinaches, *acetamiprid* in kiwi fruits).
    - Misuses of non-approved pesticides (e.g. *dimethoate* in apples, *chlorpyrifos* in peaches)
    - Contamination from previous pesticide use: uptake of residues from the soil (e.g. persistent pesticides used in the past such as *chlordecone* in dasheen taros, *heptachlor* in courgettes, *dieldrin* in cucumbers)
    - Environmental contamination resulting from inappropriate application (e.g. propamocarb in celeries, prosulfocarb in coriander leaves)
    - Use of non-EU approved pesticides (e.g. *chlorfenapyr* in tomatoes) that have not been subject to emergency authorisations[54] granted during 2021.
    - Natural presence of the substance in the crop (e.g. *dithiocarbamates* in turnips)
    - Presence of biocide residues used as pesticides in the past and continuing to be monitored under the pesticide legislation (e.g. *chlorate* in different food commodities).
    - 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. *alpha-hexachlorocyclohexane (HCH)* in swine fat or in nigella seed).

More details on the pesticide/crop combinations exceeding the legal limits are compiled in Appendix D – 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

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[53] 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.
[54] An emergency authorisation in accordance with Article 53 of Regulation (EC) 1107/2009.[7]

based on the results from the official controls provided by reporting countries. The analysis of the risk to the health posed by the finding of residues is supported by data on food consumption.

To analyse acute (short-term) and chronic (long-term) risks to consumer health, EFSA relates the amount of a residue consumed with its corresponding health-based guidance value (HBGV). HBGVs 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.

5.1. Acute deterministic risk assessment

The deterministic assessment to single substances of the acute health-risk to consumers has been performed using the International Estimation of Acute Intake (IESTI) (FAO, 2017) equation implemented in the Pesticide Residues Intake Model (PRIMo) (EFSA, 2018b) based on its revision 3.1 (EFSA, 2019c). The model has been adjusted to allow for food consumption data from the EU population.

The ARfDs established by EFSA under regulations (EC) No 1107/2009 were selected, when available. Active substances for which EFSA's most recent assessment could not conclude on the establishment of a HBGV, were treated according to one of the following two cases:

- The assessment of the genotoxic potential *in vivo* of the substance could not be completed (e.g. insufficient data): in such case, a tentative acute risk assessment was conducted using an ARfD based on the current knowledge (e.g. dimethoate, (EFSA, 2018f)).
- The substance was concluded to be an *in vivo* mutagen: in such cases, it was considered not possible to set any HBGV, and thus, the MRLs were established at the limit of quantification to protect consumers, but no assessment was conducted within the remit of this report (e.g. omethoate) (EFSA, 2017c).

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

In Appendix D – Annex II, the outcome of the deterministic exposure assessments is included. The ARfD values used are reported in Appendix D – Annex III – Table 3.5, indicating if a tentative assessment was conducted.

5.1.1. Methodology for the estimation of acute deterministic exposure

The acute risk assessment was restricted to the pesticide/crop combinations as laid down in the 2021 EU MACP, i.e. to 190 pesticides in the 12 food products: aubergines (egg plants), bananas, broccoli, cultivated fungi, grapefruit, melons, sweet peppers, table grapes, virgin olive oil, wheat, bovine fat and chicken eggs. A total of 19,499 samples were subject to this assessment of which, 5,170 samples (26.5%) were taken under the framework of the national programmes. The assessment was based on the following considerations:

- For each single pesticide/crop or product combination, the highest measured residue concentration reported to EFSA is identified and it is assumed that a large portion[55] of the respective food item is consumed typically on a single day or meal. This also applied to bulk or processed samples listed in the EU MACP (e.g. wheat or virgin olive oil) where normally for these types of commodities in MRL setting procedures; the average value of residue trial results is used instead. This is a conservatism approach followed by EFSA in previous reports (EFSA, 2017a, 2020a). Although is a deviation from the IESTI equation (FAO, 2017) where the commodities are considered blended in the residue trials, is not the case in the market i.e. no

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[55] 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.

homogeneity is found in the market for a given commodity. To retrieve the highest residue concentration for wheat, results from raw grains and whole grain flour[56] were pooled.

- The residue concentration in the first unit of a food product consumed is five or seven times higher than the measured in the sample. This aims to cover the non-uniform residue distribution among the individual units in the sample. For food commodities with a unit weight of more than 250 g (i.e. aubergines (egg plants), broccoli, grapefruit, melons and table grapes), a variability factor of 5 is applied. For mid-sized products (i.e. bananas, peppers and cultivated fungi) 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 weights less than 25 g, or composite or animal products (i.e. virgin olive oil, wheat, bovine fat and chicken eggs).[57]

- 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.

- Considering that some food items may undergo treatment before consumption (e.g. washing, peeling, cooking, etc.), PFs were used in the estimation of the exposure for specific pesticide/crop combinations when available. The source to retrieve PF was the EU PF database (Zincke, 2022). In the absence of PFs, it is assumed that the residues on the raw commodity are entirely transferred to the product as consumed. Appendix D – Annex II – Table 2.6 contains a list of the PFs for pesticide/crop combinations used in the context of this acute risk assessment.

- Monitoring data reported to EFSA are based on two different sampling plans. One, the EU MACP which relies on random sampling. The other generates data from the various national programmes (MANCP) that are carried out following risk-based sampling (Art. 30 of Regulation (EC) No 396/2005), but still aimed at assessing consumer exposure. 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. Sensitivity analysis undergone by EFSA testing the impact of selective sampling (ST10A) vs objective sampling (ST20A) showed that the exposure calculation did not significantly affect the outcome (EFSA, 2022e). Thus, both type of sampling plans can be pooled together. The selection of samples for this assessment combined the sampling strategy with the programme type taking K009A, K018A and K005A but excluding K019A (EFSA, 2022a).

- Residue levels of fat-soluble pesticides reported as bovine meat[58] for which results were expressed on the whole product, were recalculated to fat basis, assuming a default fat content of 20% (if fat percentage was not reported) (FAO, 2017). This approach was implemented only in the cases of samples with quantified residues (results $\geq$ 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 levels expressed according to the definition established for enforcement (which is in accordance with the EU MRL legislation) and were not converted into the one defined for risk assessment, as monitoring data is based on residue definitions for enforcement/monitoring and for most of the relevant substances/commodity combinations no proper conversion factor database exists to facilitate this assessment. Thus, possible underestimation of the assessment can be expected.

- For bromopropylate (RD), chlordane (RD), heptachlor (RD), hexachlorobenzene (RD), alpha-HCH (RD), beta-HCH (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

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[56] According to the 2021 EU MACP control programme, samples of wheat whole grain flour could be taken in case samples of grain were not available for monitoring purposes.

[57] 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 25 g (EFSA, 2019b).

[58] Within the 2021 EU MACP, bovine meat could be sampled in accordance with Table 3 of Annex to Directive 2002/63/EC.

possible conservative element to consider in the risk assessment because for most pesticides, the ADI is set at a lower level than the ARfD.

- Consumption data used for the deterministic exposure assessment were those used in PRIMo model revision 3.1 (EFSA, 2018b). The 97.5th percentile of the consumption distribution was taken for the 11 Member States (Belgium, Czechia, Germany, Denmark, Finland, France, Ireland, Italy, Lithuania, Poland and Spain) who derived it from national food surveys. In cases where the number of respondents reporting consumption of a certain commodity were low, alternative percentiles were selected.

- 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 (EFSA, 2014c).

- For the legal residue definition of 'cyfluthrin (cyfluthrin including other mixtures of constituent isomers (sum of isomers))', based on EFSA opinion (EFSA, 2020b), the mammalian toxicology experts agreed to read-across the toxicological profile of beta-cyfluthrin in the short-term and developmental studies (e.g. for long-term and reproductive toxicity). Thus, the cyfluthrin toxicological profile was taken.

- For the legal residue definition of lambda-cyhalothrin (including gamma-cyhalothrin) (sum of R, S and S,R isomers), the acute risk assessment was based on the acute toxicological profile of gamma isomer being the most potent of the two approved active substance (EFSA, 2017b).

- Related to cypermethrin residue definition (cypermethrin including other mixtures of constituent isomers (sum of isomers)), the toxicological profile selected to undergo the risk assessment was the one of cypermethrin being the only approved combination respect to the alpha, beta or zeta isomers (EFSA, 2018e).

- Most of the dithiocarbamates are not approved (except metiram and ziram). However, in view of having a thorough coverage of all possible uses and missuses, all five active substances (mancozeb, maneb, propineb, thiram or ziram) were considered in the risk assessment. Still no analytical method has been derived to differentiate each of the active substance. Thus, the monitoring data used in the assessment reflects the common moiety method measuring total CS_2. Metiram was not considered in this assessment because an ARfD was not available at the time this report was done.[59]

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

5.1.2. Results

The results of the acute deterministic 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).

- When PF have been used, 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 as no ARfD needed to be derived therefore, not calculated (e.g. 2-phenylphenol) or (iii) the acute risk assessment is relevant but no health-based guidance value has been derived (i.e. bromide ion,[60] isocarbophos and omethoate).

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 otherwise not available.

- Yellow cells indicate that the exposure was lower than the pesticide's ARfD.

- 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 1,000% of the ARfD, and dark red cells correspond to acute exposure estimates above 1,000% of the ARfD.

- Grey cells refer to pesticide/crop combinations not covered by the 2021 EU MACP.

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[59] Under the on-going peer review assessment, is likely that an ARfD is derived for metiram.
[60] Bromide ion assessment is put on-hold until EFSA delivers its evaluation (M-2022-00105).

- Residues marked with an asterisk (*) refer to pesticide/crop combinations with quantified residues for which the HBGVs (ADI/ARfD) were not available.

Among the 190 pesticides in 19,499 food samples, the acute risk assessment results were as follows (Figure 1):

- No HBGVs (ARfD) were allocated for three pesticides: bromide ion,[60] isocarbophos and omethoate.[61] These pesticides are marked with footnote c) in Figure 1.
- The setting of an ARfD was not necessary for 35 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), fosetyl (RD), hexythiazox (RD), iprovalicarb (RD), kresoxim-methyl (RD), lufenuron (RD), mandipropamid (RD), metrafenone (RD), pencycuron (RD), pyridalyl (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 29 pesticides, in any of the tested samples of the commodities under the 2021 EU MACP. These pesticides were: aldicarb (RD), bitertanol (RD), carbofuran (RD), chlordane (RD), dichlorvos (RD), diniconazole (RD), dodine (RD), ethion (RD), fenamidone (RD), fenarimol (RD), fenthion (RD), fluquinconazole (RD), haloxyfop (RD), heptachlor (RD), alpha-HCH, (RD), linuron (RD), methidathion (RD), methoxychlor (RD), monocrotophos (RD), oxadixyl (RD), oxydemeton-methyl (RD), paclobutrazol (RD), parathion (RD), prothioconazole (RD), tefluthrin (RD), terbuthylazine (RD), triadimefon (RD), thiodicarb (RD), vinclozolin (RD). Acute dietary exposure to any of these pesticides would not be expected to pose a concern to consumer health.
- Quantified levels for 94 pesticides resulting in exposures below the health-based acute reference values in all tested samples of the commodities under the 2021 EU MACP. This means that acute dietary exposure to these pesticides, would be expected not to be of concern to consumer health. The specific pesticides were: 2,4-D (RD), acephate (RD), azinphos-methyl (RD), bifenthrin (RD), bromopropylate (RD), buprofezin (RD), captan (RD), carbaryl (RD), chlormequat-chloride (RD), chlorothalonil (RD), chlorpropham (RD), chlorpyrifos-methyl (RD), clothianidin (RD), cyflufenamid (RD), cyfluthrin (RD), cymoxanil (RD), cyproconazole (RD), cyromazine (RD), diazinon (RD), dicloran (RD), dicofol (RD), dieldrin (RD), difenoconazole (RD), dimethomorph (RD), dithianon (RD), emamectin (RD), endosulfan (RD), epoxiconazole (RD), etofenprox (RD), famoxadone (RD), fenazaquin (RD), fenbuconazole (RD), fenbutatin oxide (RD), fenitrothion (RD), fenoxycarb (RD), fenpropathrin (RD), fenpropidin (RD), fenpyrazamine (RD), fenpyroximate (RD), fenvalerate (RD), fipronil (RD), fluazifop (RD), flubendiamide (RD), fluopicolide (RD), fluopyram (RD), flusilazole (RD), fluxapyroxad (RD), folpet (RD), glufosinate equivalents (RD), glyphosate (RD), hexachlorobenzene (RD), beta-HCH (RD), imazalil (RD), imidacloprid (RD), iprodione (RD), lindane (RD), malathion (RD), mepanipyrim (RD), mepiquat chloride (RD), metalaxyl and metalaxyl-M (RD), methamidophos (RD), methoxyfenozide (RD), myclobutanil (RD), parathion-methyl (RD), penconazole (RD), pendimethalin (RD), permethrin (RD), pirimicarb (RD), pirimiphos-methyl (RD), prochloraz (RD), procymidone (RD), profenofos (RD), propamocarb (RD), propargite (RD), propiconazole (RD), propyzamide (RD), proquinazid (RD), prosulfocarb (RD), pymetrozine (RD), pyridaben (RD), pyriproxyfen (RD), spinosad (RD), spinetoram (RD), spiromesifen (RD), spiroxamine (RD), spirotetramat (RD), tau-fluvalinate (RD), tebufenpyrad (RD), tetraconazole (RD), thiacloprid (RD), thiamethoxam (RD), tolclofos-methyl (RD), triadimenol (RD), trifloxystrobin (RD).
- There were 28 pesticides quantified in 220 samples (238 results) out of 19,499 samples (1.1%) at levels exceeding their respective health-based acute reference values: lambda-cyhalothrin (RD) (46 samples), cypermethrin (RD) (44 samples), acetamiprid (RD) (43 samples), indoxacarb (RD) (25 samples), ethephon (RD) (16 samples), phosmet (RD) (14 samples), flonicamid (RD) (7 samples), thiabendazole (RD) (6 samples), dimethoate (RD) (5 samples), abamectin (RD) (5 samples), formetanate (hydrochloride) (RD) (4 samples), oxamyl

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[61] For omethoate no HBGV has been derived due to in vivo mutagenicity being demonstrated (EFSA, 2017c).

(RD) (2 samples), methomyl (RD) (2 samples), tebuconazole (RD) (2 samples), acrinathrin (RD) (2 samples), fenpropimorph (RD) (1 sample), chlorfenapyr (RD) (2 samples), deltamethrin (RD) (2 sample), carbendazim (RD) (1 sample), thiofanate-methyl (RD) (1 samples), chlorpyrifos (RD) (1 sample), methiocarb (RD) (1 sample), pyraclostrobin (RD) (1 sample), triazophos (RD) (1 sample), fenamiphos (RD) (1 sample), fosthiazate (RD) (1 sample), flutriafol (RD) (1 sample) and hexaconazole (RD) (1 sample).

The ARfD exceedances were distributed among the EU MACP commodities as: table grapes (91 samples), grapefruits (46 samples), bananas (43 samples), sweet peppers/bell peppers (34 samples), melons (11 samples), aubergines/eggplants (6 samples), broccoli (5 samples) and wheat (2 sample). The available acute health-based guidance values were not exceeded in cultivated fungi, virgin olive oil and animal commodities (bovine fat and chicken eggs).

A more detailed analysis by pesticide exceeding in more than 20 samples the ARfD, is presented in the following paragraphs.

Dithiocarbamates (RD)

In 465 samples residues of CS_2 were quantified above the LOQ of which, 6 samples of cultivated fungi lead to non-compliant results. In the rest of the samples, the MRL was not exceeded. The commodities in which the acute health-based guidance values were exceeded by one of the dithiocarbamate precursor were: *ziram scenario* in table grapes, sweet peppers/bell peppers and melons. Not having analytical methods capable of differentiating among the different active substances, all six scenarios were considered. Thus, exceedances of the ARfD were also possible from *maneb scenario* in table grapes and melons, *mancozeb scenario* in table grapes and melons, *propineb scenario* in table grapes, sweet peppers/bell peppers and melons and *thiram scenario* in grapefruit, table grapes, bananas, sweet peppers/bell peppers and melons.

Lambda-cyhalothrin (RD) (46 samples)

Both active substances: gamma-cyhalothrin and lambda-cyhalothrin were approved for uses in the EU in 2021. The residue definition that covers both active substances is lambda-cyhalothrin (including gamma-cyhalothrin) (sum of *R,S*- and *S,R*-isomers). Since lambda and gamma-cyhalothrin cannot be distinguished during routine analyses (EURL, 2017), the risk-assessment conducted within this report has been done considering the acute HBGV of gamma-cyhalothrin, which is toxicologically the most potent isomer. This calculation is based on the critical assumption that all residues would come from the use of gamma-cyhalothrin. According to these calculations, the residues led to an exceedance of the acute estimates of gamma-cyhalothrin in bananas (32 samples), table grapes (12 samples), sweet peppers/bell peppers (1 sample) and broccoli (1 sample). None of the 46 results lead to a non-compliant result. No PFs were available to refine the exposure for any of the commodities. In case of lambda-cyhalothrin HBGV being used, still exceedances of table grapes and bananas would be identified.

In accordance with Article 43 of Regulation (EC) No 396/2005, EFSA performed a focussed assessment of the MRLs for lambda-cyhalothrin that may not be sufficiently protective for EU consumers (by using PRIMo rev. 2), if the residues would consist of the more toxic gamma-cyhalothrin (EFSA, 2017b). According to the information collected by EFSA in that framework, no uses are authorised for gamma-cyhalothrin on sweet peppers/bell peppers nor broccoli. No information was available for bananas since this commodity was out of the scope of the assessment. The situation is currently thoroughly investigated in the already ongoing review of existing MRLs for gamma cyhalothrin.

Considering the different toxicity of lambda and gamma, EFSA recommends the use of analytical methods capable of discriminating between the more toxic gamma- and less toxic lambda-cyhalothrin isomers (Cutillas et al., 2020). If a residue definition comprises different active substances with significantly different toxicological properties, only an unequivocal risk assessment is possible if the individual components can be quantified separately.

Cypermethrin (RD) (44 samples)

Cypermethrin (RD) residues exceeded the ARfD in grapefruits (18 samples), table grapes (11 samples), sweet peppers/bell peppers (8 samples), aubergines/eggplants (3 samples), wheat (2 sample), broccoli (1 samples) and melons (1 sample). Of these, two samples of table grapes from Cyprus reported as non-compliant with administrative actions. A PF of 0.33 (Zincke, 2022) for wheat was used to refine the risk assessment but still resulted in an exceedance.

Cypermethrin is a mixture of eight isomers (four diastereomeric pairs of enantiomers of alpha, beta, theta and zeta) where there are three chiral centres, resulting in eight stereoisomers and in up to four chromatographic picks/signals when using a non-chiral column (EURL, 2020). Cypermethrin approval status has been extended until 31 October 2022[62] in order to allow the renewal process to be completed and fully elucidate if is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009.

EFSA has recently adopted[63] a comprehensive MRL review (EFSA, 2023a) on the authorised uses of cypermethrin where measures for reduction of consumer exposure assessment are provided for risk managers consideration such as the lowering of the MRLs in place for the uses of table grapes, grapefruits, broccoli, aubergine/eggplants, melons, and wheat. For sweet pepper/bell peppers, no safe uses were identified; thus, in the Article 12 review of existing MRLs. EFSA recommended to lower the MRLs to the LOQ value.

In principle, alpha and beta isomers are not approved for use in the EU, but as according to the MRL review import tolerances are in place for zeta-cypermethrin and CODEX MRLs for cypermethrins (including zeta and alpha isomers) were implemented in the EU legislation (FAO, 2009; EFSA, 2010, 2016a) EFSA recommends Member States to be vigilant to the presence of these isomers in samples where residues of cypermethrin have been quantified.

Acetamiprid (RD) (43 samples)

Acetamiprid (RD) residues exceeded the ARfD in table grapes (23 samples), grapefruits (16 samples), sweet/bell pepper (3 sample) and aubergines/eggplants (1 sample). Out of the 43 samples, 6 samples lead to non-compliant results with origin Türkiye (4 samples) and Lithuania (2 samples). The action taken for the samples coming from Türkiye was not provided by the two reporting countries. For the Lithuanian samples there were follow-up investigation. The remaining 37 samples were compliant with the MRL in place for table grapes (19 samples ranging in concentrations from 0.34 to 0.81 mg/kg), grapefruits (16 samples ranging from 0.32 to 1.4 mg/kg) and sweet peppers/bell peppers (2 samples ranging from 0.56 to 0.611 mg/kg). No PF were available to refine the risk assessment.

The MRL review of acetamiprid (EFSA, 2011) was carried out using PRIMo rev. 2 and the derived in 2004 acute HBGV of 0.1 mg/kg bw. In 2016, EFSA adopted a conclusion on acetamiprid (EFSA, 2016b) meeting the approval criteria but lowering the HBGV to 0.025 mg/kg bw. In 2018, an Article 43 assessment (EFSA, 2018c) reviewed the MRLs for some commodities with the new HBGV but not for table grapes and grapefruits. If the highest residues of the residue trials supporting the current MRLs were inserted today on PRIMo rev 3.1 with the new HBGV derived, no risk to consumers would be identified. For aubergines and sweet/bell pepper, new MRL proposals have been derived in a recent MRL application, using PRIMo 3.1 (EFSA, 2021b). Thus, these exceedances are due to the methodology in place for calculating the MRL using the IESTI equation (FAO, 2017) for which the gap between the highest residues derived from residue trials and the statistical estimation of the MRL, results in this divergence (EFSA and RIVM, 2015). In view of such cases, the IESTI methodology is currently under review[64] in the EU and efforts are ongoing to also review it at international level. Thus, EFSA recommends Food Business Operators deriving processing studies for grapefruits to be able to refine the exposure assessment.

Indoxacarb (RD) (25 samples)

Indoxacarb (RD) residues exceeded the ARfD in table grapes (19 samples), sweet/bell peppers (4 samples), broccoli (1 sample) and melons (1 sample). All samples resulted in findings below the MRL. All samples were grown in an EU Member States.

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[62] Commission Implementing Regulation (EU) 2021/1449 of 3 September 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, etofenprox, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sulphur, tetraconazole, tri-allate, triflusulfuron and tritosulfuron. OJ L 313, 6.9.2021, p. 20.

[63] While writing this report the Reasoned Opinion was not yet published.

[64] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00739

Regulation (EU) No 2021/2081[65] sets the non-renewal of approval for indoxacarb with a grace period expiring on 19 September 2022 for Member States to withdraw authorisations for PPP containing this substance.

In compliance with Article 43 of Regulation (EC) No 396/2005, EFSA received a mandate[66] from the European Commission to perform a review of the MRLs for indoxacarb based on Codex maximum residue limits (CXLs) and on import tolerances which might still be maintained after the expiration of the approval of the active substance. EFSA screened the existing MRLs based on CXLs or on import tolerances considering the toxicological reference values established during the peer review process (EFSA, 2018a) and identified the MRLs for which an acute risk could not be excluded and several MRLs that are unlikely to pose a risk for consumers. Fall-back MRLs could not be proposed for the commodities exceeding the toxicological reference values as no further data were provided during the call for data. Therefore, risk managers may consider maintaining only the MRLs identified as safe for consumers and lowered to the LOQ those considered having a risk to them (EFSA, 2022d).

In the frame of the EU MACP, no HBGV could be derived for three pesticides. Thus, the estimated acute exposure is presented in Table 1 based on the commodities where results were quantified:

- bromide ion (RD) was to be analysed in sweet peppers/bell peppers. It was quantified in 119 samples. The acute risk assessment will be conducted by EFSA after having finalised the scientific opinion on the risks for human health related to the presence of bromide ion in food.[60] An estimation of the acute exposure using the food consumption data from EFSA PRIMo rev. 3.1 is presented in Table 1.
- isocarbophos (RD) was not reported in any of the sample.
- omethoate (RD) was quantified in aubergines (egg plants) (1 samples from Uganda), in table grapes (1 sample from Cyprus) and in sweet/bell peppers (1 sample from Morocco and 2 samples from Uganda which were part of EU increased control programme on imported food). All samples were considered non-compliant. Omethoate was never approved in the EU for the use in PPP. Temporary MRLs were set as it was formed as degradation product of dimethoate[67] which in 2021 were set to LOQ values.[68] It has been proven to be *in vivo* mutagenic agent (EFSA, 2017c). The exposure using the food consumption data in EFSA PRIMo rev. 3.1 is presented in Table 1.

Table 1: Estimated acute exposure without ARfD/ADI values

Pesticide	Food product	Acute exposure (in mg/kg bw per day)
Bromide ion (RD)	Sweet/bell peppers	0.279
Omethoate (RD)	Aubergines (egg plants) Sweet peppers/bell peppers Table grapes	1.0×10^{-4} 4.0×10^{-4} 6.0×10^{-5}

ARfD: acute reference dose; ADI: acceptable daily intake; bw: body weight.

Further details on the acute deterministic dietary risk assessment results for the pesticide residues found in the 12 food products covered by the 2021 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 risk as a percentage of the ARfD. The different dithiocarbamate scenarios have not been addressed here.

Overall, the results of the acute exposure assessment reflect the outcome of a deterministic method which uses several assumptions. In all cases, the exposure calculations were performed

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[65] Commission Implementing Regulation (EU) 2021/2081 of 26 November 2021 concerning the non-renewal of approval of the active substance indoxacarb, 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 Commission Implementing Regulation (EU) No 540/2011. OJ L 426, 29.11.2021, p. 28–31.

[66] M-2022-00043.

[67] Commission Regulation (EU) 2017/1135 of 23 June 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethoate and omethoate in or on certain products. OJ L 164, 27.6.2017, p. 28–51.

[68] 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.

according to the residue definition for enforcement and for extreme consumers, where large portions were considered and the variability factor were high (i.e. the highest residue in one individual unit due to a lack of uniformity of the sample, could be 7 or 5 times higher). In some cases, ADI/TDI values were used and in others, recent derived ARfD values not known before 2021 possibly increases the overestimation 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. On the contrary, this assessment only accounts for the contribution of the 12 commodities present in 2021 EU MACP and not for the remaining ones listed under the other 2 years of the 3-year cycle.

Pesticides	Aubergines/eggplants	Bananas	Broccoli	Cultivated fungi	Grapefruits	Melons	Sweet peppers/bell peppers	Table grapes	Virgin olive oil	Wheat	Eggs (chicken)	Fat (bovine)
2,4-D (RD)			0.3		11			0.5				
2-Phenylphenol (RD)[a][F]												
Abamectin (RD)	41	154			92		155	154		85		
Acephate (RD)							30					
Acetamiprid (RD)[F]	117	31	25		444	65	221	1,093				
Acrinathrin (RD)		136					29	14				
Aldicarb (RD)												
Ametoctradin (RD)[a]												
Azinphos-Methyl (RD)		19		3								
Azoxystrobin (RD)[a][F]												
Bifenthrin (RD)	3	30			6			5				
Biphenyl (RD)[a]												
Bitertanol (RD)												
Boscalid (RD)[a][F]												
Bromide Ion (RD)[c]							*					
Bromopropylate (RD)					53							
Bupirimate (RD)[a]												
Buprofezin (RD)	0.1	0.3			3	0.4	1	0.1	0.0005			
Captan (RD)	0.3					1		6	0.0009	0.1		
Carbaryl (RD)							2					
Carbendazim (RD)[F]	13		35	60	2	50	22	107		2		
Carbofuran (RD)												
Chlorantraniliprole (RD)[a][F]												
Chlordane (RD)												
Chlorfenapyr (RD)	2				22		148					
Chlormequat-Chloride (RD)				49				4		25		
Chlorothalonil (RD)[F]	25	45				2	37			0.5		
Chlorpropham (RD)			0.1	0.2		0.4				0.3		
Chlorpyrifos (RD)[F]	69	6	549	5	13		60	50	0.2	54		
Chlorpyrifos-Methyl (RD)[F]	0.05				2		35		0.005	5		
Clofentezine (RD)[a][F]												
Clothianidin (RD)	0.4				3		8	2		1		
Cyazofamid (RD)[a]												
Cyflufenamid (RD)						1	18	25				
Cyfluthrin (RD)							65		0.08			
Cymoxanil (RD)[F]						20	2	4				
Cypermethrin (RD)[F]	211	25	108	17	1,162	133	666	12,687	2	301		3
Cyproconazole (RD)		10	14					83	0.03	1		
Cyprodinil (RD)[a]												
Cyromazine (RD)	1			39		18	4					
DDT (RD)[a]												
Deltamethrin (RD)	15		58	47	26		114	126	0.3	87		0.7
Diazinon (RD)		4										3
Dichlorvos (RD)												
Dicloran (RD)					1							

Pesticides	Aubergines/eggplants	Bananas	Broccoli	Cultivated fungi	Grapefruits	Melons	Sweet peppers/bell peppers	Table grapes	Virgin olive oil	Wheat	Eggs (chicken)	Fat (bovine)
Dicofol (RD)								0.5				
Dieldrin (RD)												0.7
Diethofencarb (RD)[a]												
Difenoconazole (RD)[F]	1	0.3	19		4	17	24	15	0.006	1		
Diflubenzuron (RD)[a]												
Dimethoate (RD)					2,774		10,211	14,035	13			
Dimethomorph (RD)[F]	1		0.5		0.1	2	1	36	0.001			
Diniconazole (RD)												
Diphenylamine (RD)[a]												
Dithianon (RD)								57				
Dithiocarbamates (RD) - maneb sc.[d]	9	16		7	22	193	44	153		2		
Dithiocarbamates (RD) - mancozeb sc.	12	21		9	29	253	58	200		3		
Dithiocarbamates (RD) - metiram sc.[a]												
Dithiocarbamates (RD) - propineb sc.[d]	21	37		15	52	452	103	357		5		
Dithiocarbamates (RD) - thiram sc.[d]	67	117		48	162	1,416	321	1,118		16		
Dithiocarbamates (RD) - ziram sc.	25	44		18	61	531	121	419		6		
Dodine (RD)												
Emamectin (RD)							10	22				
Endosulfan (RD)							2					0.9
Epoxiconazole (RD)[F]		2			5					2		
Ethephon (RD)							673	384				
Ethion (RD)												
Ethirimol (RD)[a]												
Etofenprox (RD)	0.1	0.2			2			0.4		22	0.0001	
Etoxazole (RD)[a]												
Famoxadone (RD)	0.1						4	2		22		
Fenamidone (RD)												
Fenamiphos (RD)						168	72					
Fenarimol (RD)												
Fenazaquin (RD)				1								
Fenbuconazole (RD)							0.5	1				
Fenbutatin oxide (RD)				40				1				
Fenhexamid (RD)[a]												
Fenitrothion (RD)										3		
Fenoxycarb (RD)								0.04				
Fenpropathrin (RD)					43		28					
Fenpropidin (RD)		78								0.3		
Fenpropimorph (RD)		110						42				
Fenpyrazamine (RD)	0.4			0.1				9		11		
Fenpyroximate (RD)	1					25		6				
Fenthion (RD)												
Fenvalerate (RD)			6	1				14		27		
Fipronil (RD)	5			1	2			13	0.06	3	20	0.02
Flonicamid (RD)[F]	77	105	2		10		209	481				
Fluazifop (RD)	3		23									

Pesticides	Aubergines/eggplants	Bananas	Broccoli	Cultivated fungi	Grapefruits	Melons	Sweet peppers/bell peppers	Table grapes	Virgin olive oil	Wheat	Eggs (chicken)	Fat (bovine)
Flubendiamide (RD)							2					
Fludioxonil (RD) [a] [F]												
Flufenoxuron (RD) [a]												
Fluopicolide (RD) [F]			1			1	0.4	20				
Fluopyram (RD) [F]	1		0.2	2		1	5	19		0.2		
Fluquinconazole (RD)												
Flusilazole (RD)							6	22				
Flutriafol (RD) [F]	5					1	38	129		0.3		
Fluxapyroxad (RD) [F]	0.2		3			1	6	68		0.3		
Folpet (RD)	0.3		0.2				1	81	0.003	0.4		
Formetanate(Hydrochloride) (RD)	112						589	117				
Fosetyl (RD) [a] [F]						252						
Fosthiazate (RD)												
Glufosinate Equivalents (RD)		0.1			11			24				
Glyphosate (RD)		2	0.3		3	2	3	3		3		
Haloxyfop (RD)												
Heptachlor (RD)												
Hexachlorobenzene (RD)(b)											0.7	10
Hexachlorocyclohexane, alpha- (RD)(b)												
Hexachlorocyclohexane, beta- (RD)(b)											6	60
Hexaconazole (RD)(b)				6			111					
Hexythiazox (RD) [a]												
Imazalil (RD) [F]	0.3	47		2	34	53	1	1				
Imidacloprid (RD) [F]	12	23	1	0.2	11	40	60	42		1		
Indoxacarb (RD)	54	82	189			186	144	369				
Iprodione (RD)					0.3	44		11				
Iprovalicarb (RD) [a]												
Isocarbophos (RD)(c)												
Kresoxim-methyl (RD) [a]												
Lambda-cyhalothrin (RD) [F]	54	777	117		38	78	180	384	0.5	6		
Lindane (RD)												0.2
Linuron (RD)												
Lufenuron (RD) [a]												
Malathion (RD) [F]	0.3				2			0.3		0.1		
Mandipropamid (RD) [a]												
Mepanipyrim (RD)	2											
Mepiquat chloride (RD)				0.4						1		
Metalaxyl and metalaxyl-M (RD)			1		4	1	1	10				
Methamidophos (RD)							22					
Methidathion (RD)												
Methiocarb (RD)								1,138				
Methomyl (RD)	64					204	577	56				
Methoxychlor (RD)(b)												
Methoxyfenozide (RD) [F]	1				2	0.3	13	49				
Metrafenone (RD) [a]												
Monocrotophos (RD)												
Myclobutanil (RD)	0.4	19			1	1	5	14				

Pesticides	Aubergines/eggplants	Bananas	Broccoli	Cultivated fungi	Grapefruits	Melons	Sweet peppers/bell peppers	Table grapes	Virgin olive oil	Wheat	Eggs (chicken)	Fat (bovine)
Omethoate (RD)(c)	*						*	*				
Oxadixyl (RD)												
Oxamyl (RD)						1,800	961					
Oxydemeton-methyl (RD)												
Paclobutrazol (RD)												
Parathion (RD)												
Parathion-Methyl (RD)					6							
Penconazole (RD) [F]	0.5		0.5	0.04		0.1	1	7				
Pencycuron (RD) [a]												
Pendimethalin (RD)		0.4	0.2					0.1				
Permethrin (RD)(b)					22			41		10		2
Phosmet (RD)	115				2,695			281	11			
Pirimicarb (RD)	1		1		1	1	9					
Pirimiphos-Methyl (RD)	0.2				6		0.3		0.002	42		
Prochloraz (RD) [F]				31	24		79			1		
Procymidone (RD)								8		0.05		
Profenofos (RD)	1				0.02	0.03	1	0.01				
Propamocarb (RD) [F]	1		8			1	4		0.4	0.02		
Propargite (RD)	0.5				1		5		0.07			
Propiconazole (RD) [F]					2		5					
Propyzamide (RD)					0.1							
Proquinazid (RD)							1	30				
Prosulfocarb (RD)			0.3						0.01			
Prothioconazole (RD)												
Pymetrozine (RD)							27					
Pyraclostrobin (RD) [F]	3		15		8	5	60	113	0.02	2		
Pyridaben (RD) [F]	6		1		50		18					
Pyridalyl (RD) [a]												
Pyrimethanil (RD) [a] [F]												
Pyriproxyfen (RD) [F]	0.5	0.2			1	0.1	6	0.4	0.003			
Quinoxyfen (RD) [a]												
Spinetoram (RD)	0.4						3	4				
Spinosad (RD) [F]	1	17	22		3	1	13	11				
Spirodiclofen (RD) [a] [F]												
Spiromesifen (RD) [F]	0.4					0.02	1					
Spirotetramat (RD)	1	2	4		2		7	14				
Spiroxamine (RD) [F]		1						40		0.1		
Tau-Fluvalinate (RD)	1		12		14	1		61				
Tebuconazole (RD) [F]	10	15	13		6	38	94	468	0.05	99		
Tebufenozide (RD) [a]												
Tebufenpyrad (RD)	5				21		39	32				
Teflubenzuron (RD) [a]												
Tefluthrin (RD)												
Terbuthylazine (RD)												
Tetraconazole (RD)	1				24	2	12	40		1		
Tetradifon (RD) [a]												
Thiabendazole (RD) [F]	2	330					16	5	0.5			

Pesticides	Aubergines/eggplants	Bananas	Broccoli	Cultivated fungi	Grapefruits	Melons	Sweet peppers/bell peppers	Table grapes	Virgin olive oil	Wheat	Eggs (chicken)	Fat (bovine)
Thiacloprid (RD)			4		6	3	48					
Thiamethoxam (RD)	1		0.1		0.1	1	7	1		0.1		
Thiodicarb (RD)												
Thiofanate-Methyl (RD)	89		86		19	75	117	72				
Tolclofos-Methyl (RD)							5					
Triadimefon (RD)												
Triadimenol (RD)						19	6	61		0.3		
Triazophos (RD)							1,562					
Trifloxystrobin (RD) (F)	0.1		0.2		1	1	2	24	0.002			
Triflumuron (RD)(a)												
Vinclozolin (RD)												

Sc.: scenario
(a): No ARfD necessary due to low acute toxicity.
(b): Acute risk assessment was performed with the ADI/TDI, since no ARfD is available for the active substance.
(c): No ADI/ARfD allocated; in case quantified residues are reported in one or several commodities, an asterisk (*) is used to highlight it. See exposure assessment in Table 1.
(d): Exceedances of the ARfD in the cases of maneb, propineb and thiram may be disregarded due to these active substances denied regulatory approval in the EU unless an illegal use has occurred.
(F): processing factor has been used to refine exposure.

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. Acute probabilistic risk assessment

5.2.1. Introduction

For the first time, EFSA is piloting the probabilistic exposure assessment as part of the annual report on pesticide residues in food, where probabilities of exceedance of the ARfD of pesticides has been calculated in different subpopulation of European consumers. The purpose of these calculation is to provide readers with a new insight into the risk of dietary exposure to pesticides.

The deterministic assessment focuses on the risk of one consumer who actually consumes a large portion of one single commodity containing a high residue concentration of one pesticide (i.e. in this report, for each pesticide/commodity combination, the lots containing the highest recorded concentration of residues). For each pesticide, separate calculations are performed for each of the 12 commodities of the EU MACP. Due to the in-build assumptions of the deterministic model, the likelihood of such an extreme exposure event is not taken into account. For example, a single high residue found for a specific pesticide/commodity combination will always generate the same numeric outcome, irrespective if it is based on a single positive finding or a dataset with multiple quantified residues close to the selected concentration. In parallel, the large portion for the respective food commodity is derived from the 97.5th percentile of the portion size for consumers only and does not consider the frequency of consumption. For rarely consumed foods, the large portion is reached by few or even single individuals only whereas the large portion for frequently consumed foods represents dozens of individuals in the underlying consumption surveys.

Probabilistic methodology expands the scoop of the acute exposure assessment by introducing the likelihood of exposure events. In contrast to the deterministic assessment, all available consumption and occurrence data are taken into account. Results become two-dimensional distribution, providing information both on the magnitude of exposure and on the probability of individuals being exposed at such a level.

From the above, the reader will understand that the deterministic and probabilistic calculations provide different types of information. Probabilistic calculations will not simply be seen as a refinement of deterministic calculations, and do not alter the conclusions drawn in Section 5.1. A refinement of the deterministic calculations by probabilistic modelling would require specific conditions, as described in the guidance of the EFSA PPR Panel (EFSA PPR Panel, 2012) with respect to the 'high residue event' case. The probabilistic methodology introduces an estimation of the exposure in relation to the underlying population. The numeric outcome of the deterministic methodology is part of the probabilistic results too; however, it depends on the desired percentage of the subjects to be protected whether the exposure is considered to represent a significant (within the selected percentage) or insignificant (outside of the selected percentage) risk.

In contrast, the probability of exceeding the ARfD calculated in the sections below is a characterisation of the overall risk at population level, based on the actual consumption of 40 food commodities by real consumers and based on all the occurrence data in those 40 food commodities.

Although probabilistic exposure assessment cannot be considered as a refinement for the deterministic exposure assessment, it was still decided to pilot this exercise on the 29 pesticides where an exceedance of the ARfD was observed in the deterministic assessment for the 12 commodities of the 2021 EU MACP. This provides some insight on the differences between both types of calculations despite a direct comparison with the deterministic calculations is not possible, especially because the food commodities and dietary surveys considered in both assessments are different. EFSA is currently working on a revision of the PRIMo tool. This will improve future consistency between deterministic and probabilistic calculation in terms of underlying data, including the dietary surveys. Furthermore, it is EFSA's intention in the future to (gradually) increase the scope of the probabilistic exposure calculations in terms of substances.

### 5.2.2. Data and methodology

The acute probabilistic exposure to pesticide residues was assessed in accordance with the guidance on probabilistic modelling of dietary exposure to pesticide residues (EFSA PPR Panel, 2012). Hence, acute exposure estimates were obtained using a two-dimensional method where variability of exposure within the population is modelled by means of an inner loop execution, and confidence intervals around the acute exposure estimates are modelled through an outer loop execution (see Figure 2).

The primary input data required for probabilistic modelling of exposure are the occurrence data (i.e. the amounts of pesticide residue that are present in foods) and food consumption data (i.e. the types and amounts of those food consumed in a person's diet). These data are extracted from the EFSA Data Warehouse for the relevant food commodities, active substances (restricted to those covered by the residue definition where exceedance of the ARfD in the deterministic assessment were shown), associated residue definitions and dietary surveys. See Appendix C – for a full description of the data used.

Within the inner loop execution, occurrence data are subject to several simulations and imputations. These adjustments are intended to account for inaccuracies and missing information in the occurrence data set (e.g. unspecific measurements, measurements below the analytical limit of quantification (LOQ), etc.). The consumption data and adjusted occurrence data are then used to estimate acute dietary exposures using an empirical Monte Carlo simulation (i.e. with 100,000 iterations). This results in a distribution that represents the variability of acute exposures within the population. The different simulations performed during the inner loop execution require the use of additional data, referred to as secondary input data (e.g. PFs).

To quantify the confidence around the acute exposure distributions, the model uses an outer loop execution where the inner loop execution is repeated several times. Prior to each execution, the original consumption and occurrence data sets are modified by means of bootstrapping, a random resampling technique for quantifying uncertainty. By repeating the inner loop execution multiple times (i.e. 100), the model produces multiple distributions of exposure. The differences between those distributions reflect the sampling uncertainty around the true distribution of exposures.

During the output preparation, summary statistics (i.e. percentiles of exposure) are generated for the multiple distributions, resulting in multiple estimates for each percentile of exposure. From these multiple estimates, confidence intervals around each percentile are produced. Subsequently, to identify risk drivers, details on the highly exposed consumers are extracted (i.e. consumers with exposure exceeding the 99th percentile) and average contributions per food commodity are calculated.
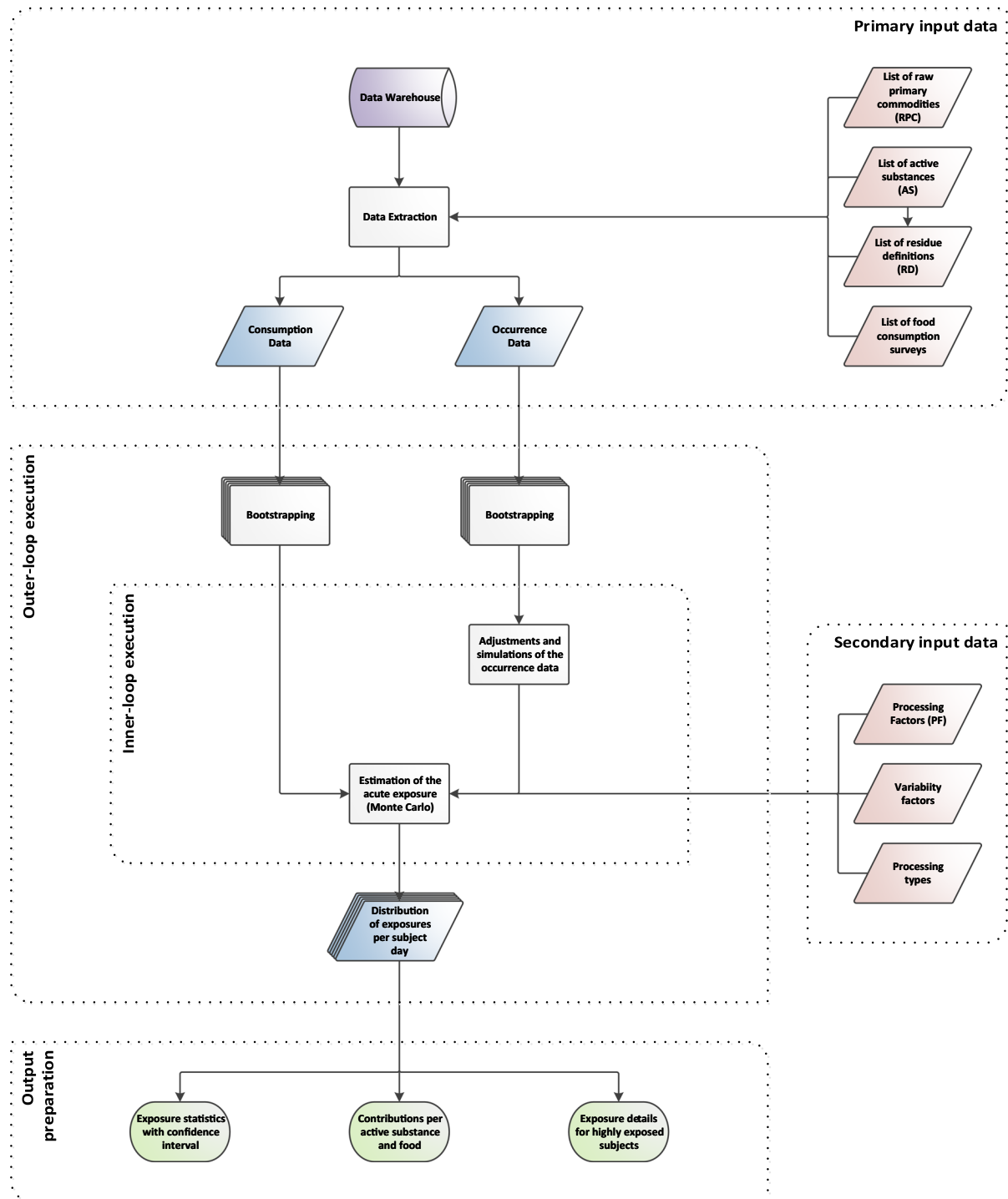
Figure 2: General process for probabilistic estimation of acute exposure to pesticide residues

The **primary and secondary input data** for the probabilistic exposure assessment were selected and prepared according to the following principles.

- To pilot the implementation of probabilistic exposure assessment in the framework of the annual report on pesticide residues, the current assessment was limited to the 29 pesticides (i.e. 28 plus dithiocarbamates) for which an exceedance of the ARfD was identified using the deterministic approach (see Section 5.1.2).
- The assessment was also restricted to the 35 raw primary commodities (RPCs) of plant origin that were ever considered in the EUCP and foods specifically intended for infants and young children. In addition, courgettes were also included because, according to EFSA's design

assessment of the pesticide monitoring programme (EFSA, 2015a), courgettes are consumed in higher amounts than other commodities previously included in the EU MACP (e.g. spinach and broccoli). Processed foods associated to aforementioned RPCs were also included in the assessment.

- Regarding the occurrence data, all samples analysed for any of the aforementioned substances (or associated residue definitions) were extracted from the EFSA Data Warehouse. Extracted samples referred to the monitoring years 2019, 2020 and 2021 were collected either under the EU MACP, the MANCP (national control programmes) or a combination of those (SSD codes for program type K005A, K009A and K018A). Samples associated with increased control programmes on imported food (SSD code K019A), were excluded as they were not considered to be representative of the market. Furthermore, only samples obtained through selective or objective sampling were retained (SSD codes sample strategy ST10A and ST20A). Samples obtained through suspect sampling (ST30A), were not considered to be representative of the market and therefore excluded.
- The extracted occurrence data do not only refer to the RPCs. When sufficient data were available for the associated processed foods (e.g. apple juice), monitoring data for the processed foods were also extracted.
- Consumption data used for the probabilistic exposure assessment were extracted from the RPC Consumption Database (EFSA, 2019a). To cover as many population groups as possible without compromising the reliability of intake estimates at the higher percentiles of the exposure distribution, only the dietary surveys with more than 300 survey participants per relevant age class were retained. This resulted in the selection of 30 population groups, covering 3 different age classes (i.e. adults, other children and toddlers) and 17 different countries. The limit of 300 survey participants for performing probabilistic exposure assessment has been derived based on experience gained so far. However, EFSA intends to initiate a research project that will derive more accurate criteria.
- For relevant active substances, RPCs and processing techniques, available PFs were extracted from the European database on PFs, which is the most recent and the most comprehensive compilation of PFs currently available at EU level (Zincke, 2022). Only the PFs indicated as reliable or indicative, were extracted. PFs indicated as unreliable were excluded from the assessment.

As part of the ***inner loop execution***, the primary and secondary input data are processed as follows to obtain the acute exposure distributions.

- When measurements refer to an unspecific residue definition (i.e. a residue definition that may be associated with multiple active substances), all associated active substances are assigned to these measurements, allowing for the estimation of exposure for each of these active substances. EFSA acknowledges that this approach may generate an important bias for substance/commodity combinations that are not authorised. EFSA will therefore explore possibilities to allow for better consideration of the authorisation status in future assessments.
- Measurements below the LOQ (i.e. left-censored measurements) are imputed with 1/2 LOQ when at least one quantified result (i.e. above LOQ) was reported for that same substance/commodity combination. Measurements for all remaining combinations were imputed with a zero (i.e. assuming a no-residue situation). As for the handling of unspecific residue definitions, EFSA acknowledges that this approach may generate an important bias for substance/commodity combinations that are not authorised and will therefore explore possibilities to allow for better consideration of the authorisation status in future assessments.
- Acute dietary exposure (i.e. within a single day) is modelled by means of an empirical Monte Carlo simulation. This means that individual days are selected at random from the consumption data set and, for each food commodity consumed within that day, random samples of the occurrence data set are assigned. Based on the measured concentrations, the individuals' consumptions and the individuals' body weights, the acute exposures resulting from each food commodity within each individual day are calculated. The exposures resulting from foods consumed within the same day are summed to obtain total acute exposure within each day. This process is repeated 100,000 times for the 30 population groups. This results in an empirical exposure distribution per population group, each consisting of 100,00 exposure estimates.

- As for the deterministic exposure assessment, the probabilistic exposure assessment also accounts for unit-to-unit variability for all food commodities which may contain non-uniform residue distributions (see Section 5.1.1). In this case, however, the unit-to-unit variability is modelled using a beta-distribution instead of a fixed variability factor.
- The acute exposure modelling also accounts, where possible, for the effect of processing prior to consumption, either by using available monitoring data in the processed food, or by incorporation of a specific PF. When information on the effect of processing was not available, it was assumed that all residues present in the RPC will reach the end consumer without any loss of residues, which is generally expected to overestimate the actual exposure.
- All acute exposure estimates are expressed as percentage of ARfD. Hence, a calculated value greater than 100% suggests that the estimated exposure exceeds the ARfD for that active substance. This also allows to calculate within each subpopulation the percentage of consumers that have an exposure exceeding the ARfD.

The **outer loop execution** allows to estimate the 95% confidence intervals around the calculated percentage of consumers exceeding the ARfD. This is evidenced by means of lower bound (LB, i.e. 2.5th percentile), middle bound (MB, i.e. 50th percentile) and upper bound (UB, i.e. 97.5th percentile) estimates.

All extractions, simulations, imputations and calculations were programmed with SAS® Studio 3.8 (Enterprise Edition). A more detailed description of the input data and methodologies applied is provided in Appendix C.

5.2.3. Results

The probabilistic risk assessment was executed for the 29 pesticides found to exceed the acute HBGV in the deterministic risk assessment (see Section 5.1.2). When multiple active substances are associated to a common residue definition (e.g. dithiocarbamates), each active substance was considered separately in contrast with the deterministic assessment (in total for the 29 pesticides, 38 active substances were considered). In the case of dithiocarbamates, metiram was not considered in this assessment because an ARfD was not available for this substance[60]. The methodology followed is described in Section 5.2.1.

The results of the acute probabilistic risk assessment are summarised in Table 2. It is reported as the MB (50th percentile) of the confidence interval for the percentage of subjects exceeding the ARfD. For each population class (adults, toddlers and other children), the minimum and the maximum value among different countries is presented in the table.

For example, for abamectin it is shown that among the 15 surveys on adults, the MB value for the percentage of subjects exceeding the ARfD varies from a minimum of 0% in one country to a maximum of 0.012% in another country. The actual countries can be retrieved from Appendix D – Annex IV – Table 4, where the minimum is reached in Czechia, Sweden and Ireland, while the maximum is reached in Finland. This means that in Finnish adults the percentage of the population exceeding the ARfD is estimated at 0.012%. For the other adult populations, the estimate is lower declining to 0% in Czechia, Sweden and Ireland.

Contrary to the deterministic calculation where EFSA identified the number of samples that might pose a risk for consumers, the probabilistic risk assessment provides more insight on how those samples may potentially affect the acute risk in different subpopulation within the EU.

Table 2: Summary of the acute probabilistic risk assessment results

| Active substance | Middle bound of the percentage of subjects exceeding the ARfD[8] | | | | | |
| | Adults | | Other children | | Toddlers | |
	MIN[1]	MAX[2]	MIN[3]	MAX[4]	MIN[5]	MAX[6]
Abamectin	0.000	0.012	0.025	0.147	0.120	0.336
Acetamiprid	0.000	0.001	0.000	0.004	0.001	0.006
Acrinathrin	0.000	0.000	0.000	0.000	0.000	0.000
Carbendazim	0.000	0.003	0.000	0.002	0.000	0.005
Cyhalothrin, gamma-	0.001	0.008	0.010	0.039	0.045	0.082

| Active substance | Middle bound of the percentage of subjects exceeding the ARfD[8] | | | | | |
| | Adults | | Other children | | Toddlers | |
	MIN[1]	MAX[2]	MIN[3]	MAX[4]	MIN[5]	MAX[6]
Cyhalothrin, lambda-	0.000	0.002	0.001	0.009	0.007	0.014
Cypermethrin	0.015	0.081	0.030	0.128	0.042	0.140
Cypermethrin, alpha-	0.184	0.436	0.358	1.061	0.679	1.253
Cypermethrin, beta-	0.127	0.342	0.238	0.716	0.393	0.843
Cypermethrin, zeta-	0.000	0.000	0.000	0.000	0.000	0.000
Deltamethrin (cis-deltamethrin)	0.000	0.001	0.000	0.014	0.001	0.030
Ethephon	0.001	0.006	0.002	0.019	0.003	0.019
Fenamiphos	0.000	0.000	0.000	0.001	0.000	0.003
Fenpropidin	0.000	0.000	0.000	0.000	0.000	0.000
Fenpropimorph	0.000	0.000	0.000	0.000	0.000	0.000
Flonicamid	0.000	0.001	0.000	0.010	0.001	0.010
Flutriafol	0.000	0.000	0.000	0.000	0.000	0.000
Formetanate hydrochloride	0.000	0.005	0.002	0.041	0.009	0.037
Fosthiazate	0.000	0.000	0.000	0.006	0.003	0.011
Indoxacarb	0.001	0.013	0.007	0.076	0.014	0.067
Methiocarb	0.013	0.090	0.148	0.689	0.298	0.670
Methomyl	0.000	0.005	0.001	0.005	0.001	0.009
Oxamyl	0.736	3.445	3.053	14.247	6.697	17.262
Phosmet	0.051	0.165	0.159	0.345	0.258	0.470
Pyraclostrobin	0.000	0.000	0.000	0.001	0.000	0.001
Tebuconazole	0.000	0.000	0.000	0.002	0.001	0.004
Thiabendazole	0.000	0.007	0.000	0.034	0.005	0.029
Thiophanate-methyl	0.000	0.001	0.001	0.014	0.003	0.014
Dithiocarbamates (RD) – Mancozeb	0.000	0.001	0.003	0.009	0.006	0.013
Dithiocarbamates (RD) – Maneb	0.000	0.000	0.001	0.004	0.002	0.006
Dithiocarbamates (RD) – Propineb	0.001	0.007	0.014	0.032	0.021	0.049
Dithiocarbamates (RD) – Thiram	0.029	0.111	0.138	0.298	0.219	0.369
Dithiocarbamates (RD) – Ziram	0.002	0.013	0.019	0.049	0.031	0.068
Chlorfenapyr[7]	0.000	0.000	0.000	0.000	0.000	0.000
Chlorpyrifos[7]	0.006	0.014	0.014	0.028	0.017	0.038
Dimethoate[7]	2.135	6.409	10.952	26.053	18.264	27.823
Hexaconazole[7]	0.000	0.000	0.000	0.000	0.000	0.000
Triazophos[7]	0.000	0.000	0.000	0.000	0.000	0.001

(1): Lowest estimated probability of exceeding the ARfD among the 15 adult populations.
(2): Highest estimated probability of exceeding the ARfD among the 15 adult populations.
(3): Lowest estimated probability of exceeding the ARfD among the 10 child populations.
(4): Highest estimated probability of exceeding the ARfD among the 10 child populations.
(5): Lowest estimated probability of exceeding the ARfD among the 5 toddler populations.
(6): Highest estimated probability of exceeding the ARfD among the 5 toddler populations.
(7): Active substance with a tentative ARfD.
(8): Even if the estimated probability is 0.000% by the model, it does not mean the true probability on the real population is 0. Therefore, the probability should be considered close to zero.

In Appendix D – Annex IV and Annex V, detailed information on the probabilistic acute risk assessment is reported. The annexes contain information on the stablished ARfD values and whether a tentative value was selected; infographics by active substance, population group and countries are presented too.

Important to note that the assessment is affected by different types of uncertainties. On the one hand, there are some considerations that might lead to an underestimation of the probabilities, such as: the reduction of the consumption data only to 36 highly consumed RPCs instead of whole diets; and the

use of the residue definition for enforcement and not for risk assessment (where additional metabolites may be included for, e.g. phosmet, methiocarb) in the calculations. This source of uncertainty is common to deterministic and probabilistic calculations. On the other hand, the probabilities here presented are in general overestimated mainly due to the uncertainty introduced with the bootstrapping selection of consumers and occurrence data; the imputation of having concentration equal to ½ LOQ for analytical result below LOQ; and the lack of PFs for processed food consumption.

To illustrate those uncertainties, the 10 active substances with the higher estimated probability for a consumer to exceed the ARfD are discussed below. A summary of the most contributing RPCs by substance is also discussed below, but for the detail by country the reader is referred to the Appendix D – Annex IV and Annex V.

Abamectin

The RPCs contributing most to the exposures, being closer to the 99th percentile, are bananas, wheat, tomatoes and mandarins. In general, potential exceedances of the ARfD are found in the upper tail (=high estimate) of the total exposure distribution and consequently listed commodities show high sensitivity on the acute dietary risk.

The absence of PFs for bananas and mandarins (e.g. peeling factors) is leading to a very conservative estimation, mostly considering that the substance has a limited systemic activity and it is expected that residues will remain mainly in the peel (EFSA, 2014b). For wheat, the high estimation is attributed to one Bulgarian subject consuming 60 g of wheat germ, corresponding to 3,000 g of wheat grain.

The methodology makes a conservative assumption that all residues present in unprocessed wheat grain are present in the wheat germ. Should a specific PF for abamectin in wheat germ be available, a more accurate and lower exposure estimate would be obtained.

For other countries with high percentage of consumers exceeding the ARfD, the high estimation is mainly lead by the absence of PFs on bananas (i.e. peeling factors).

Cypermethrins (cypermethrin, alpha-cypermethrin and beta-cypermethrin)

The high estimate of the percentage of consumers exceeding the ARfD, is driven by the consumption of processed foods for which a PF for cypermethrin is not available. Should a specific PF be available a more accurate and lower exposure estimate would be obtained. Moreover, the concentration of *Cypermethrin*, alpha-cypermethrin and beta-cypermethrin is derived from the results on the residue definition 'cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers))', taking the full amount for each active substance. This leads to a very conservative estimation and results that are difficult to interpret for not approved substances, such as alpha- and beta-cypermethrin.

Furthermore, it is the alpha and the beta within the four cypermethrins, the ones raising concern and not the mixture of the four isomers nor the z-cypermethrin, for which import tolerance have been granted. Thus, EFSA recommends Member States to be vigilant to the analytical chromatogram and look thoroughly for the alpha and beta isomer to withdraw the sample from the market if supported by a non-compliant assessment.

Indoxacarb

The major contributors are unprocessed foods, mainly driven by tomatoes and cucumbers, followed by melons, head cabbages, spinaches, potatoes. Regarding these commodities, there is less room for refinements as tomatoes and cucumbers may be consumed unpeeled.

Methiocarb

The major contributors are unprocessed foods, mainly driven by cucumbers, pears and oranges. Regarding these commodities, there is less room for refinements as cucumbers and pears may be consumed unpeeled. However, no PF is available for orange and since the active substance is not systemic, this may lead to an overestimation in the calculations.

Oxamyl

The high estimation is led by potatoes, followed by tomatoes, cucumbers and carrots.

On the one hand, the results that contribute most to the assessment are given at the limit of quantification; as for conservative assumption, the 1/2 LOQ is the concentration considered for the risk assessment, but still too high with respect to the ARfD when added over all food commodities on individual level in the probabilistic model. So, the data are not precise enough to give a good estimate of the exceedance of ARfD for oxamyl.

On the other hand, there are anyway results with values above limit of quantification for beans (with pods), cucumbers, sweet peppers/bell peppers, potatoes and carrots. Therefore, even if more accurate data (e.g. lower LOQ values) would be available, some consumers exceeding the ARfD by the consumption of these single food items would most likely still be present but the probability of such consumers occurring can currently not be reliably estimated.

Overall, the estimation obtained for oxamyl is very difficult to interpret, due to the current imputation on the LOQ and the high LOQ values currently reported. Regardless of whether more accurate data would not be available in the future, a refinement of the methodology (i.e. a change in the imputation rule for samples at LOQ) used in the probabilistic risk assessment will be explored to (partially) address this significant bias in the calculations.

Phosmet

The major contributors are food consumed unprocessed such as apples, tomatoes, mandarins and peaches. Regarding these commodities, there is little room for refinements as apples, tomatoes and peaches may be consumed unpeeled. However, no PF is available for mandarins and since the active substance is not systemic, this may lead to an overestimation in the calculations. Although the use of phosmet is no longer authorised within the EU, CXLs previously assessed by the JMPR are still in place. EFSA has recently reviewed existing MRLs under Article 12 review (EFSA, 2022c), and recommended lowering the MRLs to LOQ values for all commodities.

Dithiocarbamates (thiram)

The high estimation is led by the consumption of unprocessed foods, such as head cabbages, table grapes, pears, lettuces, apples, broccoli, cucumbers, cauliflowers, tomatoes.

However, the concentration of thiram is derived from the results on the residue definition 'dithiocarbamates (dithiocarbamates expressed as CS_2, including maneb, mancozeb, metiram, propineb, thiram and ziram)', taking the full amount for each active substance. This leads to a very conservative estimation and the true percentage of consumers exceeding the ARfD for thiram is expected to be considerably lower, considering also that among the active substances included in the dithiocarbamates residue definition, only ziram and metiram are approved.

Dimethoate

The high estimation is led by the consumption of potatoes and apples followed by mandarins, oranges, tomatoes, and peaches.

On the one hand, most of the results that contribute to the assessment are given at the limit of quantification; as for conservative assumption, half the LOQ is the concentration considered for the risk assessment, but still too high respect to the ARfD when added over all food commodities on individual level in the probabilistic model. Therefore, even if a relatively small portion of a food type (for which a sample has been analysed for dimethoate) would have been present in the consumption database, an exceedance of the HBGV will appear in the assessment. So, the data are not precise enough to give a good estimate of the probability of exceedance for dimethoate. On the other hand, there are anyway results with values above limit of quantification, the commodities contributing the most are beans (with pods), mandarins, table grapes, oranges, cucumbers and peaches. Therefore, even if more accurate data would be available, some consumers exceeding the ARfD by the consumption of these single food items would most likely still be present but the probability of such consumers occurring can currently not be reliably estimated.

Overall, the estimation obtained for dimethoate is to be considered not interpretable, due to the current imputation on the LOQ. Regardless of whether more accurate data would not be available in the future, a refinement of the methodology (i.e. a change in the imputation rule for samples at LOQ) used in the probabilistic risk assessment will be explored to (partially) address this significant bias in the calculations.

Summary

Overall, within this pilot exercise on probabilistic risk assessment, the 29 different pesticide residues with a possible risk identified in the deterministic assessment (i.e. possibly resulting from 38 active substances) have been analysed. It revealed that for most of the substances the probability for a consumer to exceed the ARfD is extremely low. For most of them, the MB (median value) of the confidence interval of the ratio of consumer potentially exceeding the ARfD is close to 0%, keeping in mind that the UB (97.5th percentile) of the confidence intervals might be higher due to rare outliers. The

probabilistic approach is modelling sampling uncertainty to give a plausible confidence interval for the estimates analysed. The detail on the confidence interval is reported in Appendix D – Annexes IV and V.

Furthermore, the assessment still needs to account for additional uncertainties that may either overestimate or underestimate the probabilistic exposure estimates reported above. This is particularly true for oxamyl and dimethoate where the results are difficult to interpret due to the high contribution of the left censored data in those calculations. Further efforts will be made in the future to improve estimates for such active substances. For thiram, alpha-cypermethrin and beta-cypermethrin, the methodology also needs to be improved to take better account of their non-approval in the EU, most likely leading to an overestimation of the exposure estimates. Similarly, for abamectin, cypermethins, methiocarb and phosmet, exposure estimates are expected to be overestimated due to the lack of PFs.

5.3. Chronic deterministic risk assessment

The chronic risk 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 chronic risk assessment compares the long-term dietary exposure for a pesticide residue to that substance's chronic health-based guidance value, the Acceptable Daily Intake (ADI in mg of residue/kg bw per day).

The ADI values established by EFSA under Regulation (EC) No 1107/2009 were selected, when available. 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:

- The assessment of the genotoxic potential *in vivo* of the substance could not be completed (e.g. insufficient data): in such case, a tentative chronic risk assessment was conducted using an ADI based on the current knowledge (e.g. dimethoate (EFSA, 2018f)).
- The substance was concluded to be an *in vivo* mutagen: in such cases, it was considered not possible to set any HBGV and thus, the MRLs were established at the limit of quantification to protect consumers, but no assessment was conducted within the remit of this report (EFSA, 2017c) (e.g. omethoate).

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

In Appendix D – Annex II, the outcome of the deterministic exposure assessments is included. The ADI values for all the active substances mentioned in this report are found in Appendix D – Annex III – Table 3.5.

5.3.1. Methodology for the estimation of chronic exposure

The assessment deals with samples submitted by the reporting countries under EU MACP and MANCP, covering the pesticides in the 2021 EU MACP, restricting to unprocessed products listed in Annex I (part A) of Regulation (EC) No 396/2005 for which consumption data are available in PRIMo rev. 3.1. In total, 69,767 samples were taken.

EFSA calculated two scenarios for chronic deterministic risk assessment: the LB and the MB.

- The LB scenario: it assumes samples with non-quantified residues (i.e. samples with residue levels reported as being < LOQ) do not contain any residue. This scenario is the less conservative one as it disregards the contribution of residues eventually present in small amounts below the LOQ. It may result in an underestimation of the chronic deterministic exposure.
- The MB scenario: it assumes samples with non-quantified residues (i.e. samples with residue levels reported as being < LOQ) contain residues at a level of 1/2 LOQ.[69] This scenario results in a likely overestimation of the chronic deterministic exposure. If results reported for a given

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[69] To judge on samples reported without quantifiable residues, SANCO/12574/2015 (rev. 5) (European Commission, 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.

pesticide/crop combination were below the LOQ for all samples analysed, this pesticide/crop combination was excluded from the calculations.

The LB and MB 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 MB 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.

For these calculated scenarios, the following were considered:

- The mean residue concentration from the analytical results for any given pesticide/crop combination, was used. Pesticide/commodity combinations for which no sample had quantified residues were not considered in the chronic exposure assessment. These are assumed to represent a no residue/no exposure situation.
- Only results for unprocessed products with available consumption data were used for this exposure calculation. Thus, no PF were use.
- Only data on the 190 pesticides listed in 2021 EU MACP and for which the analysis covered their full RD were used. Results of part of a residue definition (i.e. reported as paramTpe = P002A[70]) were not taken into consideration.
- Results from samples analysed with analytical methods for which the LOQ was greater than the corresponding MRL were disregarded.
- 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, 2022a).
- Consumption data used for the deterministic exposure assessment were those used in PRIMo model revision 3.1 (EFSA, 2018b). The mean of the consumption distribution (50th percentile) was taken for the 13 Member States (Germany, Denmark, Spain, Finland, France, Ireland, Italy, Lithuania, the Netherlands, Poland, Portugal, Romania and Sweden) who derived it from national food surveys and the relevant GEMS/Food Cluster diets relevant for the EU Member States (i.e. Cluster diet G06, G07, G08, G10, G11 and G15).
- The estimation of chronic exposure is based on the residue definition for enforcement and were not converted into the one defined for risk assessment. Thus, possible underestimation of the assessment can be expected.
- For the legal residue definition 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 (EFSA, 2014c).
- For the legal residue definition of 'cyfluthrin (cyfluthrin including other mixtures of constituent isomers (sum of isomers))', based on EFSA opinion (EFSA, 2020b), the mammalian toxicology experts agreed to read-across the toxicological profile of beta-cyfluthrin in the developmental studies (e.g. for long-term and reproductive toxicity). Thus, the cyfluthrin acute profile was taken.
- For the legal residue definition of lambda-cyhalothrin (including gamma-cyhalothrin) (sum of *R*, *S*- and *S,R*-isomers), the chronic risk assessment was based on the chronic toxicological profile of gamma isomer being the most potent of the two approved active substance (EFSA, 2017b).
- Related to cypermethrin residue definition (cypermethrin including other mixtures of constituent isomers (sum of isomers)), the chronic profile selected to undergo the risk assessment was the one of cypermethrin being the only approved combination respect to the alpha, beta or zeta isomers (EFSA, 2018e).
- Most of the dithiocarbamate active substances are not approved (except metiram and ziram). However, in view of having a thorough coverage of all possible uses and missuses, all six active substances (mancozeb, maneb, metiram, propineb, thiram and ziram each with a different ADI) were considered in this deterministic chronic risk assessment. Still no analytical method has been derived to differentiate them. Thus, the monitoring data used in the assessment reflects the common moiety method reporting total CS_2.
- For heptachlor, hexachlorobenzene, alpha-HCH and beta-HCH, 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.

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[70] P002A in accordance with ChemMon Guidance (EFSA, 2022a) means results reported as part of a residue definition for pesticide residues, i.e. individual components of a multicomponent residue definition.

5.3.2. Results

The results of the chronic deterministic exposure assessment expressed as the highest percentage of the ADI for each pesticide (LB and MB scenarios) and consumer group are reported in Table 3.

Table 3: Results of the chronic dietary exposure assessment

Pesticide	Chronic exposure (in % of ADI)	
	Lower-bound	Middle-bound
Diethofencarb (RD)	0.000002	0.004
Fenamidone (RD)	0.00004	0.009
Quinoxyfen (RD)	0.00004	0.0043
Tetradifon (RD)	0.00004	0.009
Vinclozolin (RD)	0.00004	0.005
Fenthion (RD)	0.0001	0.0688
Methoxychlor (RD)	0.0001	0.018
Dicloran (RD)	0.0002	0.11
Endosulfan (RD)	0.0002	0.293
Pencycuron (RD)	0.0002	0.022
Oxadixyl (RD)	0.0003	0.21
Bromopropylate (RD)	0.0004	0.0183
Thiodicarb (RD)	0.0004	0.04
Ametoctradin (RD)	0.001	0.001
Biphenyl (RD)	0.001	0.106
Hexachlorocyclohexane, alpha- (RD)**	0.001	0.001
Kresoxim-Methyl (RD)	0.001	0.025
Methidathion (RD)	0.001	0.132
Parathion-Methyl (RD)	0.001	0.16
Propyzamide (RD)	0.001	0.05
Tolclofos-Methyl (RD)	0.001	0.05
Triadimefon (RD)	0.001	0.001
Carbaryl (RD)	0.002	0.063
Diphenylamine (RD)	0.002	0.151
Pendimethalin (RD)	0.002	0.1
Pymetrozine (RD)	0.002	0.03
Teflubenzuron (RD)	0.002	0.78
Terbuthylazine (RD)	0.002	0.47
Paclobutrazol (RD)	0.002	0.33
Chlorantraniliprole (RD)	0.003	0.011
Clothianidin (RD)	0.003	0.084
Etoxazole (RD)	0.003	0.258
Hexachlorobenzene (RD)**	0.003	1.3
Triadimenol (RD)	0.003	0.311
Cymoxanil (RD)	0.004	0.225
Dicofol (RD)	0.004	0.3
Fenbutatin Oxide (RD)	0.004	0.114
Fenitrothion (RD)	0.004	0.942
Fenpropathrin (RD)	0.004	0.081
Flubendiamide (RD)	0.004	0.324
Flusilazole (RD)	0.004	1.5
Chlordane (RD)	0.007	1.86
Diflubenzuron (RD)	0.009	0.084

Pesticide	Chronic exposure (in % of ADI)	
	Lower-bound	Middle-bound
Fenoxycarb (RD)	0.009	0.163
Mepiquat chloride (RD)	0.009	0.039
Azinphos-methyl (RD)	0.01	2.8
Clofentezine (RD)	0.01	0.18
Cyproconazole (RD)	0.01	0.68
Diniconazole (RD)	0.01	0.03
Metrafenone (RD)	0.01	0.03
Procymidone (RD)	0.01	0.82
Profenofos (RD)	0.01	0.13
Propargite (RD)	0.01	0.31
Prothioconazole (RD)	0.01	0.7
Pyridalyl (RD)	0.01	0.08
Spinetoram (RD)	0.01	0.2
Tefluthrin (RD)	0.01	0.89
Ethion (RD)	0.012	1.023
Fenpropidin (RD)	0.012	0.234
Hexachlorocyclohexane, beta- (RD)**	0.012	12.5
Iprodione (RD)	0.012	0.672
Ethirimol (RD)	0.015	0.251
Fenvalerate (RD)	0.016	0.593
Cyazofamid (RD)	0.018	0.045
Lufenuron (RD)	0.018	0.939
Cyfluthrin (RD)	0.019	1.2
Fenpyrazamine (RD)	0.019	0.033
Hexaconazole (RD)	0.019	0.23
Methomyl (RD)	0.019	0.657
Buprofezin (RD)	0.02	0.74
Cyromazine (RD)	0.02	0.13
Fluopicolide (RD)	0.02	0.081
Fosthiazate (RD)	0.02	0.78
Glufosinate Equivalents (RD)	0.02	0.83
Flufenoxuron (RD)	0.02	0.03
Metalaxyl and Metalaxyl-M (RD)	0.024	0.108
Fenazaquin (RD)	0.025	1.72
Hexythiazox (RD)	0.025	0.395
Mepanipyrim (RD)	0.025	0.178
Malathion (RD)	0.026	0.447
Acrinathrin (RD)	0.03	0.97
Bupirimate (RD)	0.03	0.31
DDT (RD)	0.03	5.01
Mandipropamid (RD)	0.03	0.061
Tebufenpyrad (RD)	0.03	1.03
Thiamethoxam (RD)	0.03	0.52
Cyflufenamid (RD)	0.032	0.197
Heptachlor (RD)**	0.032	2.9
Methoxyfenozide (RD)	0.037	0.17
Penconazole (RD)	0.04	0.36
Pyridaben (RD)	0.04	0.48

Pesticide	Chronic exposure (in % of ADI)	
	Lower-bound	Middle-bound
Spiromesifen (RD)	0.04	0.13
Spiroxamine (RD)	0.04	0.3
Tebufenozide (RD)	0.04	0.51
Imidacloprid (RD)	0.041	0.382
Flutriafol (RD)	0.045	1.1
Chlorpyrifos-methyl (RD)	0.05	2.66
Fenpyroximate (RD)	0.05	1.003
Fenamiphos (RD)	0.056	3.5
Propamocarb (RD)	0.06	0.09
Formetanate(Hydrochloride) (RD)	0.07	0.93
Monocrotophos (RD)	0.07	0.5
Fenbuconazole (RD)	0.073	1.5
Chlorothalonil (RD)	0.08	1.25
Fluazifop (RD)	0.08	0.54
Dodine (RD)	0.084	0.171
Chlorfenapyr (RD)	0.085	0.85
Linuron (RD)	0.085	0.309
Fenhexamid (RD)	0.095	0.113
Famoxadone (RD)	0.099	0.806
Prosulfocarb (RD)	0.1	1.8
Trifloxystrobin (RD)	0.1	0.22
Abamectin (RD)	0.11	12.24
Methamidophos (RD)	0.11	2.1
Pirimicarb (RD)	0.11	0.37
Spirodiclofen (RD)	0.11	1.05
2-Phenylphenol (RD)	0.12	0.12
Acephate (RD)	0.12	0.5
Propiconazole (RD)	0.13	0.23
Tetraconazole (RD)	0.14	3.31
Thiacloprid (RD)	0.14	1.2
Iprovalicarb (RD)	0.147	0.275
Proquinazid (RD)	0.15	0.8
Spinosad (RD)	0.16	0.77
Lindane (RD)	0.166	10.6
Permethrin (RD)	0.17	1.04
Bifenthrin (RD)	0.19	0.61
Dimethomorph (RD)	0.2	0.3
Triazophos (RD)	0.2	1.02
Fipronil (RD)	0.23	16.4
Emamectin (RD)	0.238	9.5
Thiofanate-Methyl (RD)	0.24	0.82
Etofenprox (RD)	0.268	0.663
2,4-D (RD)	0.27	0.56
Pyriproxyfen (RD)	0.28	0.52
Chlorpropham (RD)	0.29	0.47
Spirotetramat (RD)	0.29	0.98
Fludioxonil (RD)	0.299	0.337
Tebuconazole (RD)	0.3	1

Pesticide	Chronic exposure (in % of ADI)	
	Lower-bound	Middle-bound
Flonicamid (RD)	0.32	1.24
Azoxystrobin (RD)	0.33	0.43
Myclobutanil (RD)	0.34	0.81
Carbendazim (RD)	0.34	1.1
Triflumuron (RD)	0.34	0.86
Dieldrin (RD)	0.37	39.9
Tau-Fluvalinate (RD)	0.38	2.75
Pyraclostrobin (RD)	0.39	0.86
Indoxacarb (RD)	0.41	2.98
Fenpropimorph (RD)	0.41	1.4
Prochloraz (RD)	0.41	1.0
Carbofuran (RD)	0.44	12.1
Glyphosate (RD)	0.54	0.6
Fluxapyroxad (RD)	0.55	1.3
Epoxiconazole (RD)	0.56	1.6
Diazinon (RD)	0.56	18.3
Dichlorvos (RD)	0.57	14.9
Difenoconazole (RD)	0.64	2.6
Cyprodinil (RD)	0.76	1.1
Acetamiprid (RD)	0.93	1.5
Ethephon (RD)	0.93	1.2
Deltamethrin (RD)	0.95	3.4
Captan (RD)	1.07	1.2
Methiocarb (RD)	1.1	15.8
Oxamyl (RD)	1.2	36.1
Boscalid (RD)	1.4	1.8
Fluopyram (RD)	1.4	3.0
Folpet (RD)	1.4	1.6
Haloxyfop (RD)	1.5	5.1
Pyrimethanil (RD)	1.5	1.5
Cypermethrin (RD)	1.6	7.1
Thiabendazole (RD)	1.6	1.7
Chlorpyrifos (RD)	1.6	20.3
Dithianon (RD)	1.7	2.7
Chlormequat-chloride (RD)	1.8	2.0
Fosetyl (RD)	2.4	2.4
Lambda-cyhalothrin (RD)	3.2	20.6
Dithiocarbamates (RD) - maneb scenario	3.5	6.9
Dimethoate (RD)	4.1	101
Phosmet (RD)	5.2	16.8
Pirimiphos-Methyl (RD)	5.5	7.5
Dithiocarbamates (RD) - propineb scenario	7.7	15.3
Dithiocarbamates (RD) - mancozeb scenario	7.8	15.5
Dithiocarbamates (RD) - thiram scenario	10.0	19.9
Imazalil (RD)	14.4	14.9
Dithiocarbamates (RD) - metiram scenario	25.1	49.7
Dithiocarbamates (RD) − ziram scenario	33.4	66.3

Pesticide	Chronic exposure (in % of ADI)	
	Lower-bound	Middle-bound
Aldicarb (RD)	n.r.	
Bitertanol (RD)	n.r.	
Fenarimol (RD)	n.r.	
Fluquinconazole (RD)	n.r.	
Parathion (RD)	n.r.	
Oxydemeton-Methyl (RD)	n.r.	
Bromide Ion (RD)*	No ADI	
Omethoate (RD)*	No ADI	
Isocarbophos (RD)*	No ADI/n.r.	

ADI: acceptable daily intake; n.r.: No quantified residues in any of the samples analysed; sc: scenario.
*: Active substance for which no ADI was established.
**: Tentative risk assessment.

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 LB scenario. The top 3 highest chronic risk estimates corresponded to *dithiocarbamate (RD) scenarios: ziram* with 33.4% of the ADI (NL, toddler on major contributor pears) and *metiram* with 25.1% of the ADI (NL, toddler on major contributor pears) and *imazalil* 14.4% of the ADI (DE, child on major contributor oranges).

When chronic risk assessment was based on the MB scenario, the chronic intake for:

Dimethoate (RD)

The highest estimate was 101% of the ADI (DE, child). No PFs have been used to refine the exposure. The major food contributors to the total chronic exposure were apples (55.7% of the ADI), oranges (18.3% of the ADI) and table grapes (6% of the ADI). The total number of samples quantified for dimethoate (RD) were 91 out of 69,767 (i.e. 0.13% quantification rate), mainly in sweet cherries (10 samples with origin Türkiye) and oranges (9 samples with origin Egypt). Since 17 October 2019, the grace period granted for PPP used on cherries containing dimethoate expired; for other crops, it was 17 July 2020.[71] Omethoate was also reported in 55 samples, of which 11 samples were also sweet cherries mainly coming from Türkiye. Therefore, EFSA keeps recommending the analysis of dimethoate/omethoate under EU MACP and to keep monitoring cherries for these pesticides within the MANCP.

Dithiocarbamates (RD)

This chemical class estimates for the adjusted MB scenario were below 100% of the ADI. However, the highest estimate was for ziram scenario (66.3% of ADI; NL toddler) and metiram scenario (49.7% of ADI; NL toddler). The major food contributors to the total chronic estimates were pears, apples and oranges. The total number of samples quantified for dithiocarbamates (RD) were 1,292 out of 69,767 (i.e. 1.9% quantification rate), mainly in roman rocket/rucola (190 samples), table grapes (175 samples) and grapefruits (119 samples).

Dieldrin (RD)

The highest estimate was 39.9% (FI, 3 year). No PFs have been used to refine exposure. The major food contributors to the total chronic exposure were potatoes (28.7% of ADI), cucumber (6.1% of ADI) and carrots (4.7% of ADI). The total number of samples quantified for dieldrin (RD) were 32 out of 69,767 (i.e. 0.05% quantification rate, very small rate). All samples reported to have origin the EU and was mainly found in courgettes (12 samples). This substance is banned at EU level but persistent in the environment that is why it is being quantified.

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[71] Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 concerning the non-renewal of approval of the active substance dimethoate, 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 173, 27.6.2019, p. 39–41.

Oxamyl (RD)

The highest estimate was 36.1% (NL, toddler). The major food contributors to the total chronic exposure were potatoes (20.5% of ADI), carrots (5.2% of ADI) and tomatoes (4.7% of ADI). The total number of samples quantified for oxamyl (RD) were 12 out of 69,767 (i.e. 0.017% quantification rate). Most of them lead to non-compliant results and the lots were recalled from the market.

In the adjusted MB scenario, the estimated chronic exposure for 166 pesticides was less than 10% of the ADI whereas for 116 of them, the result was lower or equal to 1% of the ADI.

For aldicarb (RD), bitertanol (RD), fenarimol (RD), fluquinconazole (RD), isocarbophos (RD), oxydemeton-methyl (RD) and parathion (RD) covered by the 2021 EU MACP, quantifiable residues were not reported for any of the food samples tested and therefore they were excluded from the calculation.

The active substance omethoate was quantified in 26 different food commodities. As *in vivo* mutagenicity was demonstrated, no chronic risk was calculated. The active substance bromide ion was quantified in 100 different food commodities. Until EFSA has not finalised its scientific opinion on the risks for human health related to the presence of bromide ion in food and risks on animal health and transfer from feed to food of animal origin related to the presence of bromine ion in feed[61], EFSA will not undergo a full chronic risk assessment of this substance. The exposure estimates for both substances using the food consumption in EFSA PRIMo rev. 3.1, is reported in Table 4.

Table 4: Results of chronic exposure assessment for omethoate and bromide ion

Pesticide	Chronic exposure (in mg/kg bw per day)	
	Lower-bound approach	**Adjusted middle-bound approach**
Bromide ion[60]	3×10^{-3}	0.01
Omethoate	1×10^{-7}	1×10^{-5}

bw: body weight.

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-years cycle of the EU-coordinated programme. This can be seen in Appendix D – Annex II, on the contribution to chronic exposure, in the graph under 'other products'.

In general, the estimated exposure was notably lower in the LB scenario compared to the MB approach. EFSA noted that the high proportion of samples with pesticide residues below the LOQ may result in particularly high MB estimates due to the assumption that even if not quantified, residues are present in all samples at half the LOQ level.

5.4. Chronic probabilistic risk assessment

5.4.1. Introduction

As for acute risk assessments, EFSA piloted a probabilistic method and calculated probabilities of exceedance of the ADI of pesticides in different subpopulation of European consumers. Here as well, the purpose of these calculation is to provide readers with a new insight into the risk of dietary exposure to pesticides.

Chronic risks depend on the average chronic exposure, and not on single exposure events, as this is the case for acute effects. Hence, chronic exposure assessments, regardless of being deterministic or probabilistic, rely on the assumption that all commodities contain an average residue concentration, calculated from the available monitoring data.

The main difference between chronic deterministic and probabilistic exposure assessment is in the handling of consumption data. In deterministic assessments, the risk of one 'virtual' consumer is calculated, assuming an average consumption of all commodities consumed by the population he belongs to. In contrast, in probabilistic modelling, the risk of hundreds of real consumers is calculated, based on their own individual dietary pattern. This allows capturing extreme levels of exposure within consumer populations.

5.4.2. Data and methodology

As for the acute probabilistic exposure assessment (see Section 5.2.1), chronic estimates were also obtained using a two-dimensional method where variability of exposure within the population is modelled by means of an inner loop execution, and confidence intervals around the chronic exposure estimates are modelled through an outer loop execution. The main differences compared to the acute exposure assessments are described below (see also Figure 3).

Whereas acute exposure (within the inner loop execution) is modelled through a Monte Carlo simulation, the chronic exposure is modelled through the Observed Individual Means (OIM) approach (EFSA, 2012). This method uses the mean consumption over the survey days of each individual to estimate the individuals' long-term consumption for each food commodity. Using the individuals' bodyweight and the mean occurrence values calculated for each food commodity, the individuals' chronic exposures resulting from each food commodity are calculated and added to obtain the individuals' total chronic exposure. Exposure estimates are then expressed as percentage of ADI. Hence, a calculated exposure greater than 100% suggests that the estimated exposure exceeds the ADI for that active substance. This also allows to calculate within each subpopulation the percentage of consumers that have an exposure exceeding the ADI.

Further details on the input data and methodologies applied for probabilistic exposure assessment are provided in Appendix C.
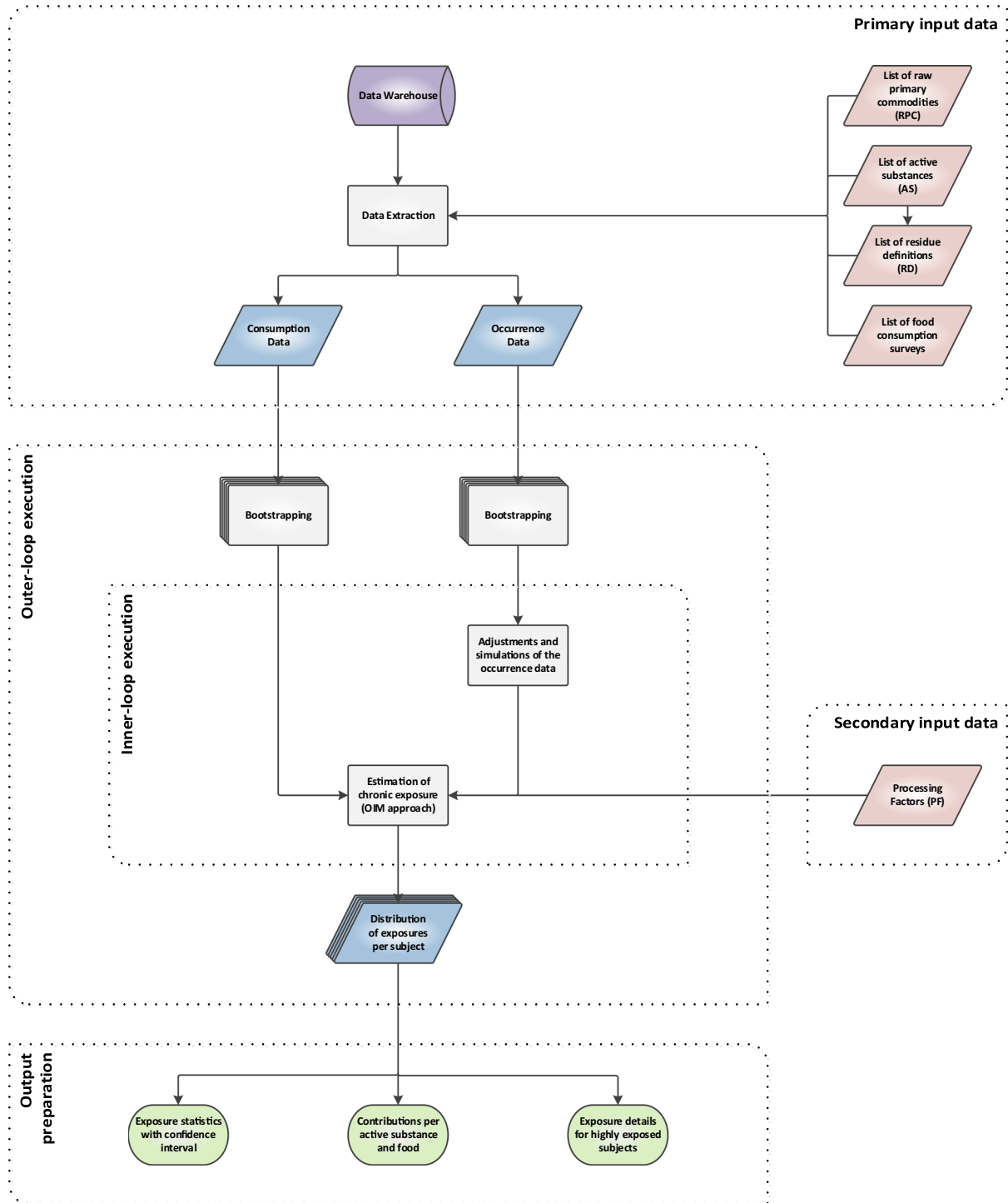
Figure 3: General process for probabilistic estimation of chronic exposure to pesticide residues

5.4.3. Results

For this pilot assessment, the probabilistic risk assessment was executed for the 29 pesticides found to exceed the acute HBGV in the deterministic risk assessment (see Section 5.1.2). When multiple active substances are associated to a common residue definition (e.g. dithiocarbamates), each active substance was considered separately. The methodology followed is described in Section 5.4.1, carried out to those 29 pesticides equivalent to 39 active substances (as metiram is now considered in the chronic assessment).

Ideally, substances should have been selected based on the chronic deterministic calculations, but consistency with the substances selected for acute probabilistic calculations was also considered

important. Meanwhile, it is important to note that these substances are not necessarily the most critical ones in terms of chronic exposure, in future assessments the scope for chronic probabilistic calculations will be widened.

The results of the chronic probabilistic risk assessment are summarised in Table 5. For each population class (adults, toddlers and other children), it is shown the minimum and the maximum value among different countries of the MB (50th percentile) for the confidence interval of the percentage of subjects exceeding the ADI.

Table 5: Summary of chronic probabilistic risk assessment results

Active substance	Middle bound of the percentage of subjects exceeding the ADI[8]					
	Adults		Other children		Toddlers	
	MIN[1]	MAX[2]	MIN[3]	MAX[4]	MIN[5]	MAX[6]
Abamectin	0.000	0.000	0.000	0.000	0.000	0.000
Acetamiprid	0.000	0.000	0.000	0.000	0.000	0.000
Acrinathrin	0.000	0.000	0.000	0.000	0.000	0.000
Carbendazim	0.000	0.000	0.000	0.000	0.000	0.000
Cyhalothrin, gamma-	0.000	0.000	0.000	0.000	0.000	0.000
Cyhalothrin, lambda-	0.000	0.000	0.000	0.000	0.000	0.000
Cypermethrin	0.000	0.000	0.000	0.000	0.000	0.000
Cypermethrin, alpha-	0.000	0.000	0.000	0.000	0.000	0.000
Cypermethrin, beta-	0.000	0.000	0.000	0.000	0.000	0.000
Cypermethrin, zeta-	0.000	0.000	0.000	0.000	0.000	0.000
Deltamethrin (cis-deltamethrin)	0.000	0.000	0.000	0.000	0.000	0.000
Ethephon	0.000	0.000	0.000	0.000	0.000	0.000
Fenamiphos	0.000	0.000	0.000	0.000	0.000	0.000
Fenpropidin	0.000	0.000	0.000	0.000	0.000	0.000
Fenpropimorph	0.000	0.000	0.000	0.000	0.000	0.000
Flonicamid	0.000	0.000	0.000	0.000	0.000	0.000
Flutriafol	0.000	0.000	0.000	0.000	0.000	0.000
Formetanate hydrochloride	0.000	0.000	0.000	0.000	0.000	0.000
Fosthiazate	0.000	0.000	0.000	0.000	0.000	0.000
Indoxacarb	0.000	0.000	0.000	0.000	0.000	0.000
Methiocarb	0.000	0.077	0.000	0.000	0.000	0.234
Methomyl	0.000	0.000	0.000	0.000	0.000	0.000
Oxamyl	0.000	0.079	0.000	5.543	0.218	9.600
Phosmet	0.000	0.000	0.000	0.000	0.000	0.000
Pyraclostrobin	0.000	0.000	0.000	0.000	0.000	0.000
Tebuconazole	0.000	0.000	0.000	0.000	0.000	0.000
Thiabendazole	0.000	0.000	0.000	0.000	0.000	0.000
Thiophanate-methyl	0.000	0.000	0.000	0.000	0.000	0.000
Dithiocarbamates (RD) – Mancozeb	0.000	0.000	0.000	0.000	0.000	0.000
Dithiocarbamates (RD) – Maneb	0.000	0.000	0.000	0.000	0.000	0.000
Dithiocarbamates (RD) – Metiram	0.000	0.000	0.000	0.000	0.000	0.000
Dithiocarbamates (RD) – Propineb	0.000	0.000	0.000	0.000	0.000	0.000
Dithiocarbamates (RD) – Thiram	0.000	0.000	0.000	0.160	0.000	0.000
Dithiocarbamates (RD) – Ziram	0.000	0.077	0.000	0.462	0.000	1.863
Chlorfenapyr[7]	0.000	0.000	0.000	0.000	0.000	0.000
Chlorpyrifos[7]	0.000	0.000	0.000	0.000	0.000	0.000
Dimethoate[7]	0.000	1.020	3.759	26.790	9.487	32.477
Hexaconazole[7]	0.000	0.000	0.000	0.000	0.000	0.000
Triazophos[7]	0.000	0.000	0.000	0.000	0.000	0.000

(1): Lowest estimated probability of exceeding the ADI among the 15 adult populations.
(2): Highest estimated probability of exceeding the ADI among the 15 adult populations.
(3): Lowest estimated probability of exceeding the ADI among the 10 child populations.
(4): Highest estimated probability of exceeding the ADI among the 10 child populations.
(5): Lowest estimated probability of exceeding the ADI among the 5 toddler populations.
(6): Highest estimated probability of exceeding the ADI among the 5 toddler populations.
(7): Active substance with a tentative ADI.
(8): Even if the estimated probability is 0.000% by the model, it does not mean that the true probability on the real population is 0. Therefore, the probability should be considered close to zero.

In Appendix D – Annex VI and Annex VII, is reported the detailed information of the chronic probabilistic risk assessment, together with infographics for each active substance, population groups and countries.

For most of the 29 pesticides (i.e. 39 active substances assessed), the estimated percentage of consumers exceeding the ADI is close to 0 (at the 50th percentile of the confidence interval), for every country. For the remaining five active substances, there was at least one consumer exceeding the ADI in at least one country; the results are discussed below. As for the acute exposure calculations; however, these estimates are subject to multiple uncertainties that may either underestimate or overestimate the exposure.

Methiocarb

For the following three surveys with at least one consumer exceeding the ADI are the following:

– For adults in Finland, the exceedance is linked to a very high consumption of orange juice concentrate for one subject (622.5 g/day), and no PF being available.
– For toddlers in Bulgaria, the exceedance is linked to a very high consumption of peaches (621 g/day) for one subject.
– For adults in Germany, the exceedance is linked to a very high consumption of orange juice concentrate for one subject (420 g/day), and table grapes juice (2696 g/day) and no PF being available.

Oxamyl

The results that contribute most to the exposure estimates are at the limit of quantification; as for conservative assumption, ½ LOQ (often set at the default MRL of 0.01 mg/kg) is the concentration considered for the risk assessment, but still too high with respect to the ADI of oxamyl (set at 0.0001 mg/kg bw per day) (EFSA, 2022b). So, the data are not precise enough to give a good estimate of the exposure for oxamyl. Regardless of whether more accurate data would not be available in the future, a refinement of the methodology (i.e. a change in the imputation rule for samples at LOQ) used in the probabilistic risk assessment will be explored to (partially) address this significant bias in the calculations. Meanwhile, the estimation obtained for oxamyl is to be considered difficult to interpret, due to the current imputation on the LOQ.

Dithiocarbamates (thiram scenario)

For the following survey at least one consumer exceeding the ADI was identified:

– For other children in Belgium the exceedance is linked to a very high consumption of mandarin juice for one subject (460.83 g/day), and no PF being available.

Dithiocarbamates (ziram scenario)

For the following surveys at least one consumer exceeding the ADI was identified:

– For adults in Finland, the exceedance is linked to an average consumption of orange juice concentrate (622.5 g/day) for one subject, and no PF is available.
– For adults in Germany, the exceedance is linked to an average consumption of wheat germ (180 g/day) for one subject, and no PF is available.
– For adults in Ireland, the exceedance is linked to an average consumption of apple cider (4,630 g/day) for one subject, and no PF is available.
– For other children in Belgium, the exceedance is linked to an average consumption of mandarin juice (460 g/day) for one subject, and no PF is available.

 – For other children in Bulgaria, the exceedance is linked to an average consumption of mandarin juice (287 g/day) for one subject, and no PF is available, and an average consumption of head cabbage (263 g/day) for another subject.
 – For Other children in Finland, the exceedance is linked to an average consumption of mandarin juice (233–315 g/day) for three subjects, and no PF is available.
 – For toddlers, all country the exceedance is mainly lead by one average consumption of wheat germ (30 g/day), and by consumption of mandarin juice, followed by consumption of pears and head cabbages.

Furthermore, the concentration of *thiram* and *ziram* is derived from the results on the residue definition 'dithiocarbamates (dithiocarbamates expressed as CS_2, including maneb, mancozeb, metiram, propineb, thiram and ziram)', taking the full amount for each active substance. This leads to a very conservative estimation.

Dimethoate

The results that contribute most to the assessment are given at the limit of quantification; as for conservative assumption, half the LOQ (often set at 0.01 mg/kg) is the concentration considered for the risk assessment, but still too high with respect to the ADI (set at 0.0001 mg/(kg bw per day)). So, the data are not precise enough to give a good estimate of the percentage of exceedance of ADI for dimethoate. Regardless of whether more accurate data would not be available in the future, a refinement of the methodology (i.e. a change in the imputation rule for samples at LOQ) used in the probabilistic risk assessment will be explored to (partially) address this significant bias in the calculations. Meanwhile, the estimation obtained for dimethoate is to be considered difficult to interpret, due to the current imputation on the LOQ.

Summary

Overall, the chronic probabilistic risk assessment shows that only for five active substances (out of the 39 analysed) the ADI is exceeded for at least one subject. For two of them (oxamyl and dimethoate) high frequency of left-censored data and numerical LOQs being too high compared to the ADI, lead to an overconservative estimate that is very difficult to interpret. For the other three substances (methiocarb, thiram and ziram), the estimate is linked to a high (or extreme) consumption of a specific processed food (for which a PF is not available) by few (1–3) subjects per survey.

Moreover, it is confirmed that the probability to exceed the ADI is close to 0% for 33 over 39 active substances, as concluded by the deterministic approach, while for 2 substances the outcome could not be interpreted. For the remaining three substances, the estimated probability for consumers to exceed the ADI ranges from close to 0% to 1.9% but these estimates are still subject to uncertainties, that are more likely to overestimate than to underestimate the risk.

Compared to the deterministic approach that considers the average consumption of specific food among the population of the surveys, the probabilistic approach is analysing the average consumption of any single subject. Therefore, it is more sensitive to extreme consumers, but gives a clearer view on the probability that certain consumers within the population might be at risk. Nevertheless, the probabilistic risk assessment is performed on occurrence data from 2019 to 2021, while the deterministic is performed on the 2021 data only. Also, the source of consumption data is different, being RPC Consumption Database (EFSA, 2019a) for the probabilistic approach different from the surveys included in PRIMo rev. 3.1 for the deterministic one.

In future reports, a wider evaluation of all the pesticides present in the EU MACP will be considered both in acute and chronic, consumption surveys considered will be harmonised for deterministic and probabilistic assessments as well as the overall methodology will gradually evolve to a full implementation of probabilistic assessments in the context of this report, allowing a better quantification of the uncertainties and thus of the risk to European consumers.

6. Conclusions and recommendations

The 2021 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 Appendix D – Annex I[2] allowing stakeholders to scroll through.

A total of 87,863 samples were analysed, similar number as in 2020 (88,141 samples). Of the total, 96.1% of the samples fell within the legal limit, keeping the figure constant over the last years (94.9% in

2020; 96.1% in 2019); of these, 48,916 samples (55.7%) did not contain quantifiable residues (results below the LOQ for each pesticide analysed), while 40.4% contained quantified residues not exceeding the legal limits (35,483 samples). The MRL exceedance rate decreased from 2020 (5.1%) to 3.9% in 2021 (3,464 samples), notably also for glyphosate (0.15% in 2021 vs 0.6% in 2020). When due consideration is given to the measurement uncertainty, it was found that 2.5% (2,207 samples) of all samples triggered legal sanctions or enforcement actions, a decrease in comparison with 2020 (3.6%).

Of the total 87,863 samples, 63,803 samples were reported as having origin one of the reporting countries. Of these, 38% were found to be below the LOQ, while 24% contained residues at or above the LOQ but below or equal to the MRL. 2% of the samples exceeded the MRL and of these, 1.3% were non-compliant with the MRL (after taking into account measurement uncertainty). A remaining 19,053 samples were imported from third countries, of which 42% were reported as without quantifiable residues, while in 47.7% of samples contained quantifiable residues within the legal limits. The MRL exceedance rate (10.3%) was higher than in those samples grown in one of the reporting countries, as well as the non-compliant rate (6.4%). The remaining 5,007 samples (5.7%) were reported as origin unknown of which, 225 samples (4.5%) exceeded the MRL.

The random sampling under the EU MACP commodities (Regulation (EU) No 2020/585) consumed by EU citizens (i.e. aubergines/egg plants, bananas, broccoli, cultivated fungi, grapefruit, melons, sweet peppers, table grapes, wheat, virgin olive oil, bovine fat and chicken eggs) provides a snapshot of the level of pesticide residues in those food products. These were compared with the same food products as sampled in 2018 and 2015 EU monitoring programmes.

A total of 13,845 samples were reported under the EU MACP and analysed for 190 pesticide residues. In 8,043 of those samples (58.1%) no quantifiable residues were reported (residues were below the LOQ). The number of samples with pesticide residues within legally permitted levels (at or above the LOQ but below or at the MRL) was 5,507 (39.8%). MRLs were exceeded in 2.1% (295) of samples, of which 1.3% (184) were found to be non-compliant after taking into consideration the measurement uncertainty.

The overall MRL exceedance rate rose from 1.4% in 2018 to 2.1% in 2021. However, 2021 rate was distorted by the high exceedance rate from grapefruits coming from Türkiye. The data resulting from RASFF notifications and the information regarding official controls performed by Member States and provided to SANTE during the 2021, indicate the emergence of a concern of this commodity coming from this country. Therefore, the level of official controls on entries of such consignments was increased to 10% as set in increased import control Regulation (EU) No 2021/2246. If grapefruits would have been taken out from the average calculation, the MRL exceedance rate for 2021 would have been 1.4% as in 2018.

Among the rest of the food commodities, MRL exceedance rates rose in aubergines (from 0.4% to 1.6% and to 2.1%), bananas (from 0.3% to 1.7% and to 2.3%), sweet/bell peppers (from 0.8% to 2.4% and to 3.4%) and wheat (from 0.6% to 0.6% and to 1.5%) from 2015 to 2018 and to 2021, respectively. An increased trend for those food products to be sampled only in 2018 and 2021 (not included in 2015) was also observed for cultivated fungi (from 1.2% to 2.2%). On the contrary, decreases were noticed on the exceedance rates from 2015 to 2018 and 2021 for broccoli (from 3.4% to 2.0% and to 1.7%), chicken eggs (from 0.2% to 0.1% and to 0%), melons (although not included in 2015 programme, decreased from 2.2% in 2018 to 1.3% in 2021) and virgin olive oil (from 0.9% to 0.6% and to 0.3%). The tendency for table grapes was an increase compared to 2015 (1.7%) but a decreased compared to 2018 (2.6%) in respect to 2021 (2.1%).

On average, out of the total EU MACP samples, 53.3% were domestic samples, 22.8% were from other EU countries, 19.6% from third countries (an increase compared to 14% in 2020) and 4.3% were of unknown origin. The increase on samples from third countries allows explaining the high non-compliance rate observed in some commodities compared to previous years (e.g. grapefruits) and the actions taken.

The results from the monitoring programmes are a valuable source of information for estimating the dietary exposure of EU consumers. An analysis of the acute and chronic health risk to consumers was performed using the deterministic Pesticide Residues Intake Model (PRIMo rev. 3.1). For the first time, pilot methodologies on acute and chronic probabilistic assessments were performed to those active substance exceeding the acute HBGV on the deterministic calculations. In this pilot, the aim was to be able to express the percentage of consumers exceeding the HBGV previously exceeded using a deterministic acute assessment. Probabilistic exposure assessment cannot be considered as a refinement of the deterministic exposure assessment. Further work is still needed to align the surveys and food commodities as starting points.

The acute deterministic exposure assessment was carried out on 190 pesticides in 19,499 samples (i.e. those pesticide/food product combinations covered by the 2021 EU MACP plus those from the MANCP that matched those combinations). The health-based guidance value (ARfD) was found to be exceeded in 1.1% of these samples. The pesticides found to be the most responsible were lambda-cyhalothrin (RD) (46 samples), cypermethrin (RD) (44 samples), acetamiprid (RD) (43 samples) and indoxacarb (RD) (25 samples).

The chronic deterministic exposure assessment to the pesticides covered by the 2021 EU MACP reported in those raw commodities for which consumption data are available was conducted on 69,767 samples. The estimated exposure in the LB scenario no exceedance was observed whereas in the MB the calculated exposure for non-approved dimethoate was estimated to be at the level of 101% of the ADI. This possible exceedance could have been refined if PFs would have been available.

From the 29 different pesticide residues exceeding the acute HBGV in the deterministic model (i.e. possibly resulting from 38 different active substances), a pilot for probabilistic risk assessment revealed that for 22 of those pesticide residues (i.e. for 30 active substances), the probability for a consumer to exceed the ARfD is expected to be low (i.e. close to 0%), while for two other substances the outcome of the risk assessment could not be interpreted. For the six remaining substances, the probability for a consumer to exceed the ARfD ranged from close to 0 to 1.2% depending on the substance, country and age class. When those same 29 pesticides were assessed under the pilot for chronic probabilistic assessment, it is confirmed that the probability to exceed the ADI is close to 0% for 33 over 39 active substances, and for another 2 substances the outcome could not be interpreted. For the remaining 3 substances, the estimated probability for consumers to exceed the ADI ranged from close to 0 to 1.9%. However, both chronic and acute exposure estimates are still subject to uncertainties, that are more likely to overestimate than to underestimate the calculated risks.

Overall, for most of the samples analysed in the framework of the 2021 pesticide monitoring programmes (EU MACP and MANCP), the probability of EU consumers to be at risk for pesticides for which HBGVs were available is very low. Furthermore, for the specific pesticide/product combinations where the highest probability of exceeding the health-based guidance value were calculated, unquantified uncertainties remain, and further refinement of the calculated probabilities is still possible.

Based on the 2021 pesticide monitoring findings, EFSA recommends the following:

- EFSA recommends reporting countries to take the necessary measures to fulfil the minimum number of samples set in Annex II of the EU MACP Regulations regarding the 12 food commodities and the specific provisions for organic and baby food.
- EU non-approved chlorpyrifos (RD) and fluazifop (RD) were mainly found in wheat and broccoli, respectively, grown in the EU and randomly sampled at levels exceeding the legal limit. Furthermore, EU approved ethephon (RD) was reported in sweet/bell peppers grown in EU at concentrations exceeding the legal limit. Dithiocarbamates (RD), currently under different approval status, and EU approved 2-phenylphenol (RD) were quantified at levels exceeding the legal limits in cultivated fungi grown in EU. EFSA recommends reporting countries to keep monitoring these combinations in their scope of analysis. Given the high non-compliance rates on grapefruits from Türkiye, known to the EU Member States and where increased frequency of the import controls was raised, EFSA recommends keep monitoring these pesticide/crop combinations.
- Nineteen pesticides: pencycuron (RD), dithianon (RD), 2-phenylphenol (RD), glufosinate (RD), fosetyl (RD), bromide ion (RD), 2,4-D (RD), prochloraz (RD), chlordane (RD), spirotetramat (RD), haloxyfop (RD), fluazifop (RD), ethephon (RD), mepiquat chloride (RD), formetanate hydrochloride (RD), pyridalyl (RD), dithiocarbamates (RD), cyflufenamid (RD) and fenbutatin oxide (RD), most of them requiring the use of single residue methods, did not reach the target number of analysis. EFSA reiterates its recommendation for Member States to take necessary measures to be able to enforce properly these substances.
- When considering the results of the overall monitoring programmes (EU MACP and MANCP), samples imported from third countries showed a 5-fold MRL exceedance rate (10.3%) and non-compliance rate (6.4%) compared with food produced within the EU (2% MRL exceedances and 1.3% non-compliance). Member States' National authorities are recommended to keep monitoring pesticides residues in samples imported from third countries with a wide analytical scope.
- High MRL exceedance rate (6.6%) was reported for ethylene oxide due to a specific incident that started in the year 2021, which was addressed by strict measures taken by the Member

States. Considering that this represents a 40% of the overall exceedance rate, EFSA recommends Member States to continue monitoring this active substance in sesame seeds, curcuma, rice and chilli peppers coming from India.

- The number of samples with multiple pesticide residues remained steady in 2021 (26.4%) compared with the previous year (27%). Unprocessed apples, table grapes, strawberries, bananas, grapefruits, oranges, pears, peaches, sweet peppers/bell peppers were the commodities having the highest multiple residues quantified. The highest frequency of multiple residues in processed food samples was found in wine grapes, raisins, dried celery leaves, marjoram, grape leaves and similar species (salted and canned). EFSA recommends Member States to continue monitoring these foodstuffs under their programmes.

- The MRL exceedance (4.5%) and non-compliance (3.1%) rates observed in processed food in 2021 were higher than those reported in 2020 (2.6% for MRL exceedance and 1.2% for non-compliance). Those processed food products exhibiting the higher non-compliance rate were grape leaves and similar species (56.6%), dried chilli peppers (19.1%), dried laver (13.9%) and dried dill leaves (11.9%). Unprocessed food products showed MRL exceedance (3.9%) and non-compliance (2.3%) rates lower than those processed, being passion fruit/maracujas (14.9%), granate apples/pomegranates (12.8%) and chilli peppers (13.9%) those with the highest non-compliance rate. It is recommended to continue monitoring these processed and unprocessed food items in the various national control programmes throughout the EU.

- Despite MRL exceedance and non-compliance rates were steady in 2021 respect to 2020 (exceedances: 1.8% in 2021 vs 1.5% in 2020; non-compliance rate: 1% in 2021 vs 0.6% in 2020), non-authorised substances in organic farming were reported sporadically in samples coming from third countries: imazalil (RD) (mostly in miscellaneous fruits with inedible peel from Ecuador), chlorpyrifos (RD) (mostly in buckwheat and other pseudo-cereals from Bolivia) and ethylene oxide (mostly in turmeric/curcuma from India) were found in crops labelled as organic. Member States are recommended to investigate the reasons for these findings and to widen the analytical scope in organic samples as much as possible.

- The pesticide/crop combinations giving to MRL exceedances in animal products were:

  - bromide ion (RD) in chicken eggs and bovine fat.
  - copper compounds in honey, bovine liver and wild terrestrial vertebrate animals.
  - chlordecone (RD) in chicken eggs and bovine fat.
  - BAC (RD) and DDAC (RD) in cattle milk.
  - chlorate (RD) in quail egg.

  EFSA recommends Member States elucidating the reasons why some substances appear in some animal commodity and not in others, and to food business operators reviewing their food handling practice aiming at reducing the MRL exceedance of these substances derived from sanitising practices. In the case of chlordecone, a banned persistent pollutant, EFSA reiterates its past recommendation of continuing monitoring this substance under focused programmes for products produced in areas where chlordecone was used in the past.

  A decrease on the quantified rates is noted for honey in comparison with 2020 (MRL exceedance: 2.1% vs 5.5% in 2020; non-compliance: 1.6% vs 3.5% in 2020). However, honey still presents the highest number of quantified pesticides (28) among the animal products, being the most frequent thiacloprid and acetamiprid. Notably, thiacloprid showed a downward trend following the decision for non-renewal of approval taken in early 2021. Nonetheless, Member States are recommended to keep monitoring honey and other apicultural products in their national programmes, with a wide analytical scope investigating the reasons for the presence of these substances.

- Actions taken by reporting countries for some non-compliant samples leading to acute exceedances were not provided to EFSA. Considering that this is an important piece of information for traceability on non-compliant samples and analysis of potential health risks, reporting countries' competent authorities should make sure that this information is provided when reporting the sample results to EFSA.

- In view of the outcome of the risk assessment for cypermethrin (sum of isomers) with regards the non-approved alpha and beta isomers, reporting countries are recommended to be vigilant to the analytical chromatogram and look thoroughly for these two isomers in samples where residues of cypermethrin were quantified.

- Given the outcome of the exposure calculations where exceedances of the acute HBGV were driven by food products that are usually consumed peeled or processed, i.e. acetamiprid in grapefruits; cypermethrin in melons; abamectin in bananas, mandarins and wheat germ and phosmet in mandarins, it is recommended to authorisation holders of these active substances to generate processing (and peeling) factors to further refine the risk assessment.
- In view of the outcome of the risk assessment for non-approved dimethoate (RD), EFSA reiterates its recommendation to keep monitoring the presence of this active substance and its degradation product, omethoate (never approved in the EU), under EU MACP and to keep monitoring of cherries within the MANCP.
- Probabilistic acute and chronic calculations for some pesticides (e.g. dimethoate, oxamyl), were strongly influenced by the uncertainty related to left censored data. EFSA will further explore possibilities to better account for this uncertainty but in this respect, it is also reiterated the usefulness of reporting to EFSA the LOQ of the instrument (if validated and lower than the reporting level provided) as this could contribute to refine the exposure assessment.
- Risk managers may consider the inclusion of processed food samples in the EU MACP to reduce the uncertainty related to food processing in the exposure calculations.
- Although only metiram and ziram are currently approved in the EU and given that the current residue definition is 'dithiocarbamates expressed as CS_2, including maneb, mancozeb, metiram, propineb, thiram and ziram', having analytical methods capable of discriminating among the active substances belonging to the dithiocarbamates family would be crucial to identify misuses and refine the risk assessment.

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

Reporting country codes

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

Other abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
BAC	benzalkonium Chloride
BCP	border control posts
bw	body weight
CAG	Cumulative Assessment Group
CP	control Point
CS_2	carbon disulfide
DDAC	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
IESTI	International Estimation of Acute Intake

LOD	limit of detection
LOQ	limit of quantification
MANCP	Multiannual National Control Programme
MRL	maximum residue level
MS	Member States
POP	persistent organic pollutants
PRIMo	Pesticide Residue Intake Model
RASFF	Rapid Alert System for Food and Feed
RPC	raw primary commodity
RD	residue definition
SRM	single residue method
SSD	standard sample description
TDI	tolerable daily intake
VMPR	veterinary medicinal product residues
WHO	World Health Organization

Appendix A – Authorities responsible for reporting 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	https://www.ages.at/themen/rueckstaende-kontaminanten/pflanzenschutzmittel-rueckstaende/pestizidmonitoringberichte/
Belgium	Federal Agency for the Safety of the food Chain (FASFC)	https://www.favv-afsca.fgov.be/publicationsthematiques/pesticide-residue-monitoring-food-plant-origin.asp
Bulgaria	Risk Assessment Centre on Food Chain	https://www.babh.government.bg/en/
Croatia	Ministry of Agriculture	https://www.mps.hr/
Cyprus	Ministry of Health, Pesticides Residues Laboratory of the State General Laboratory	https://www.moh.gov.cy/sgl
	Ministry of Health, Department of Medical and Public Health Services (MPHS)	
Czech Republic	Czech Agriculture and Food Inspection Authority	https://www.szpi.gov.cz
	State Veterinary Administration	https://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	https://www.food.dtu.dk/publikationer/kemikaliepaavirkninger/pesticider-i-kosten
Estonia	Veterinary and Food Board	https://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)	https://www.economie.gouv.fr/dgccrf/securite/produits-alimentaires
	Ministère de l'Agriculture et de l'Alimentation, Direction générale de l'alimentation (DGAL)	https://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	https://www.minagric.gr/index.php/en/citizen-menu/foodsafety-menu
		https://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	www.mast.is
Ireland	Department of Agriculture Food and the Marine	www.pcs.agriculture.gov.ie

Country	National competent authority	Web address for published national monitoring reports
Italy	Ministero della Salute – Direzione Generale per l'Igiene e la Sicurezza degli Alimenti e la Nutrizione – Ufficio 7	https://www.salute.gov.it/portale/fitosanitari/dettaglioContenutiFitosanitari.jsp?lingua=italiano&id=1105&area=fitosanitari&menu=vegetali
Latvia	Ministry of Agriculture	www.zm.gov.lv
	Food and Veterinary Service of Latvia	
Lithuania	National Food and Veterinary Service (SFVS)	www.nmvrvi.lt
Luxembourg	Ministry of Health, Directorate for public health, Division of Food Safety (Secualim)	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
		www.mattilsynet.no/mat_og_vann/uonskede_stofferimaten/rester_av_plantevernmidler_i_mat/#overvakings_og_kartleggingsprogrammer
Poland	The State Sanitary Inspection	www.gis.gov.pl
Portugal	Direção-Geral de Alimentação e Veterinária (DGAV)	www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=4217393&cboui=4217393t
Romania	National Sanitary Veterinary and Food Safety Authority	www.ansvsa.ro
	Ministry of Agriculture and Rural Development	www.madr.ro
	Ministry of Health	
Slovakia	State Veterinary and Food Administration of the Slovakian Republic	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	www.uvhvvr.gov.si/si/delovna_podrocja/ostanki_pesticidov
Spain	Spanish Agency for Food Safety and Nutrition (AESAN)	www.aecosan.msssi.gob.es/AECOSAN/web/seguridad_alimentaria/subseccion/programa_control_residuos.htm
Sweden	National Food Agency	www.livsmedelsverket.se
Northern Ireland[1]*	Department of Agriculture, Environment and Rural Affairs (DAERA). Sanitary and Phytosanitary Policy and Logistics Division	www.daera-ni.gov.uk/

Appendix B – Detailed results on deterministic risk assessment

Results of acute risk assessment for food products in focus of the 2021 EU MACP, expressed as percentage of the ARfD are presented in this appendix.

In the following figures,[72] 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 multiannual control 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, number of samples with quantified residues below or at the MRL, and the number of samples with residues above the MRL.[73]

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[72] 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.

[73] 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.
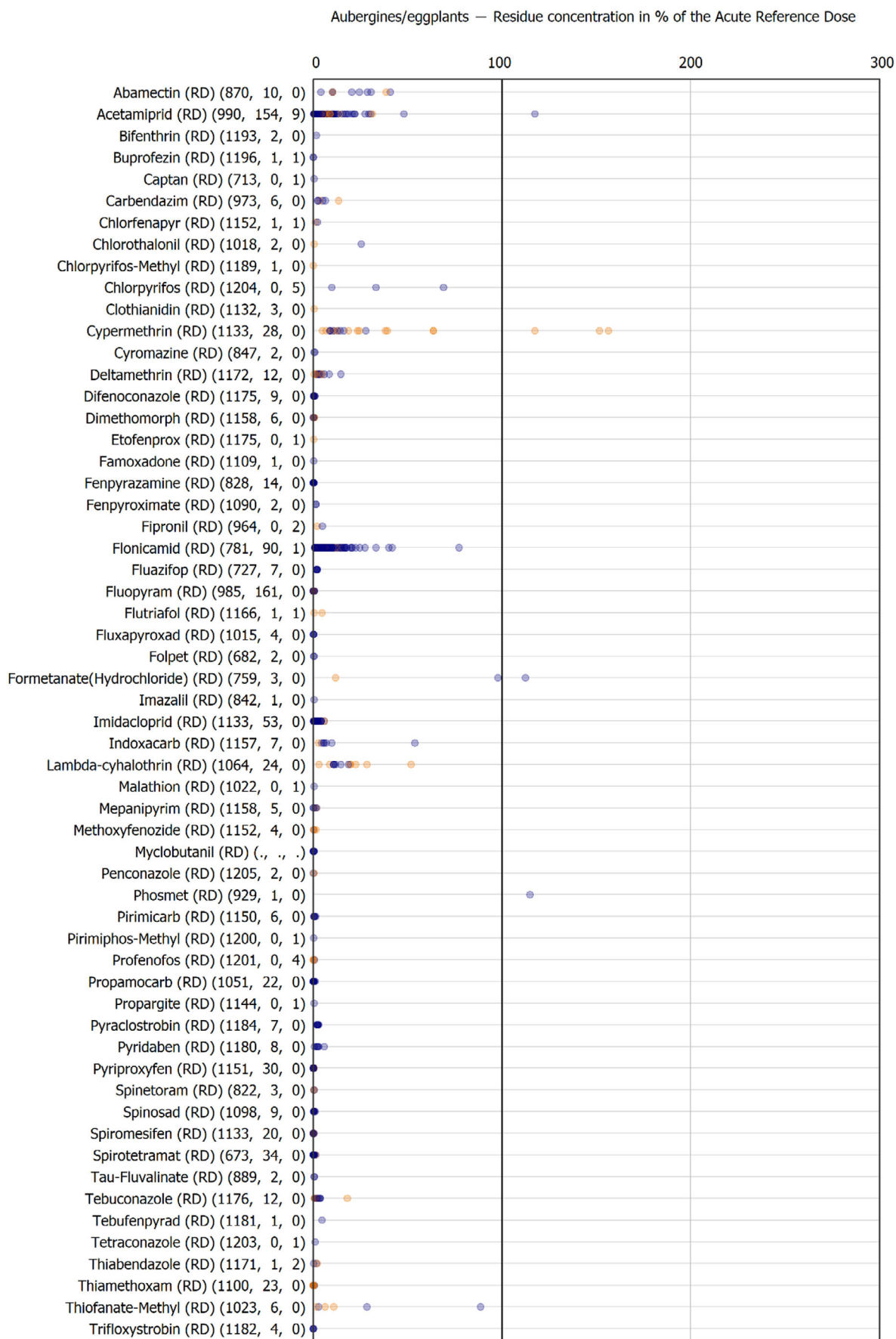
Figure B.1: Acute dietary exposure assessment − aubergines/eggplants

Bananas − Residue concentration in % of the Acute Reference Dose
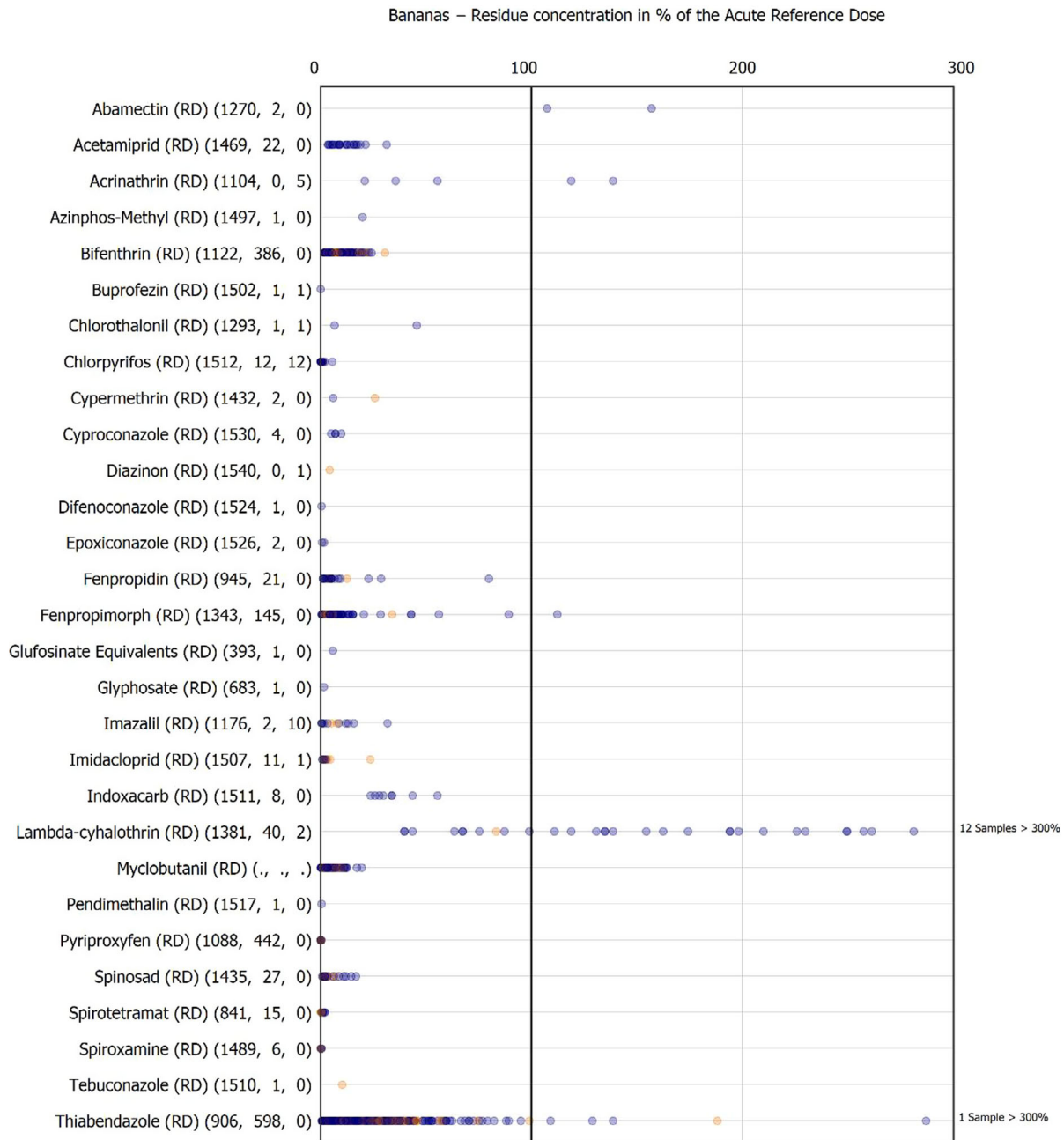
Figure B.2: Acute dietary exposure assessment – bananas
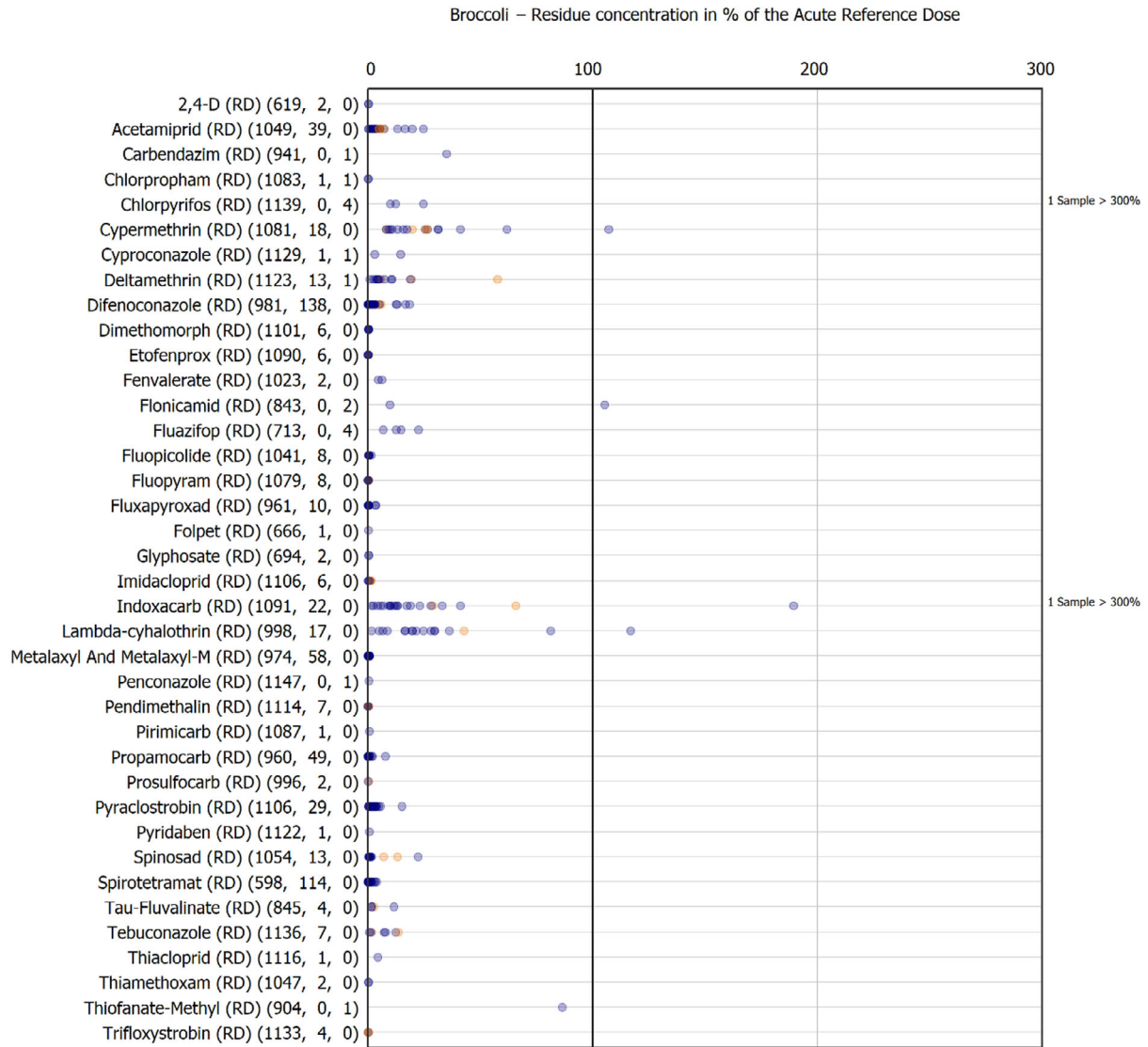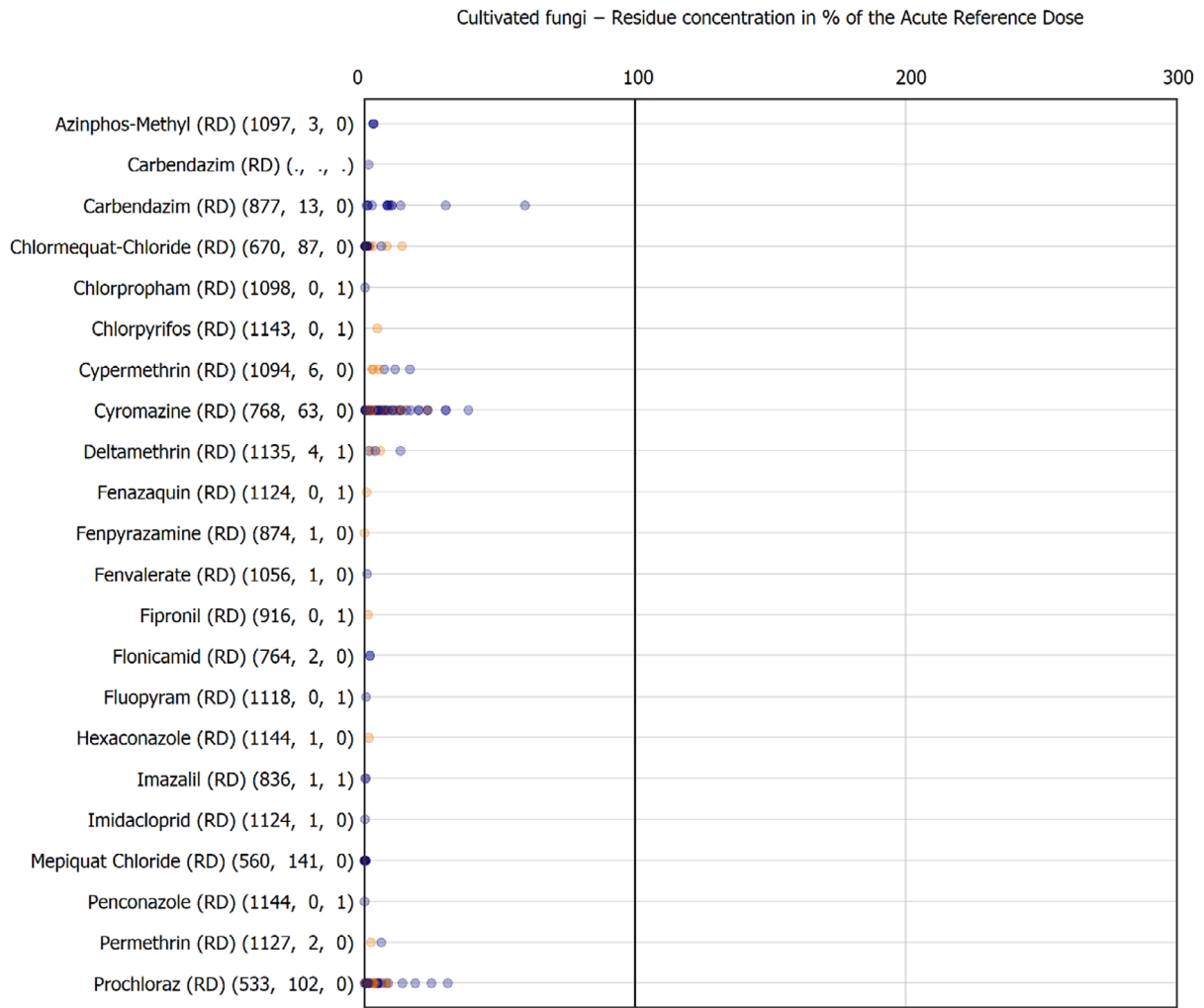
Figure B.3: Acute dietary exposure assessment – broccoli

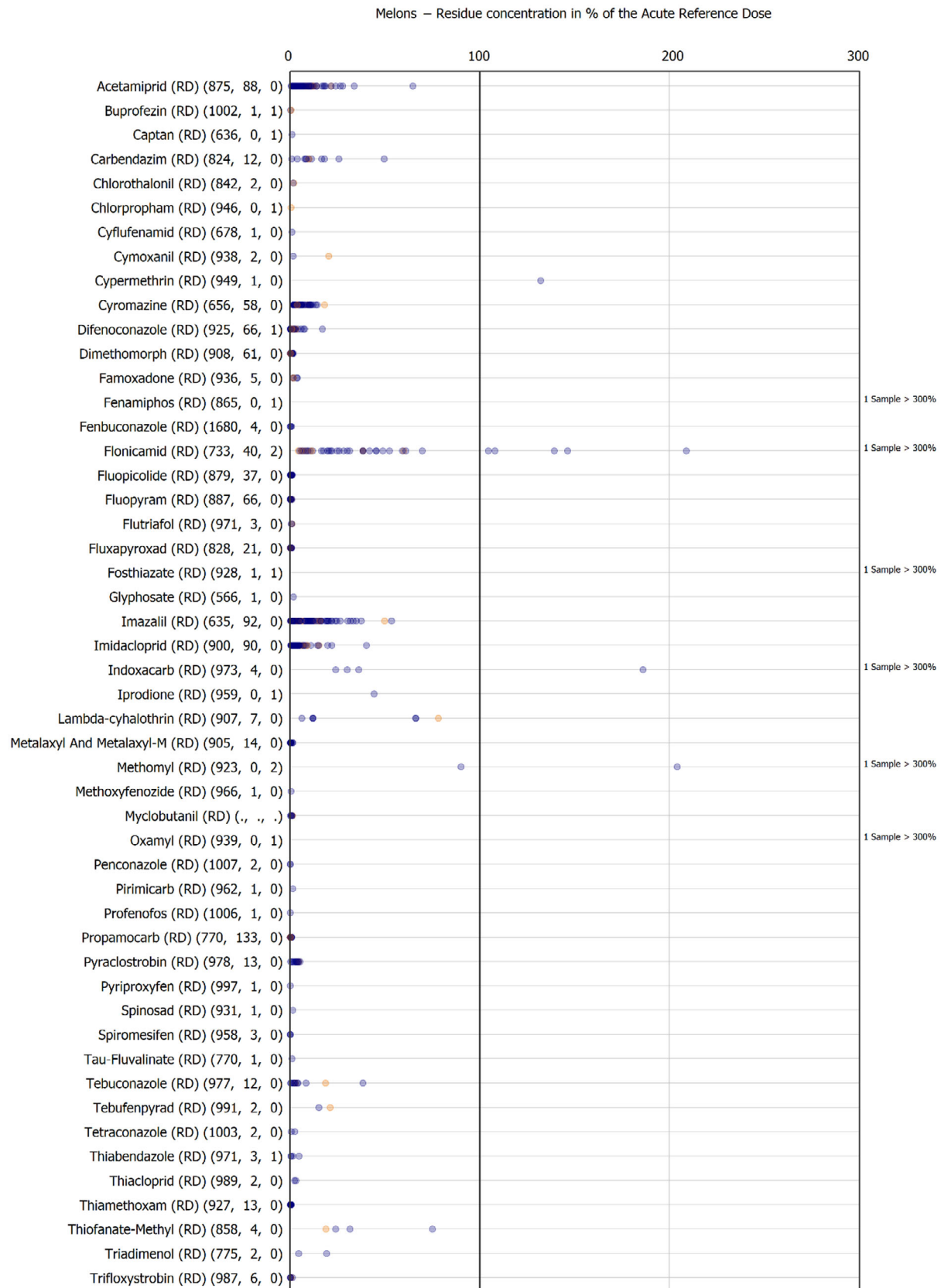**Figure B.4:** Acute dietary exposure assessment – cultivated fungi

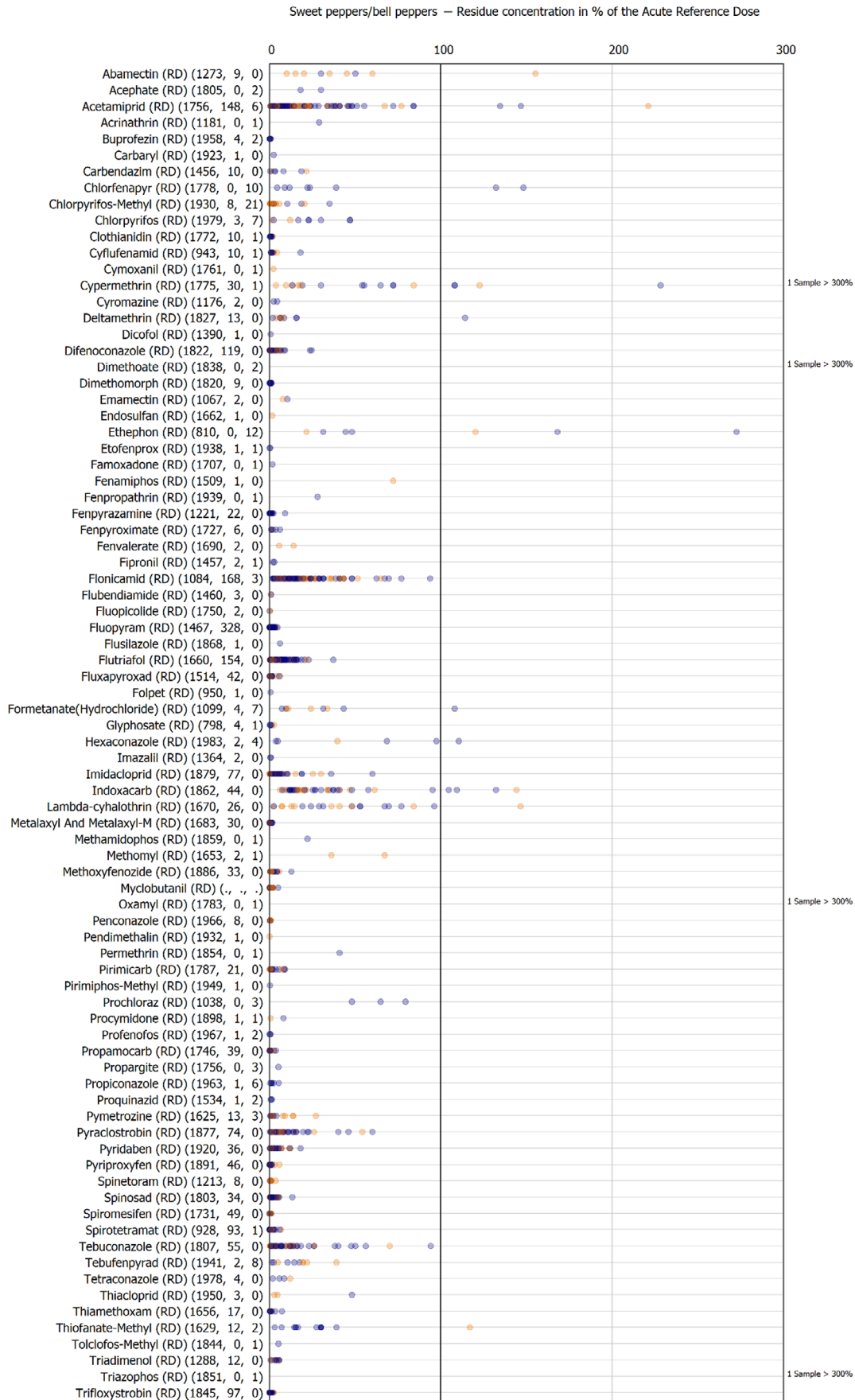**Figure B.5:** Acute dietary exposure assessment – grapefruits
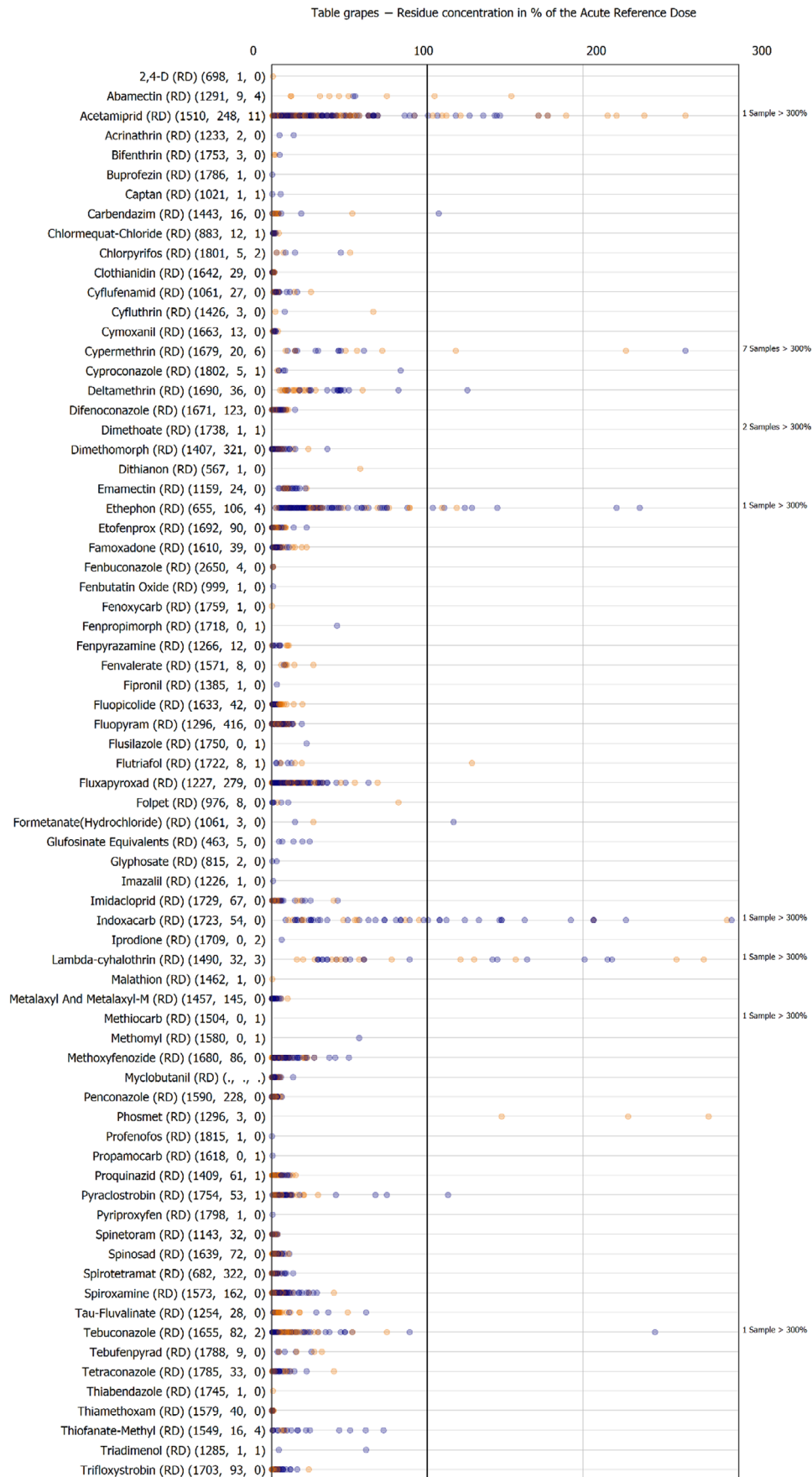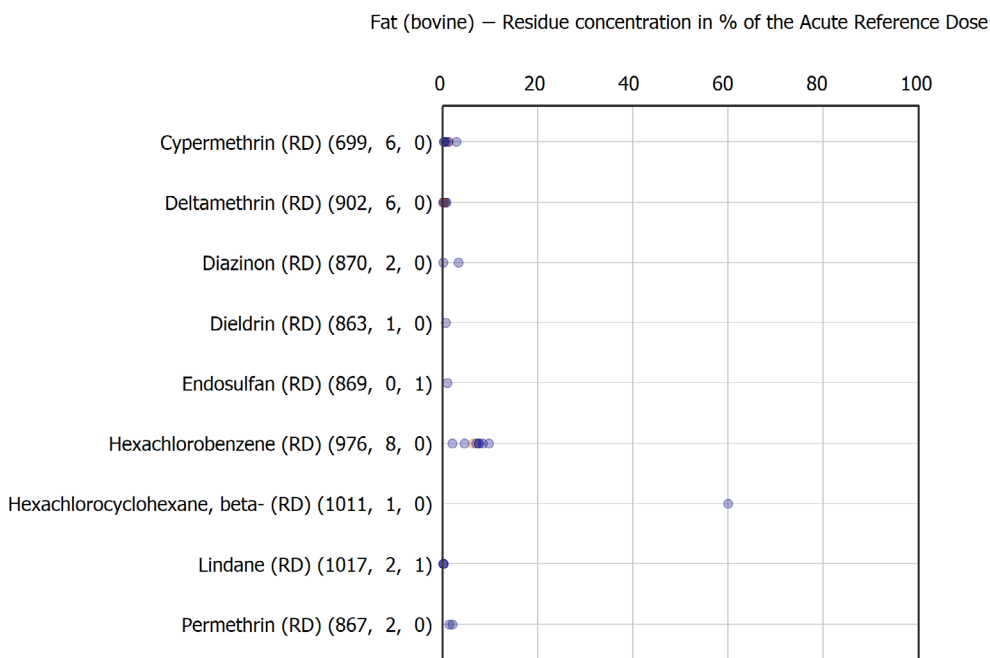
Figure B.6: Acute dietary exposure assessment – melons

Figure B.7: Acute dietary exposure assessment – sweet/bell peppers

Figure B.8: Acute dietary exposure assessment – table grapes

Figure B.9: Acute dietary exposure assessment – wheat
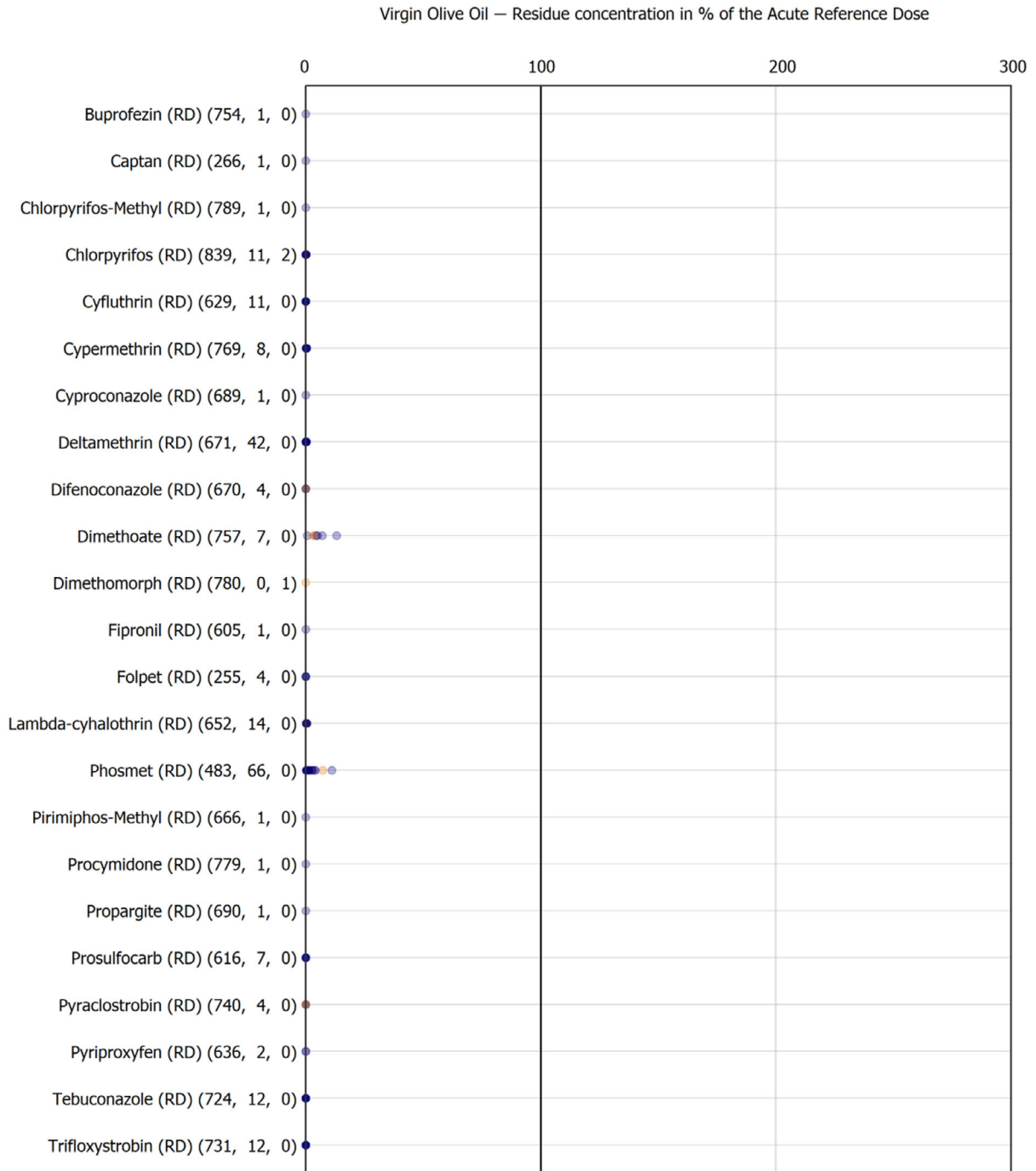
Figure B.10: Acute dietary exposure assessment – virgin olive oil

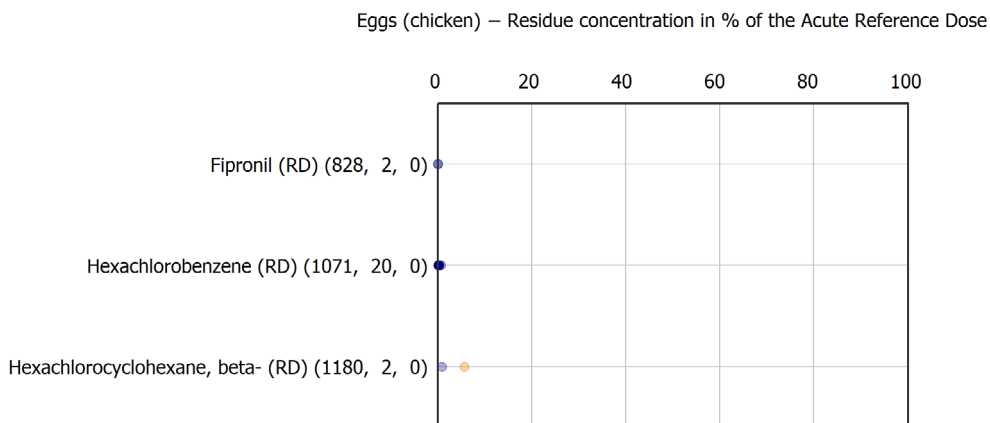**Figure B.11:** Acute dietary exposure assessment – bovine fat

Figure B.12: Acute dietary exposure assessment – chicken eggs

Appendix C – Detailed description of the input data and methodologies applied in the probabilistic assessment

C.1. Description of the data

C.1.1. Primary input data

C.1.1.1. Raw primary commodities

To pilot the probabilistic risk assessment to pesticide residues, EFSA selected the 35 raw primary commodities (RPCs) of plant origin that that were ever considered in the EU MACP. In addition, courgettes were also included because, according to EFSA's design assessment of the pesticide monitoring programme (EFSA, 2015a), courgettes are consumed in higher amounts than other commodities previously included in the EU MACP (e.g. spinach and broccoli). Foods specifically intended for infants and young children were integrated in the exposure assessment.

The full list of the included food commodities is provided in Table C.1.

Table C.1: RPC list

prodCode[1]	prodName[2]
P0110010A	Grapefruits
P0110020A	Oranges
P0110050A	Mandarins
P0130010A	Apples
P0130020A	Pears
P0140030A	Peaches
P0151010A	Table grapes
P0151020A	Wine grapes
P0152000A	Strawberries
P0162010A	Kiwi fruits
P0163020A	Bananas
P0211000A	Potatoes
P0213020A	Carrots
P0220020A	Onions
P0231010A	Tomatoes
P0231020A	Peppers
P0231030A	Aubergines (egg plants)
P0232010A	Cucumbers
P0232030A	Courgettes
P0233010A	Melons
P0241010A	Broccoli
P0241020A	Cauliflower
P0242020A	Head cabbage
P0251020A	Lettuce
P0252010A	Spinach
P0260010A	Beans (with pods)
P0260040A	Peas (without pods)
P0270060A	Leek
P0280010A	Cultivated funghi
P0300010A	Beans (dry)
P0402010A	Olives for oil production
P0500010A	Barley
P0500050A	Oats
P0500060A	Rice

prodCode[1]	prodName[2]
P0500070A	Rye
P0500090A	Wheat
PX100001A	Baby foods other than processed cereal-based foods
PX100003A	Processed cereal-based foods for infants and young children
PX100004A	Infant formulae
PX100005A	Follow-on formulae

(1): Code of the raw primary commodity as defined by EFSA's harmonised terminology for scientific research (MATRIX catalogue; EFSA, 2022f).

(2): Name of the raw primary commodity as defined by EFSA's harmonised terminology for scientific research (MATRIX catalogue; EFSA, 2022f).

C.1.1.2.   Active substances

The active substances under analysis are those found to exceed the acute HBGV in the acute deterministic risk assessment. The list of active substances, which incorporates the key input data for the prioritisation exercise, is presented in Section C.1.1.3.

C.1.1.3.   Residue definitions

While the probabilistic risk assessment is executed at the level of the active substances, the occurrence data reported to EFSA refer to the residue definition for enforcement. As the residue definitions defined in Regulation (EC) No 396/2005 may change over time, single active substances may be associated to multiple residue definitions throughout the reference period 2019–2021. EFSA therefore, collected all the residue definitions that were applicable to the selected food commodities and active substances during the reference period. The residue definitions collected are presented in Table C.2.

Table C.2:   List of residue definitions and related active substances

paramCode_RD[1]	paramName_RD[2]	paramCode_AS[3]	paramName_AS[4]
RF-00004655-PAR	Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a)	RF-00000011-VET	Abamectin
RF-0014-001-PPP	Acetamiprid	RF-0014-001-PPP	Acetamiprid
RF-00007632-PAR	Acrinathrin and its enantiomer	RF-0018-001-PPP	Acrinathrin
RF-0041-001-PPP	Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim)	RF-0041-002-PPP	Carbendazim
RF-0077-001-PPP	Chlorfenapyr	RF-0077-001-PPP	Chlorfenapyr
RF-0087-001-PPP	Chlorpyrifos	RF-0087-001-PPP	Chlorpyrifos
RF-0112-001-PPP	Cypermethrin (Cypermethrin including other mixtures of constituent isomers (sum of isomers))	RF-0112-004-PPP	Cypermethrin
RF-0112-001-PPP	Cypermethrin (Cypermethrin including other mixtures of constituent isomers (sum of isomers))	RF-00000161-VET	Cypermethrin, alpha-
RF-0112-001-PPP	Cypermethrin (Cypermethrin including other mixtures of constituent isomers (sum of isomers))	RF-0112-003-PPP	Cypermethrin, beta-
RF-0112-001-PPP	Cypermethrin (Cypermethrin including other mixtures of constituent isomers (sum of isomers))	RF-0112-005-PPP	Cypermethrin, zeta-
RF-0115-001-PPP	Cyromazine	RF-0115-001-PPP	Cyromazine
RF-0120-001-PPP	Deltamethrin (cis-deltamethrin)	RF-0120-001-PPP	Deltamethrin (cis-deltamethrin)

paramCode_RD[1]	paramName_RD[2]	paramCode_AS[3]	paramName_AS[4]
RF-0139-003-PPP	Dimethoate	RF-0139-003-PPP	Dimethoate
RF-0151-001-PPP	Dithiocarbamates (Dithiocarbamates expressed as CS2, including Maneb, Mancozeb, Metiram, Propineb, Thiram and Ziram)	RF-0151-004-PPP	Mancozeb
RF-0151-001-PPP	Dithiocarbamates (Dithiocarbamates expressed as CS2, including Maneb, Mancozeb, Metiram, Propineb, Thiram and Ziram)	RF-0151-003-PPP	Maneb
RF-0151-001-PPP	Dithiocarbamates (Dithiocarbamates expressed as CS2, including Maneb, Mancozeb, Metiram, Propineb, Thiram and Ziram)	RF-0151-002-PPP	Metiram
RF-0151-001-PPP	Dithiocarbamates (Dithiocarbamates expressed as CS2, including Maneb, Mancozeb, Metiram, Propineb, Thiram and Ziram)	RF-0359-002-PPP	Propineb
RF-0151-001-PPP	Dithiocarbamates (Dithiocarbamates expressed as CS2, including Maneb, Mancozeb, Metiram, Propineb, Thiram and Ziram)	RF-0423-001-PPP	Thiram
RF-0151-001-PPP	Dithiocarbamates (Dithiocarbamates expressed as CS2, including Maneb, Mancozeb, Metiram, Propineb, Thiram and Ziram)	RF-0451-001-PPP	Ziram
RF-0160-001-PPP	Ethephon	RF-0160-001-PPP	Ethephon
RF-0173-001-PPP	Fenamiphos (sum of fenamiphos and its sulfoxide and sulfone expressed as fenamiphos)	RF-0173-004-PPP	Fenamiphos
RF-0184-001-PPP	Fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin)	RF-00007586-PAR	Fenpropidin
RF-0185-001-PPP	Fenpropimorph (sum of isomers)	RF-00012326-PAR	Fenpropimorph
RF-00004683-PAR	Flonicamid (sum of flonicamid, TFNA and TFNG expressed as flonicamid)	RF-0194-002-PPP	Flonicamid
RF-0220-001-PPP	Flutriafol	RF-0220-001-PPP	Flutriafol
RF-0223-001-PPP	Formetanate: Sum of formetanate and its salts expressed as formetanate (hydrochloride)	RF-00001688-PAR	Formetanate hydrochloride
RF-0226-001-PPP	Fosthiazate	RF-0226-001-PPP	Fosthiazate
RF-0241-001-PPP	Hexaconazole	RF-0241-001-PPP	Hexaconazole
RF-0251-001-PPP	Indoxacarb (sum of indoxacarb and its R enantiomer)	RF-00004822-PAR	Indoxacarb
RF-1004-001-PPP	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)	RF-0585-001-PPP	Cyhalothrin, gamma-
RF-1004-001-PPP	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)	RF-0261-001-PPP	Cyhalothrin, lambda-
RF-0291-001-PPP	Methiocarb (sum of methiocarb and methiocarb sulfoxide and sulfone, expressed as methiocarb)	RF-0291-002-PPP	Methiocarb
RF-0293-003-PPP	Methomyl	RF-0293-003-PPP	Methomyl
RF-0320-001-PPP	Oxamyl	RF-0320-001-PPP	Oxamyl
RF-0338-001-PPP	Phosmet (phosmet and phosmet oxon expressed as phosmet)	RF-0338-002-PPP	Phosmet

paramCode_RD[1]	paramName_RD[2]	paramCode_AS[3]	paramName_AS[4]
RF-00012032-PAR	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz)	RF-0349-002-PPP	Prochloraz
RF-0370-001-PPP	Pyraclostrobin	RF-0370-001-PPP	Pyraclostrobin
RF-0403-001-PPP	Tebuconazole	RF-0403-001-PPP	Tebuconazole
RF-0416-001-PPP	Thiabendazole	RF-0416-001-PPP	Thiabendazole
RF-0422-001-PPP	Thiophanate-methyl	RF-0422-001-PPP	Thiophanate-methyl
RF-0432-001-PPP	Triazophos	RF-0432-001-PPP	Triazophos

(1): Code of the residue definition as defined by EFSA's harmonised terminology for scientific research (PARAM catalogue; EFSA, 2022f).

(2): Name of the residue definition as defined by EFSA's harmonised terminology for scientific research (PARAM catalogue; EFSA, 2022f).

(3): Code of the associated active substance(s) as defined by EFSA's harmonised terminology for scientific research (PARAM catalogue; EFSA, 2022f).

(4): Name of the associated active substance(s) as defined by EFSA's harmonised terminology for scientific research (PARAM catalogue; EFSA, 2022f).

Depending on the metabolism and availability of analytical methods, the residue definitions may either be equal to the active substance, may include additional metabolites, or even incorporate multiple active substances. When the residue definition includes additional metabolites that are specific to the active substance (i.e. complex residue definition), the measurements of the related residue definition are assigned to all associated active substances, allowing for the estimation of exposure for each of these active substances.

C.1.1.4. Occurrence data

The occurrence data collected under Article 31 of Regulation (EC) No 396/2005 are the most appropriate data available to EFSA for performing a probabilistic risk assessment. These data are obtained from the official control activities carried out in the EU Member States[1*], Iceland and Norway. These data are reported to EFSA using the Standard Sample Description ver2 (SSD2) (EFSA, 2013). Although the occurrence data are collected at the level of individual measurements, the SSD2 allows identification of measurements associated to a single food sample (e.g. samples analysed for multiple pesticide residues). After validation by EFSA, the collected data are integrated in the EFSA's Scientific Data Warehouse (sDWH).

All occurrence data referring to the relevant food commodities (see Section C.1.1.1) and residue definitions (see Section C.1.1.3) were extracted from the sDWH. Only measurements validated under 2019, 2020, and 2021 EU reports on pesticide residues in food, were included.

The following additional criteria were applied to the extracted data:

- Only samples resulting from the EU-coordinated multiannual control programme (EU MACP), national control programmes (MANCP) or a combination of those were selected (SSD2 programme type codes K005A, K009A and K018A). Samples associated to increased control programmes or any other type of programme were excluded as they were not considered to be representative of the market.
- Only samples obtained through selective or objective sampling were retained (SSD2 sampling strategy codes ST10A and ST20A). Samples obtained through suspect sampling, or any other type of sampling were not considered to be representative of the market and therefore excluded.
- When the occurrence data were primarily reported for the RPC, samples for processed commodities were excluded and the assessment was based on the RPCs. However, when a sufficient number of samples were found, the occurrence data for the processed foods were also retained. The detailed list of the processed and unprocessed products retained for the assessment is reported in Table C.2.
- Only measurements reported as a numerical (i.e. quantifiable) value or as a non-quantified value were considered useful for the assessment (SSD2 resType codes VAL and LOQ). Other result types were not considered valid and therefore excluded.

- Only measurements reported for the enforcement residue definition that was applicable at the time of sampling, or for the most complete subset of that enforcement residue definition were used (SSD2 paramType codes P004A and P005A). Measurements referring to parts of the residue definition were excluded from the assessment.
- When the LOQ value for a measurement could not be reported by the Member States (i.e. for residue definitions composed of multiple components), the median LOQ of all measurements referring to the same residue definition/commodity combination was assumed.
- When the LOQ value for a measurement was found to be more than 100 times higher compared to the median LOQ of all measurements referring to the same combination of commodity and residue definition, the measurement was no longer considered valid and excluded from the assessment.
- When a measurement was reported at LOQ, the concentration used for the assessment was set at 1/2 LOQ.
- When several measurements with overlapping residue definitions were reported for the same sample, only the measurement referring to the most recent enforcement residue definition was retained for assessment.

Table C.2:   Complete list of products retained for the assessment

Prodcode[1]	PRODNAME[2]	PRODTREAT[3]	PRODTREAT_DESC[4]
P0110010A	Grapefruits	F28.A07LN	PROCESS=Juicing
P0110010A	Grapefruits	F28.A0C0S	PROCESS=Unprocessed
P0110020A	Oranges	F28.A07LN	PROCESS=Juicing
P0110020A	Oranges	F28.A0C0S	PROCESS=Unprocessed
P0110050A	Mandarins	F28.A0C0S	PROCESS=Unprocessed
P0130010A	Apples	F28.A07KG	PROCESS=Drying (dehydration)
P0130010A	Apples	F28.A07LN	PROCESS=Juicing
P0130010A	Apples	F28.A0C0S	PROCESS=Unprocessed
P0130020A	Pears	F28.A07LN	PROCESS=Juicing
P0130020A	Pears	F28.A0C0S	PROCESS=Unprocessed
P0140030A	Peaches	F28.A0C0S	PROCESS=Unprocessed
P0151010A	Table grapes	F28.A07KG	PROCESS=Drying (dehydration)
P0151010A	Table grapes	F28.A07LN	PROCESS=Juicing
P0151010A	Table grapes	F28.A0C0S	PROCESS=Unprocessed
P0151020A	Wine grapes	F28.A0C00 $F10.A0F2R	PROCESS=Winemaking, QUAL=White
P0151020A	Wine grapes	F28.A0C00 $F10.A0F2S	PROCESS=Winemaking, QUAL=Red
P0151020A	Wine grapes	F28.A0C0S	PROCESS=Unprocessed
P0152000A	Strawberries	F28.A0C0S	PROCESS=Unprocessed
P0162010A	Kiwi fruits (green, red, yellow)	F28.A0C0S	PROCESS=Unprocessed
P0163020A	Bananas	F28.A07KG	PROCESS=Drying (dehydration)
P0163020A	Bananas	F28.A0C0S	PROCESS=Unprocessed
P0211000A	Potatoes	F28.A0C0S	PROCESS=Unprocessed
P0213020A	Carrots	F28.A0C0S	PROCESS=Unprocessed
P0220020A	Onions	F28.A0C0S	PROCESS=Unprocessed
P0231010A	Tomatoes	F28.A07KG	PROCESS=Drying (dehydration)
P0231010A	Tomatoes	F28.A07LN	PROCESS=Juicing
P0231010A	Tomatoes	F28.A0BYP	PROCESS=Canning/jarring
P0231010A	Tomatoes	F28.A0C0S	PROCESS=Unprocessed
P0231010A	Tomatoes	F28.A0C6N	PROCESS=Pulping/mashing
P0231010A	Tomatoes	F28.A0C6N $F28.A07KF	PROCESS=Pulping/mashing, PROCESS=Concentration/ evaporation

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Prodcode[1]	PRODNAME[2]	PRODTREAT[3]	PRODTREAT_DESC[4]
P0231020A	Sweet peppers/ bell peppers	F28.A07KG $F28.A07LA	PROCESS=Drying (dehydration), PROCESS=Grinding/ milling/crushing
P0231020A	Sweet peppers/ bell peppers	F28.A0C0S	PROCESS=Unprocessed
P0231030A	Aubergines/ eggplants	F28.A0C0S	PROCESS=Unprocessed
P0232010A	Cucumbers	F28.A0C0S	PROCESS=Unprocessed
P0232030A	Courgettes	F28.A0C0S	PROCESS=Unprocessed
P0233010A	Melons	F28.A0C0S	PROCESS=Unprocessed
P0241010A	Broccoli	F28.A0C0S	PROCESS=Unprocessed
P0241020A	Cauliflowers	F28.A0C0S	PROCESS=Unprocessed
P0242020A	Head cabbages	F28.A0C0S	PROCESS=Unprocessed
P0251020A	Lettuces	F28.A0C0S	PROCESS=Unprocessed
P0252010A	Spinaches	F28.A07KQ	PROCESS=Freezing
P0252010A	Spinaches	F28.A0C0S	PROCESS=Unprocessed
P0260010A	Beans (with pods)	F28.A0C0S	PROCESS=Unprocessed
P0260040A	Peas (without pods)	F28.A0C0S	PROCESS=Unprocessed
P0270060A	Leeks	F28.A0C0S	PROCESS=Unprocessed
P0280010A	Cultivated fungi	F28.A0C0S	PROCESS=Unprocessed
P0300010A	Beans (dry)	F28.A0C0S	PROCESS=Unprocessed
P0402010A	Olives for oil production	F28.A0C02 $F02.A068M	PROCESS=Oil production, PART=Vegetable fats and oils (as part-nature)
P0402010A	Olives for oil production	F28.A0C0S	PROCESS=Unprocessed
P0500010A	Barley	F28.A0BZV	PROCESS=Polishing
P0500010A	Barley	F28.A0C03 $F02.A067Z	PROCESS=Grain milling, PART=Flour/meal or finely ground powder (as part-nature)
P0500010A	Barley	F28.A0C0L	PROCESS=Malting
P0500010A	Barley	F28.A0C0S	PROCESS=Unprocessed
P0500050A	Oat	F28.A07LA	PROCESS=Grinding/milling/crushing
P0500050A	Oat	F28.A07LH	PROCESS=Flattening/rolling
P0500050A	Oat	F28.A0C03 $F02.A067Y	PROCESS=Grain milling, PART=Bran (as part-nature)
P0500050A	Oat	F28.A0C03 $F02.A067Z	PROCESS=Grain milling, PART=Flour/meal or finely ground powder (as part-nature)
P0500050A	Oat	F28.A0C0S	PROCESS=Unprocessed
P0500060A	Rice	F28.A0BZV	PROCESS=Polishing
P0500060A	Rice	F28.A0BZV $F28.A07LK	PROCESS=Polishing, PROCESS=Parboiling/pre-gelatinising
P0500060A	Rice	F28.A0C0S	PROCESS=Unprocessed
P0500070A	Rye	F28.A07LA	PROCESS=Grinding/milling/crushing
P0500070A	Rye	F28.A0C03 $F02.A067Z $F10.A06HR	PROCESS=Grain milling, PART=Flour/meal or finely ground powder (as part-nature),QUAL=Integral/not refined
P0500070A	Rye	F28.A0C03 $F02.A067Z $F10.A07XK	PROCESS=Grain milling, PART=Flour/meal or finely ground powder (as part-nature),QUAL=White/refined
P0500070A	Rye	F28.A0C03 $F02.A067Z $F10.A0EZZ	PROCESS=Grain milling, PART=Flour/meal or finely ground powder (as part-nature),QUAL=Semi-refined
P0500070A	Rye	F28.A0C0S	PROCESS=Unprocessed

Prodcode[1]	PRODNAME[2]	PRODTREAT[3]	PRODTREAT_DESC[4]
P0500090A	Wheat	F28.A07LA	PROCESS=Grinding/milling/crushing
P0500090A	Wheat	F28.A0C03 $F02.A067Y	PROCESS=Grain milling, PART=Bran (as part-nature)
P0500090A	Wheat	F28.A0C03 $F02.A067Z $F10.A06HR	PROCESS=Grain milling, PART=Flour/meal or finely ground powder (as part-nature), QUAL=Integral/not refined
P0500090A	Wheat	F28.A0C03 $F02.A067Z $F10.A07XK	PROCESS=Grain milling, PART=Flour/meal or finely ground powder (as part-nature), QUAL=White/refined
P0500090A	Wheat	F28.A0C03 $F02.A067Z $F10.A0EZZ	PROCESS=Grain milling, PART=Flour/meal or finely ground powder (as part-nature), QUAL=Semi-refined
P0500090A	Wheat	F28.A0C03 $F02.A068C	PROCESS=Grain milling, PART=Semolina or coarse ground powder (as part-nature)
P0500090A	Wheat	F28.A0C0S	PROCESS=Unprocessed

(1): Code of the raw primary commodity as defined by EFSA's harmonised terminology for scientific research (MATRIX catalogue; EFSA, 2022f).

(2): Name of the raw primary commodity as defined by EFSA's harmonised terminology for scientific research (MATRIX catalogue; EFSA, 2022f).

(3): Codes of FoodEx2 facet describing the processing technique, including additional descriptors such as qualitative information, part consumed or the nature of the food (MTX catalogue; EFSA, 2015b).

(4): Names of FoodEx2 facet describing the processing technique, including additional descriptors such as qualitative information, part consumed or the nature of the food (MTX catalogue; EFSA, 2015b).

C.1.1.5. Consumption data

The EFSA Comprehensive European Food Consumption Database (Comprehensive Database) provides a compilation of existing national information on food consumption at individual level. Details on how the Comprehensive Database is used are published in the Guidance of EFSA (EFSA, 2011). Data reported in the Comprehensive Database may either refer to raw primary commodities (RPCs), RPC derivatives (i.e. single-component foods altered by processing) or composite foods (i.e. multicomponent). Consumption data for RPC derivatives and composite foods, however, cannot be used in exposure assessments when the occurrence data are reported for the RPCs.

To address the above issue, EFSA transformed the Comprehensive Database into a new RPC Consumption Database by means of the RPC model (EFSA, 2019a). This model converts the consumption data for composite foods or RPC derivatives into their equivalent quantities of RPCs, except foods for infants and young children.[74] The RPC model was applied to the Comprehensive Database as of 31 March 2018, when it contained results from 51 different dietary surveys carried out in 23 different Member States covering 94,523 individuals.

Furthermore, in order to cover as many populations as possible without compromising the reliability of intake estimates at the 99.9th percentile of the distribution, only the dietary surveys with more than 300 survey subjects were retained, covering 17 different countries.

- Toddlers:[75] Bulgaria, Denmark, Finland, Germany, Netherlands.
- Other children:[76] Belgium, Bulgaria, Czechia, Finland, France, Germany, Greece, Netherlands, Spain, Sweden.
- Adults:[77] Austria, Belgium, Czechia, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden.

For chronic exposure assessment, individuals who participated for only 1 day of the dietary survey were excluded because at least two survey days per individual are normally required to assess repeated exposure (EFSA, 2011).

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[74] Consumption data for foods for infants and young children were not converted to their equivalent amounts of RPC because, in this case, chemical occurrence data are collected for the processed food commodity.

[75] The population class 'toddlers' refers to participants from $\geq$ 12 months to < 36 months old.

[76] The population class 'other children' refers to participants from $\geq$ 36 months to < 10 years old.

[77] The population class 'adults' refers to participants from $\geq$ 18 years to < 65 years old.

The full dataset is not reported in the remit of this report. However, the description of the variables is provided in Table C.

Table C.3: Description of the variable contained in the food consumption database used for this assessment

Name	Label	Description
Country	Country	Country where the dietary survey took place as defined by EFSA's harmonised terminology for scientific research (COUNTRY catalogue; EFSA, 2022f).
Survey	Survey	Acronym of the dietary survey
PopClass	Population class	Participant's population class, based on age, as defined by EFSA's harmonised terminology for scientific research (AGECLS catalogue; EFSA, 2022f).
ORSUBID	Subject ID	A pseudonymised subject ID number generated by EFSA upon receipt of the data
Weight	Body weight	Bodyweight of the subject (in kg)
ndays	Number of survey days	Number of days on which the participant's consumption was surveyed
day	Survey day	Ordinal number of the day on which the participant's consumption was surveyed
prodCode	RPC code	Code of the raw primary commodity as defined by EFSA's harmonised terminology for scientific research (MATRIX catalogue; EFSA, 2022f).
prodName	RPC name	Name of the raw primary commodity as defined by EFSA's harmonised terminology for scientific research (MATRIX catalogue; EFSA, 2022f).
FoodEx2_Facets	Processing code	FoodEx2 facet code describing the processing technique, including additional descriptors such as qualitative information, part consumed or the nature of the food (EFSA, 2015b).
RPCD_amount	RPCD amount	Amount of raw primary commodity derivative (in grams)
RPC_amount	RPC amount	Amount of raw primary commodity (in grams)

C.1.2.   Secondary input data

C.1.2.1.   Maximum residue level

Certain assumptions on the extrapolation of occurrence data (see Section C.1.1.4) require information on the maximum residue levels (MRLs). An MRL is the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with Regulation (EC) No 396/2005. This regulation also defines a procedure for the setting and modification of MRLs. MRLs may therefore have been modified throughout the 2019–2021 reference period. In order to obtain a single list of MRLs, EFSA decided to use the MRLs as of 31 December 2021 (i.e. the end of the current reference period). Hence it was assumed that those MRLs were applicable during the entire reference period, regardless of whether the MRL or residue definition may have changed during that period.

MRLs for the relevant food commodities (see Section C.1.1.1) and enforcement residue definitions (see Section C.1.1.3) were extracted from the EU Pesticides Database and organised in a data format that can be used directly for exposure assessment.

C.1.2.2.   Authorised uses

In some cases, the imputations and simulations performed on the occurrence data rely on the authorisations for use of the active substance(s) (see Section C.1.1.4). While the approval status of an active substance under Regulation (EC) No 1107/2009 is regulated at EU level, the authorisations for plant protections products (PPP, i.e. formulated products containing the active substances) are delivered at national level within the EU Member States. A centralised database compiling these national authorisations is not yet available at EU level.

National authorisations can be reported to EFSA under Regulation (EC) No 396/2005, either for an MRL application under Article 10, or for an MRL review under Article 12. There is, however, no legal obligation to systematically report all national authorisations and the MRL review program is still in

progress. A comprehensive overview of all pesticides authorisations within the EU is therefore also not available to EFSA. Meanwhile, a tentative list of authorised uses was elaborated according to the following principles.

- When the MRL for a given combination of active substance and RPC was not set at the LOQ (see Section C.1.2.1), the active substance was assumed to be authorised for use on that specific commodity. This assumption also accounts for uses authorised outside the EU and for which treated products may be placed on the EU market. Furthermore, this assumption concerns non-approved substances, including persistent organic pollutants, which are assumed to be authorised on crops for which MRLs are above the LOQ.

- When non-LOQ MRLs referred to unspecific residue definitions (i.e. including or applying to multiple active substances, see also Section C.1.1.3), only the substances approved under Regulation 1107/2009 were assumed to be authorised for use on that crop. If none of the active substances was approved, it was assumed that any substance may be authorised for use outside the EU.

- When non-LOQ MRLs refer to an active substance that is phased out under Regulation 1107/2009 (e.g. carbendazim) but may still occur as a metabolite from another active substance (thiophanate-methyl), the MRL was not considered to represent an authorised use of the active substance that was phased out.

- For the group of dithiocarbamates, which comprises six substances, Regulation (EC) No 396/2005 provides specific information on the active substances that were considered for deriving the MRLs. Authorised uses for these active substances were identified accordingly.

- When the MRL was set at LOQ and a review under Article 12 of Regulation (EC) No 396/2005 had not been issued, it was assumed that the use was not authorised.

- For the remaining combinations of active substance and RPC (i.e. where the MRL was set at LOQ), EFSA screened the relevant reasoned opinions issued under Article 12 of Regulation (EC) No 396/2005 and the subsequent reasoned opinions issued under Article 10. Any authorised use reported in those reasoned opinions was recorded. The combinations that have been considered authorised are listed in the Table C.

Table C.4: Authorised use

paramCode_AS	paramName_AS	prodCode	prodName	adoptionDate	Reference[1]
RF-00000011-VET	Abamectin	P0151010A	Table grapes	2014-09-02	https://doi.org/10.2903/j.efsa.2014.3823
RF-00000011-VET	Abamectin	P0151020A	Wine grapes	2014-09-02	https://doi.org/10.2903/j.efsa.2014.3823
RF-00000011-VET	Abamectin	P0220020A	Onions	2014-09-02	https://doi.org/10.2903/j.efsa.2014.3823
RF-00000011-VET	Abamectin	P0233010A	Melons	2014-09-02	https://doi.org/10.2903/j.efsa.2014.3823
RF-00000011-VET	Abamectin	P0260040A	Peas (without pods)	2014-09-02	https://doi.org/10.2903/j.efsa.2014.3823
RF-00000011-VET	Abamectin	P0270060A	Leek	2014-09-02	https://doi.org/10.2903/j.efsa.2014.3823
RF-0014-001-PPP	Acetamiprid	P0211000A	Potatoes	2011-07-18	https://doi.org/10.2903/j.efsa.2011.2328
RF-0018-001-PPP	Acrinathrin	P0130010A	Apples	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0130020A	Pears	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0140030A	Peaches	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0151010A	Table grapes	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0152000A	Strawberries	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203

paramCode_AS	paramName_AS	prodCode	prodName	adoptionDate	Reference[1]
RF-0018-001-PPP	Acrinathrin	P0163020A	Bananas	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0220020A	Onions	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0231010A	Tomatoes	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0231020A	Peppers	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0231030A	Aubergines (egg plants)	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0232010A	Cucumbers	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0232030A	Courgettes	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0233010A	Melons	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0251020A	Lettuce	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0018-001-PPP	Acrinathrin	P0260010A	Beans (with pods)	2015-07-14	https://doi.org/10.2903/j.efsa.2015.4203
RF-0112-004-PPP	Cypermethrin	P0402010A	Olives for oil production	2011-06-17	https://doi.org/10.2903/j.efsa.2011.2280
RF-0690-003-PPP	Esfenvalerate	P0211000A	Potatoes	2011-10-27	https://doi.org/10.2903/j.efsa.2011.2432
RF-0690-003-PPP	Esfenvalerate	P0260040A	Peas (without pods)	2011-10-27	https://doi.org/10.2903/j.efsa.2011.2432
RF-0690-003-PPP	Esfenvalerate	P0300010A	Beans (dry)	2011-10-27	https://doi.org/10.2903/j.efsa.2011.2432
RF-0160-001-PPP	Ethephon	P0130020A	Pears	2009-10-08	https://doi.org/10.2903/j.efsa.2009.1347
RF-00001688-PAR	Formetanate hydrochloride	P0140030A	Peaches	2012-08-17	https://doi.org/10.2903/j.efsa.2012.2866
RF-00001688-PAR	Formetanate hydrochloride	P0251020A	Lettuce	2012-08-17	https://doi.org/10.2903/j.efsa.2012.2866
RF-00001688-PAR	Formetanate hydrochloride	P0260010A	Beans (with pods)	2010-09-29	https://doi.org/10.2903/j.efsa.2010.1832
RF-00001688-PAR	Formetanate hydrochloride	P0270060A	Leek	2010-09-29	https://doi.org/10.2903/j.efsa.2010.1832
RF-0320-001-PPP	Oxamyl	P0211000A	Potatoes	2010-09-29	https://doi.org/10.2903/j.efsa.2010.1830
RF-0320-001-PPP	Oxamyl	P0213020A	Carrots	2010-09-29	https://doi.org/10.2903/j.efsa.2010.1830
RF-0320-001-PPP	Oxamyl	P0231010A	Tomatoes	2010-09-29	https://doi.org/10.2903/j.efsa.2010.1830
RF-0320-001-PPP	Oxamyl	P0231020A	Peppers	2010-09-29	https://doi.org/10.2903/j.efsa.2010.1830
RF-0338-002-PPP	Phosmet	P0211000A	Potatoes	2012-02-13	https://doi.org/10.2903/j.efsa.2012.2582
RF-0403-001-PPP	Tebuconazole	P0152000A	Strawberries	2011-08-22	https://doi.org/10.2903/j.efsa.2011.2339

(1): EFSA Journal reference to the relevant reasoned opinion (i.e. when the information was retrieved from an MRL review or application).

C.1.2.3. Processing factors

Occurrence data for pesticide residues are collected at the level of the RPC (see Section C.1.1.4). Food consumption data may be collected at the level of RPC, RPC derivative or composite food, but for the purpose of this assessment all consumption data for composite foods and RPC derivatives were converted into their equivalent quantities of RPCs (see Section C.1.1.5). Combining occurrence and consumption data at RPC level implies that all residues present in the RPC will reach the end consumer. This assumption, however, is conservative. In reality, residue concentrations will most likely change due to processing, such as peeling, washing, cooking etc.

The effect of processing is usually addressed by means of processing factors. A processing factor accounts for the change in residue concentrations and is specific to each RPC, processing type and active substance. Processing factors are quantified by dividing the residue concentration in the processed commodity by the residue concentration in the raw commodity.

The European database on processing factors is the most recent and the most comprehensive compilation of processing factors currently available at EU level (Zincke, 2022). Processing factors for the active substances and RPCs under assessment were extracted from the database according to the following criteria:

- For each active substance, RPC and processing technique only the median processing factor was extracted.
- Only the processing factors indicated as reliable, or indicative were extracted. Processing factors indicated as unreliable were excluded from the assessment.

Processing techniques reported in the processing factor database were then compared to the processing techniques reported in the RPC consumption dataset. The processing techniques from both databases were matched according to the following principles:

- When a generic processing technique was reported in the RPC consumption database (e.g. juice) while more specific processing techniques were reported in the processing factor database (e.g. pasteurised juice and unpasteurised juice), the specific processing technique with the highest processing factor was selected.
- When a specific processing technique was reported in the RPC consumption database (e.g. mashed potato) while a more generic processing technique was reported in the processing factor database (e.g. boiled potato), the generic processing factor was applied to the specific processing techniques.
- Processing factors were extrapolated between raw primary commodities with similar properties (i.e. oranges and mandarins, apples and pears, table and wine grapes, wheat and rye grain).
- Processing factors for peeling were applied to the corresponding fruit with inedible peel, even when the processing technique was not specified in the RPC consumption database (i.e. oranges, mandarins, bananas and melons).

Although the European database on processing factors is the most comprehensive compilation of processing factors currently available at EU level, this compilation is limited to all processing factors that have been evaluated by EFSA until 31 December 2021. Meanwhile, additional processing factors have been assessed by EFSA in the framework of Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009. Additional processing factors evaluated by EFSA until August 2023 will be integrated in future updates of the European PF database. The list of PFs is available in the Appendix D – Annex III – Table 3.6.

C.1.2.4. Variability factors

The occurrence data used for the assessment are related to the average concentrations in composite laboratory samples (see Section C.1.1.4). Consumers on the other hand are exposed to individual units of the commodity. Residue concentrations may vary among the individual units, referred to as unit-to-unit variability.

Acute exposure assessments for pesticide residues should account for variability among the single commodity units of the composite laboratory samples. To account for this variability, several parameters are required for each food commodity.

- Unit weight: estimated weight for a single commodity unit.
- Units per sample: estimated number of units within a composite laboratory sample.

- Variability factor (VF): expected variability among the single unit concentrations, which is defined as the ratio between the 97.5th percentile and mean of the distribution of unit concentrations.

Unit weights for each commodity were retrieved from the Pesticide Residues Intake Model (EFSA, 2018b). Residue concentrations may vary among the individual units, referred to as unit-to-unit variability. For RPCs that have a unit weight inferior to 25 g and for processed foods that were subject to blending or bulking, the unit-to-unit variability is not considered relevant since the residue concentration in the composite laboratory sample is expected to reflect the residue concentration in the portion that would be consumed (FAO, 2003).

The number of units per sample was obtained from Commission Directive 2002/63/EEC, establishing community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin. This directive defines a minimum weight and a minimum number of units for composite laboratory samples of each food category. Hence, the minimum number of units (as defined by Directive 2002/63/EEC) was used, unless the minimum sample weight divided by the corresponding unit weight was higher. In that case, the latter calculated value (rounded up to the next integer) was retained.

VFs were also retrieved from the Pesticide Residues Intake Model (EFSA, 2018b).

While a fixed VF is usually applied for acute deterministic calculations, for probabilistic exposure assessment the use of a distribution of unit concentrations is considered more adequate than using a fixed VF. Therefore, unit-to-unit variability is modelled using a beta distribution, which can be bounded between 0 and an upper limit. Indeed, if the average concentration in a composite sample is 1, the concentration in a single unit can never be higher than the number of units within the composite sample (assuming all other units have a concentration of zero). Hence, for each RPC with a unit weight exceeding 25 g, the beta distribution was parametrised with the following restrictions.

- Lower bound $= 0$
- Mean $= 1$
- 97.5th percentile $=$ VF
- Upper bound $=$ number of units per sample

Stochastic VFs can then be drawn from the beta distribution and multiplied with the composite sample concentration to obtain a plausible estimate of the unit concentration. When the portion consumed by an individual is smaller than a single unit, the stochastic VF is directly applicable to the consumed portion. When the consumed portion is composed of multiple units however, multiple stochastic VFs will be drawn from the same beta distribution to estimate concentration in the whole portion consumed. Therefore, the concentration in the whole portion is estimated by multiplying the sample concentration with a weighted VF, which is calculated as follows.

$$WVF = SVF_n \text{ if } n = 1$$

$$WVF = \frac{\left(\sum_{i=1}^{n-1} SVF_i\right) + SVF_n \cdot (n_0 - n + 1)}{n_0} \text{ if } n > 1$$

WVF   is the weighted VF
SVF_i is the stochastic VF drawn for unit i;
n_0 is the estimated number of units within the consumed portion (unrounded), assuming the unit weights reported in Section C.1.2.4;
n   is the number of stochastic VFs to be drawn (i.e. ceiling of n_0).

In Table C.5, are shown the stochastic VFs parameters for each RPCs selected for the probabilistic risk assessment. If the information is missing, it means that the unit-to-unit variability is not relevant.

Table C.5: Variability factor parameters

prodCode[1]	prodName[2]	Cat_2002_63_EC[3]	Samp Weight[4]	min Units[5]	Unit Weight[6]	NrUnits[7]	VF[8]	α[9]	β[10]
P0110010A	Grapefruits	Large, 250 g or more	2,000	5	270.5	8	5	0.341154	2.388078
P0110020A	Oranges	Medium, 25 to 250 g	1,000	10	160	10	7	0.158731	1.428581
P0110050A	Mandarins	Medium, 25 to 250 g	1,000	10	100	10	7	0.158731	1.428581
P0130010A	Apples	Medium, 25 to 250 g	1,000	10	112	10	7	0.158731	1.428581
P0130020A	Pears	Medium, 25 to 250 g	1,000	10	206.5	10	7	0.158731	1.428581
P0140030A	Peaches	Medium, 25 to 250 g	1,000	10	127.6	10	7	0.158404	1.425633
P0151010A	Table grapes	Large, 250 g or more	2,000	5	581.55	6	5	0.248312	1.241558
P0151020A	Wine grapes								
P0152000A	Strawberries								
P0162010A	Kiwi fruits	Medium, 25 to 250 g	1,000	10	83	13	7	0.184385	2.21262
P0163020A	Bananas	Medium, 25 to 250 g	1,000	10	100	10	7	0.158731	1.428581
P0211000A	Potatoes	Medium, 25 to 250 g	1,000	10	216	10	7	0.158731	1.428581
P0213020A	Carrots	Medium, 25 to 250 g	1,000	10	80	13	7	0.184385	2.21262
P0220020A	Onions	Medium, 25 to 250 g	1,000	10	105.8	10	7	0.158731	1.428581
P0231010A	Tomatoes	Medium, 25 to 250 g	1,000	10	142.5	10	7	0.158731	1.428581
P0231020A	Peppers	Medium, 25 to 250 g	1,000	10	154.9	10	7	0.158731	1.428581
P0231030A	Aubergines (egg plants)	Large, 250 g or more	2,000	5	271	8	5	0.341154	2.388078
P0232010A	Cucumbers	Large, 250 g or more	2,000	5	411.4	6	5	0.248312	1.241558
P0232030A	Courgettes	Medium, 25 to 250 g	1,000	10	114	10	7	0.158731	1.428581
P0233010A	Melons	Large, 250 g or more	2,000	5	540	6	5	0.248312	1.241558
P0241010A	Broccoli	Medium, 25 to 250 g	1,000	10	186	10	7	0.158731	1.428581
P0241020A	Cauliflower	Large, 250 g or more	2,000	5	689.9	6	5	0.248312	1.241558
P0242020A	Head cabbage	Large, 250 g or more	2,000	5	1281.9	6	5	0.248312	1.241558
P0251020A	Lettuce	Large, 250 g or more	2,000	5	534.7	6	5	0.248312	1.241558
P0252010A	Spinach								
P0260010A	Beans (with pods)								
P0260040A	Peas (without pods)								

prodCode[1]	prodName[2]	Cat_2002_63 _EC[3]	Samp Weight[4]	min Units[5]	Unit Weight[6]	NrUnits[7]	VF[8]	α[9]	β[10]
P0270060A	Leek	Medium, 25 to 250 g	1,000	10	168.8	10	7	0.158731	1.428581
P0280010A	Cultivated funghi	Medium, 25 to 250 g	1,000	10	25	40	7	0.227164	8.859387
P0300010A	Beans (dry)								
P0402010A	Olives for oil production								
P0500010A	Barley								
P0500050A	Oats								
P0500060A	Rice								
P0500070A	Rye								
P0500090A	Wheat								
PX100001A	Baby foods other than processed cereal-based foods								
PX100003A	Processed cereal-based foods for infants and young children								
PX100004A	Infant formulae								
PX100005A	Follow-on formulae								

(1): Code of the RPC as defined by EFSA's harmonised terminology for scientific research (MATRIX catalogue; EFSA, 2022f).
(2): Name of the RPC as defined by EFSA's harmonised terminology for scientific research (MATRIX catalogue; EFSA, 2022f).
(3): Commodity classification defined by Table 4 of the Annex to Commission Directive 2002/63/EC.
(4): Minimum size of each laboratory sample (expressed in g) defined by Table 4 of the Annex to Commission Directive 2002/63/EC.
(5): Minimum size of each laboratory sample (expressed in number of units) defined by Table 4 of the Annex to Commission Directive 2002/63/EC.
(6): Estimated weight (expressed in g) for a single commodity unit as reported in the Pesticide Residues Intake Model (EFSA, 2018b).
(7): Estimated number of units required to obtain the minimum size of a laboratory sample, both in terms of weight and number of units.
(8): Default VF as reported in the Pesticide Residues Intake Model (EFSA, 2018b). This factor represents the variability among the single unit concentrations, which is defined as the ratio between the 97.5th percentile and mean of the distribution of unit concentrations.
(9): Computed α parameter of the beta distribution.
(10): Computed β parameter of the beta distribution.

C.1.2.5. Processing types

Variability among the single commodity units of the composite laboratory samples is not relevant when the food consumed is subject to processing techniques that involve bulking and blending.

EFSA therefore extracted all processing techniques reported in the RPC consumption data (see Section C.1.1.5) and identified the processes that normally involve blending or bulking. Typically, these are processing techniques performed at industrial level (e.g. milling, oil production, etc.). Household processes, however, were assumed not to involve any bulking or blending (e.g. boiling, stewing, etc.). Although juicing may also be carried out at household level, EFSA assumed that most fruit juices are produced at industrial level.

C.1.2.6. Health Based Guidance Values

The ARfDs and ADIs established by EFSA under regulations (EC) No 1107/2009 were selected. The same assumptions taken for the deterministic assessment on tentative ADIs and ARfDs were done, see Sections 5.1 and 5.3 for details. The list of HBGVs is available in the Appendix D – Annex III – Table 3.5.

Appendix D – Supporting Information

Annex I – The data visualisation (EU MACP and MANCP) of 2021 ARPR: https://multimedia.efsa.europa.eu/pesticides-report-2021/

Annex II – The PRIMo exposure model on the 2021 EU annual report on pesticide residue results (ARPR): https://doi.org/10.5281/zenodo.7767236

Annex III – Input and output data of the 2021 EU pesticide residues report on food: https://doi.org/10.5281/zenodo.7767236

Table 3.1: The 2021 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

New annexes related to probabilistic assessment:

Annex IV – Acute individual Exposure Assessment, Primary of 2021 ARPR: https://doi.org/10.5281/zenodo.7767236

Figure 4.1: Histogram presenting the distribution of the hazard quotient per active substance and survey

Figure 4.2: Box plot presenting the 95% confidence intervals of the hazard quotient at different percentiles per active substance and survey

Figure 4.3: Pie chart presenting the average contributions of RPCs to the exposures exceeding the 99th percentile

Table 4.4: Estimated 95% confidence intervals of the hazard quotient at different percentiles per active substance and survey

Table 4.5: Distribution of the hazard quotient calculated per active substance, survey and bootstrap

Table 4.6: Average contributions of RPCs to the exposures exceeding the 99th percentile per active substance and survey

Table 4.7: Detailed records for subjects with exposures closer to the 99th percentile

Table 4.8: Overview of RPCs and active substances with limited occurrence data

Annex V – Acute individual Exposure Assessment, Tentative of 2021 ARPR: https://doi.org/10.5281/zenodo.7767236

Figure 5.1: Histogram presenting the distribution of the hazard quotient per active substance and survey

Figure 5.2: Box plot presenting the 95% confidence intervals of the hazard quotient at different percentiles per active substance and survey

Figure 5.3: Pie chart presenting the average contributions of RPCs to the exposures exceeding the 99th percentile

Table 5.4: Estimated 95% confidence intervals of the hazard quotient at different percentiles per active substance and survey

Table 5.5: Distribution of the hazard quotient calculated per active substance, survey and bootstrap

Table 5.6: Average contributions of RPCs to the exposures exceeding the 99th percentile per active substance and survey

Table 5.7: Detailed records for subjects with exposures closer to the 99th percentile

Table 5.8: Overview of RPCs and active substances with limited occurrence data

Annex VI – Chronic individual Exposure Assessment, Primary of 2021 ARPR: https://doi.org/10.5281/zenodo.7767236

Figure 6.1: Histogram presenting the distribution of the hazard quotient per active substance and survey

Appendix E – Outcome of the Member States consultation

Appendix E is available under the Supporting Information section on the online version of the scientific output.