



Vitenskapskomiteen for mattrygghet Norwegian Scientific Committee for Food Safety

Comparison of organic and conventional food and food production

Part V: Human health – pesticide residues

Opinion of the Panel on Plant Protection Products and the Steering Committee of the Norwegian Scientific Committee for Food Safety

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Summary

The present report is based on data from the 2010 EFSA Report on pesticide residues in food, the Norwegian monitoring programmes 2007-2012 and data from peer reviewed literature and governmental agencies. It is a challenge to perform quantitative estimates and comparative studies of residue levels due to large variation in the measured levels, and the large number of different pesticides present in the samples. Thus, the focus is on the frequency of observed contaminations in relation to regulatory limits and to present examples to illustrate the variation in residue values and number of detected substances.

Pesticide residues in conventional and organic products

Of the 12,168 samples (plant- and animal products) in the 2010 EU-coordinated programme, 1.6% exceeded the respective maximum residue level (MRL) values, and 47.7% had measurable residues above the limit of quantification (LOQ), but below or at the MRL. Of the 1168 samples analysed in Norway in 2012 (from both imported and domestic products), 1.9% exceeded MRL and 53% contained measurable pesticide residues. Direct comparison of these values is however not possible, since they contain different types of food samples, and are analysed for a different number of pesticides.

When organic and conventional samples from fruit, vegetables and other plant products in the 2010 EU-coordinated programme were compared, 4.2% of the conventional and 1.0% of the organic samples exceeded the MRL values, while 43.2% of the conventional and 10.8% of the organic samples had measurable residues below or at the MRL value. Most of the pesticide residues detected in organic samples are not permitted for use in organic farming.

Of the 624 organic samples analysed in Norway 2007 - 2012, 0.2% (one sample) had residues exceeding MRL, while measurable residues were detected in 1.8% of the samples (11 samples).

Conventional products were often found to contain different pesticides while most organic samples were found to contain few or only one type of pesticide.

Lack of data on pesticide residue levels of organic samples in the EU-coordinated programme, and few Norwegian samples do not allow for a quantitative comparison of pesticide residue levels in organic and conventional samples. Comparative estimation of pesticide residues faces a number of challenges and uncertainties. However, it seems unquestionable based on available data that organic plant products contain fewer and substantially lower amounts of pesticide residues than conventional products.

Health risk associated with pesticide residues

The general level of pesticide residues in both conventional and organic food is low, and well below what is likely to result in adverse health effects. This conclusion is based on the comparison of estimated dietary exposure with toxicological reference values i.e. acceptable daily intake (ADI) for chronic effects, and acute reference dose (ARfD) for acute effects. The finding of pesticide residues that exceeds established regulatory limits in a minority of tested samples is not considered to represent a health risk.

When dietary exposure that was estimated in six different food commodities in the 2010 EUcoordinated programme was compared with their relevant reference values, EFSA concluded that for 79 of 18243 conventionally grown fruit and vegetable samples, a short-term acute consumer health risk could not be excluded. The conclusion was based on the exceeding of ARfD. None of these 79 samples were organic. It is important to also consider that the exceeding of the acute reference value only occurred in 0.4% of the samples and that the scenario used for acute intake assessment is conservative, suggesting that the toxicological implications are limited. This is also reflected in the chronic exposure assessment, where none of the samples were found to exceed the toxicological reference value ADI.

Dietary exposure assessments on the basis of Norwegian samples of apples, tomatoes, carrots, strawberries and lettuce did not show an exceeding of any toxicological reference value.

Combined exposure and cumulative risk assessment of pesticide residues

No generally accepted methodology is at present established for cumulative risk assessment of combined exposure to pesticide residues. Available data suggest however that combined exposure is not likely to result in increased human health risk.

Norsk sammendrag

Denne rapporten er basert på data fra EFSA-rapport (2013) som inneholder analyser av rester av plantevernmidler i næringsmidler fra 2010, de norske overvåkingsprogrammene fra 2007-2012 og andre rapporterte data. Det er en stor utfordring å gjøre kvantitative sammenlikninger av rester av plantevernmidler på grunn av store nivåvariasjoner i målt restmengde samt et bredt spekter av forskjellige plantevernmidler. Fokus har derfor vært på hvor ofte plantevernmiddelrester påvises i produktene, og hvor ofte funnene overskrider etablerte grenseverdier.

Plantevernmiddelrester i konvensjonelle og økologiske produkter

Av 12 168 prøver (plante- og animalske produkter) i det EU-koordinerte overvåkningsprogrammet overskred 1,6 % grenseverdiene for plantevernmiddelrester (MRL), og 47,7 % hadde målbare nivåer over grensen for mulig kvantifisering (LOQ), men lavere enn MRL. Av 1168 prøver som ble analysert i Norge i 2012 (både importerte og norske varer) var 1,9 % over MRL og 53 % med målbare plantevernmiddelrester. Disse verdiene kan ikke sammenlignes direkte, siden programmene inneholder prøver fra forskjellige typer matvarer, samt at de er analysert for et ulikt antall plantevernmidler.

Sammenligning av økologiske og konvensjonelle prøver fra frukt, grønnsaker og andre planteprodukter i EFSA-rapporten viste at 4,2 % av de konvensjonelle og 1,0 % av de økologiske prøvene oversteg MRL, mens 43,2 % av de konvensjonelle og 10,8 % av de økologiske prøvene hadde målbare plantevernmiddelrester under eller lik MRL. De fleste plantevernmiddelrester som ble funnet i de økologiske prøvene er ikke tillatt brukt i økologisk landbruk.

Av 624 økologiske prøver analysert i Norge 2007-2012, hadde 0,2 % (én prøve) plantevernmiddelrester som oversteg MRL, mens målbare rester ble påvist i 1,8 % (11 prøver).

Konvensjonelle produkter ble ofte funnet å inneholde flere forskjellige plantevernmidler, mens de fleste økologiske prøver inneholdt få eller kun én type stoff.

Mangel på informasjon om målingene av plantevernmiddelrester i økologiske prøver fra EUprogrammet, og få norske målinger tillater ikke en sikker kvantitativ sammenligning av restmengder i økologiske og konvensjonelle prøver. Imidlertid synes det klart basert på tilgjengelige data at økologiske produkter generelt inneholder færre og vesentlig lavere mengder av plantevernmiddelrester enn konvensjonelle produkter.

Helserisiko ved eksponering for plantevernmiddelrester

De generelle nivåene av plantevernmiddelrester i både konvensjonell og økologisk mat er svært lave, og godt under det som er sannsynlig å ville medføre en økt helserisiko. Denne konklusjonen er basert på sammenligning av beregnet eksponering gjennom kosten med toksikologiske referanseverdier som akseptabelt daglig inntak (ADI) for kroniske effekter, og akutt referansedose (ARfD) for akutte effekter. Funn av rester av plantevernmidler som overskrider toksikologiske referanseverdier i et lite antall undersøkte prøver anses som lite sannsynlig å representere en økt helserisiko. EFSA konkluderte i sin rapport med at en kortsiktig akutt effekt ikke kunne utelukkes for 79 av 18243 konvensjonelt dyrkede frukt- og grønnsaksprøver. Denne konklusjonen var basert på overskridelser av ARfD. Ingen av disse 79 prøvene var økologiske. Det er viktig å ta i betraktning at overskridelser av den akutte referanseverdien bare forekom for 0,4 % av prøvene, og at det ved beregning av akutt inntak er lagt inn betydelige sikkerhetsmarginer, noe som tilsier at sannsynligheten for helseeffekter er svært liten. Dette gjenspeiles også av den kroniske eksponeringsberegningen, der ingen av prøvene ble funnet å overstige ADI.

Eksponerings-beregninger på grunnlag av norske prøver av epler, tomater, gulrøtter, jordbær og salat viste ingen overskridelser av toksikologiske referanseverdier.

Risikovurdering av eksponering for flere typer plantevernmiddelrester

Ingen allment akseptert metodikk er i dag etablert for kumulativ risikovurdering av kombinert eksponering for plantevernmiddelrester. Tilgjengelige data tyder imidlertid på at slik kombinert eksponering ikke vil medføre økt helserisiko.

Keywords

Pesticide residues, organic food, conventional food, health risk, combined and cumulative effects

Abbreviations

ADI; Acceptable Daily Intake ANSES; The French Agency for Food, Environmental and Occupational Health and Safety **ARfD:** Acute Reference Dose CAG; Common Assessment Group CI; Confidence Interval CRA; Cumulative Risk Assessment Debio; Norwegian certifier of organic products EFSA; European Food Safety Authority EU; European Union GAP; Good Agricultural Practice GMO; Genetically Modified Organism HI: Hazard Index LOQ; Limit of Quantification Mattilsynet; Norwegian Food Safety Authority MLR; Ministry of Rural Affairs in Baden-Württemberg, Germany MRL; Maximum Residue Level NIEHS; National Institute of Environmental Health Sciences, USA OCP; Organo-chlorine pesticide RASFF; Rapid Alert System for Food and Feed US EPA; US Environmental Protection Agency VKM; Norwegian Scientific Committee for Food Safety

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Background

The goal of the Norwegian government is that 15% of the agricultural production is organic in 2020 (St. Meld. 9, 2011-2012). However, knowledge on the impact of an increase in organic production in Norway is limited. If and how organic production practices may affect human health, animal health and welfare, plant health, the environment and sustainability is not clear.

In order to be able to give scientifically based information and advice on this issue to consumers and other target groups, the Norwegian Food Safety Authority (NFSA) requested a scientific evaluation of current research and other data on organic food and food production from The Norwegian Scientific Committee for Food (VKM). The scientific evaluation and the knowledge will also be used in connection with the NFSA's regulatory and international work on organic food production. The NFSA first prepared a draft request that was put out for public consultation. Remarks from the bodies that commented on the proposal clearly stated that there are limitations in the basic data for such an evaluation. NFSA therefore limited the scope and focus of the request somewhat. Sustainability aspects and environmental impact of organic and conventional agricultural practices are not addressed. In addition, organic aquaculture, which has only been practiced for a few years, is excluded from the request.

All foodstuffs on the market shall be safe and wholesome. Whereas all food produced and marketed shall comply with relevant legislation, food marketed as organic must in addition comply with regulations specific for organic production.

Organic food production is defined in Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products as "The use of the production method compliant with the rules established in this Regulation, at all stages of production, preparation and distribution". The regulation on organic food production is part of the EEA Agreement and covers inputs, crop production, livestock production, rules for processing, labeling, and inspection, and provides provisions for imports from third countries.

According to Council Regulation (EC) No 834/2007, organic production shall be based on the following principles (article 4):

(a) the appropriate design and management of biological processes based on ecological systems using natural resources which are internal to the system by methods that:

- i) use living organisms and mechanical production methods;
- ii) practice land-related crop cultivation and livestock production or practice aquaculture which complies with the principle of sustainable exploitation of fisheries;
- iii) exclude the use of GMOs and products produced from or by GMOs with the exception of veterinary medicinal products;
- iv) are based on risk assessment, and the use of precautionary and preventive measures, when appropriate;

(b) the restriction of the use of external inputs. Where external inputs are required or the appropriate management practices and methods referred to in paragraph (a) do not exist, these shall be limited to:

- i) inputs from organic production;
- ii) natural or naturally-derived substances;
- iii) low solubility mineral fertilisers;

(c) the strict limitation of the use of chemically synthesised inputs to exceptional cases these being:

- i) where the appropriate management practices do not exist; and
- ii) the external inputs referred to in paragraph (b) are not available on the market; or
- iii) where the use of external inputs referred to in paragraph (b) contributes to unacceptable environmental impacts;

(d) the adaptation, where necessary, and within the framework of this Regulation, of the rules of organic production taking account of sanitary status, regional differences in climate and local conditions, stages of development and specific husbandry practices.

Terms of reference

The Norwegian Food Safety Authority (NFSA) requests the Norwegian Scientific Committee for Food Safety (VKM) to evaluate current scientific knowledge on organic production and organically produced food based on existing national and international research results and other documentation. The NFSA wants the evaluation to focus primarily on Norwegian production.

NFSA has found it appropriate to divide this comprehensive evaluation of organic production and organic food into five parts:

- 1. Plant health plant production
- 2. Animal health animal welfare and feed
- 3. Human health nutrition and contaminants
- 4. Human health hygiene and pathogens
- 5. Human health pesticide residues

NFSA would like VKM to compare the effects of organic versus conventional production based on the evaluations that are done in the five areas above. If lack of data prevents such a comparison, this fact should also be reported.

Part V. Human health - pesticide residues

NFSA requests VKM to identify and/or assess:

- the difference in levels and intake of pesticide residues from organic versus conventional products, and the influence on human health.
 For the evaluation, Norwegian monitoring data (Bioforsk/Mattilsynet) and data from Europe (EFSA) should be used.
- consequences of combination effects of multiple pesticide residues on human health.

1 Introduction

The Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) has at the request of the Norwegian Food Safety Authority (Mattilsynet, NFSA) compared organic and conventional food and food production in relation to possible impact on plant health, animal health and welfare and human health. The assessment is based on published peer reviewed scientific literature and assessment reports by international and national scientific bodies.

The following aspects of organic food production were not addressed in the assessment as they were not part of the request; sustainability aspects and environmental impacts of organic and conventional agricultural practices, and furthermore: aquaculture, because organic aquaculture has only been practiced for a few years.

At the request of the Norwegian Food Safety Authority the assessment was divided into five parts addressing:

- I) Plant health and plant production (assessed by Panel on Plant Health)
- II) Animal health and animal welfare (assesses by Panel on Animal Health and Welfare)
- III) Humane health nutrition and contaminants (Panel on Nutrition, Dietetic Products, Novel Food and Allergy)
- IV) Human health hygiene and pathogens (assessed by Panel on Biological Hazards)
- V) Pesticide residues (assessed by Panel on Plant Protection Products)

The present report focuses solely on pesticide residues. VKM appointed a working group consisting of VKM members and external experts to prepare a draft opinion. The opinion was approved by VKMs Panel on Plant Protection Products. The Scientific Steering Committee of VKM approved the final opinion, i.e. this document.

Pesticides - Use and toxicity

Conventional agriculture uses a large number of synthetic chemicals that have been shown to leave residues in the farmed products. Presently, there is close to 1000 different pesticides from more than 100 different chemical classes on the market worldwide. In Norway the number of authorized pesticides is about 110 (different active compounds). In the European Union (EU), a review of existing pesticides has led to the removal from the market of pesticides that cannot be used safely. About 250 active substances have passed the harmonised EU safety assessment (EU, 2009b).

Pesticides have been defined as any substance or mixture of substances deliberately added to the environment and intended for preventing, destroying, repelling or mitigating pests (Casarett et al., 2003). Pests can be insects, fungi, mould, weeds, rodents or other unwanted organisms. These organisms often lead to extensive damage on the products, which give lower quality and loss of food crops. Thus, pesticides occupy a rather unique position among the many chemicals that we encounter daily as they are added for the purpose of killing and injuring some form of life. Ideally, their deleterious action would be highly specific for undesirable targets. In fact most pesticides are not very selective, but are generally toxic to many non-target species, including humans. Therefore, the use of pesticides must minimize the possibility of exposure of non-target organisms to injurious quantities of these chemicals. Considerations around the use of pesticides must balance the benefits versus the possible risks of injury to human health or degradation of environmental quality. In the past 20 years, the

amount (weight) of pesticides used has levelled off, due to more efficacious compounds, more integrated pest management approaches and also organic farming.

Several types of pesticides will obviously have the potential of causing adverse health effects. The three major classes of pesticides according to target organism are insecticides, herbicides and fungicides. Furthermore, within each class, several subclasses exist, with substantially different chemical and toxicological characteristics. For example among insecticides, one can find organophosphate compounds, carbamates, organochlorines, pyrethroids and many other chemicals. Most of the chemical insecticides in use today act by affecting the central nervous system of the insects (IRAC, 2012).

Furthermore, as a class, insecticides have high toxicity for humans, compared to other pesticides. However, highly toxic compounds will not induce health effects in non-target organisms including humans if the exposure is below a threshold to induce adverse effects. Thus, risk of toxic effects of pesticides is both dependent on the toxic property of the compound and on level and route of exposure. Safe exposure levels with negligible risk of adverse effects in humans of pesticides (so-called health based guidance values) are normally determined by extrapolating the effects of fairly high pesticide doses observed in biological test systems. Such extrapolation is a challenge in health risk assessment. To assess possible risk of adverse effects of pesticide residues in food products, exposure levels have to be compared with pesticide doses causing adverse effects in biological test systems.

Pesticides may pose a threat via occupational exposure or from the consumption of residues from treated agricultural products. In this report the focus is on dietary residues, possible health risk from occupational exposure will not be included. Food is the most important source for chronic exposure of pesticides to the general population in Norway. Analysis of the presence of pesticide residues in food is performed in most countries worldwide.

Definitions of limit of quantification, maximum residue levels and toxicological reference values

Monitoring of pesticide residues in food is necessary to ensure food safety. The levels of pesticide residues in food are reported in mg/kg and related to the Limit of Quantification (LOQ) and Maximum Residue Level (MRL). LOQ is defined as the lowest concentration or mass of the analyte that has been validated with acceptable accuracy by applying the complete analytical method (SANCO, 2013). Furthermore, MRL is defined as the upper allowed level of a pesticide residue (expressed in mg/kg) for a specific type of food or feed in accordance with Regulation (EC) No 396/2005 (EU, 2005), based on authorized Good Agricultural Practice (GAP) and the lowest possible exposure to protect vulnerable consumers. Food and feed of plant or animal origin with pesticide residues above the MRL shall not be placed on the market. MRLs are not primarily toxicological safety limits, but reflect the use of minimum quantities of pesticides to achieve effective plant protection, applied in such a manner that the amount of residue is the smallest practicable and are set at levels which are safe for consumers. A default MRL of 0.01 mg/kg is applied where no specific MRL is set, and used until a specific MRL is determined.

Generally, the MRLs are well below the concentrations that are expected to lead to adverse health effects for consumers. If a pesticide residue in a given crop is found at or below the MRL, the crop can be considered safe for the consumer. On the other hand, if a residue exceeds the MRL, it is not necessarily true that the consumer is at risk: a specific assessment has to be performed, comparing the expected exposure with the toxicological reference values (ADI, ARfD). If the exposure exceeds the toxicological reference values, a potential consumer health risk is identified.

The Acceptable Daily Intake (ADI) is the estimated amount of a substance in food, usually expressed in mg/kg bodyweight that can be ingested daily over a lifetime without appreciable chronic or long-term risk to the consumer. The ADI is set on the basis of all known facts at the time of evaluation, taking into account sensitive groups within the population (e.g. children). Acute Reference Dose (ARfD) is the estimated amount of substance in food, usually expressed in mg/kg body weight, which can be ingested over a short period of time, usually during one day, without appreciable risk to the consumer. The ARfD is set on the basis of the data produced by appropriate toxicological studies, taking into account the sensitive groups within the population. An ARfD is set only for active substances that have potential of acute toxicity.

Exposure to multiple pesticides

Although the MRLs, ADI and ARfD are established for each pesticide, a product may have more than one pesticide residue and the total diet will contain residues of several pesticides. The exposure to low levels of several pesticides in one food item or from different food items will be described. Furthermore, the challenge in health risk assessment of combined exposure will be discussed in the report.

National and international regulation of pesticides

Regulation exists to ensure that pesticide residues are maintained at levels below those that would cause any adverse human health effects. EU has created a harmonized Union-wide framework for the use of pesticides (EU, 2009a). According to Regulation (EC) No 396/2005 (EU, 2005), EU member states and the two EFTA countries (Iceland and Norway) have to carry out control programmes on pesticide residues in food commodities and to report the results to the European Food Safety Authority (EFSA). In each European reporting country, two control programmes are in effect; a national control programme (designed individually by each country) and a European coordinated multiannual control programme, which gives clear guidance on which specific control activities that have to be performed by the Member States.

The national control programmes in all European countries include both surveillance and enforcement samples. The majority of the samples are classified as surveillance samples. Enforcement samples are collected when there are suspicions about the safety of a product and/or as a follow-up of previous violations. In addition, boarder controls are carried out according to Commission Regulation (EC) No 669/2009 (with later amendments) for specific commodities from third countries. Enforcement and border control samples are not included in the present report.

The Norwegian Food Safety Authority is responsible for the monitoring of pesticide residues in food in Norway ("Plantevernmiddelrestforskriften") (Lovdata, 2009). The programme is organized as a nationwide analysis of samples from both domestic and imported food products where the collection of samples reflects both the pattern of consumption (surveillance), and attention towards products experienced to contain pesticide residues (enforcement). The finding of pesticide residues above the level for consumer concern is reported to the Rapid Alert System for Food and Feed (RASFF), and further measures are taken by the Norwegian Food Safety Authority (Matportalen, 2014).

Organic food – definitions and status

Food safety has received increased attention over the last decades, and has become an important part of debates and opinions among the public, health professionals and policy makers (Crutchfield, 2000, Woteki et al., 2001, EFSA, 2014). One much debated aspect of food safety has been the increased demand for organically grown food products and its safety in relation to use of pesticides. Organic certification and practice vary worldwide. Organic foods are supposed to be grown without synthetic fertilizers and pesticides, antibiotics or growth hormones. The regulation of organic production in Norway is strict and only a few substances are allowed to be used (Mattilsynet, 2012b). The allowed substances are some microorganisms, iron salts, fatty acids, sulphur and a few plants extracts. Synthetic pesticides are not allowed.

All providers of organic products in Norway are certified by Debio on behalf of the Norwegian Food Safety Authority. Most of Debio's services deal with the inspection of organic production in accordance with the Norwegian "Regulations on the Production and Labelling of Organic Agricultural Products". The inspection services are based on an agreement with the Norwegian Food Safety Authority, and the regulation is based on the EU Council Regulation 2092/91 (EU, 1991). It covers farming, processing, import and marketing of organic agricultural products. In EU, this regulation is replaced by the Commission Regulation (EC) No 889/2008 (EU, 2008).

The objective of the present report

There have been some attempts in the literature to assess existing evidence regarding the quality and safety of organically and conventionally grown food. Most of these reports have however dealt with nutritional value, and less with safety characterization of the produce. In this report, we will present a comparison of organic and conventional farming when it comes to pesticide residues. We will present data to illustrate the differences in the occurrence of pesticide residues in organic versus conventional food products based on Norwegian and European control programmes, and assess the possible role of these residues for human health risk. We have also reviewed available scientific literature comparing organic and conventional food products in the same context. However, the literature of epidemiological studies with differences in pesticide levels in the body fluid or health effects after consumption of organic or conventional food have not been reviewed.

For the evaluation of Norwegian data, the focus has been on five commodities: apples, tomatoes, carrots, strawberries and lettuce. These commodities are selected, because they are both cultured in Norway and imported, and are established ingredients in the Norwegian diet. In addition pesticides have been detected in these products during the monitoring programme. The time period selected for the Norwegian residue data is 2007-2012, to ensure a large enough database. Based on these measurements, consumer exposure assessments are performed for the five target food commodities. The estimated intake of these vegetables and fruits are based on data from Norkost 3 (Totland, 2012).

2 Pesticide residues in organic and conventional food 2.1 PESTICIDE RESIDUES REPORTED BY EFSA

Every year EFSA presents the results of the control programmes for pesticide residues in food commodities sampled in EU Member States and the EFTA countries Iceland and Norway. The report also includes risk assessment concerning the exposure of consumers to pesticide residues in food.

In the last 2010 report from EFSA, published July 2013, analyses of pesticide residues in more than 77,000 samples from 500 different types of food are presented, providing a unique collection of data. For the first time, EFSA presented a pilot cumulative risk assessment for exposure to multiple pesticide residues.

The report from EFSA deals with data from two different control programmes: A **National control programme** designed by each participating country, and an **EU-coordinated programme**, where guidance on the specific control activities is given. The EU-coordinated programme is focused on the provision of statistically representative data where the samples are collected randomly in order to serve as a reliable indicator for the compliance rate of the food with regulatory limits and allow an estimation of actual consumer exposure. In the National control programme, enforcement samples where suspicion towards certain types of food and producers may have influenced the process of selecting samples are also included. In the present report, only data from the EU-coordinated programme or surveillance samples are used.

Results from the 2010 EU-coordinated programme

A total of 12,168 samples were analysed in the 2010 EU-coordinated control programme. The type of food commodities analysed is changed every three years, and the products included this year were apples, head cabbage, leek, lettuce, milk, peaches, pears, rye or oats, strawberries, swine meat and tomatoes. The total number of pesticides analysed for was 178.

The results of the analyses show that 197 (1.6%) of the 12,168 samples exceeded the respective MRL values, while 5,802 (47.7%) had measurable residues above the LOQ but below or at the MRL. Thus, 6,169 of the samples (50.7%) were without measurable pesticide residues.

The results from the last four EU-coordinated programmes (2007 - 2010) are relatively stable, with only small variations. The number of samples exceeding the MRL values ranges from 1.2 - 2.3% at this time period.

The frequency of MRL exceeding samples of different type of food is shown in Figure 1. Oats had the highest rate with 5.3% of the samples above MRL, followed by lettuce (3.4%), strawberries (2.8%), peaches (1.8%), apples (1.3%), pears (1.3%), tomatoes (1.2%), leek (1.0%), head cabbage (0.9%) and rye (0.2%). No MRL exceeding samples were reported for milk and swine meat samples. Peaches had the highest percentage of samples with measurable pesticide residues above the LOQ, 73\%, followed by 68\% of apple and strawberry samples.

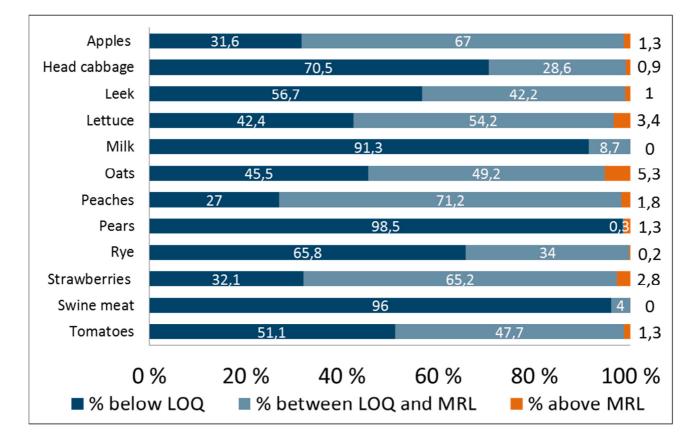


Figure 1. Percentage of samples without measurable pesticide residues (dark blue), residue levels below MRL (light blue) and levels above MRL (orange). The figure shows the surveillance samples in the 2010 EU-coordinated programme (EFSA, 2013a).

Variations in MRL exceeding among reporting countries

The MRL exceeding rates in 2010 among reporting countries are shown in Figure 2. The rates vary from 0% - 6.0% in the samples analysed in each country.

In the upper panel, the frequencies of MRL exceeding samples among the total number of analysed samples in each country is depicted, while in the lower panel, the data is restricted to samples from food produced in the respective country itself. The observed differences between the countries in the upper panel may, in part, be explained by the ratio of domestic versus imported food available in each country and by the pesticide use in the producing countries. The percentage of organic samples taken in each individual country may also affect the result.

For the Nordic countries, Norway, Sweden and Finland, it is clear that the 0.3 - 1.5% of food samples exceeding MRL are all taken from imported food commodities, since no exceeding samples were found among the food samples produced in these countries.

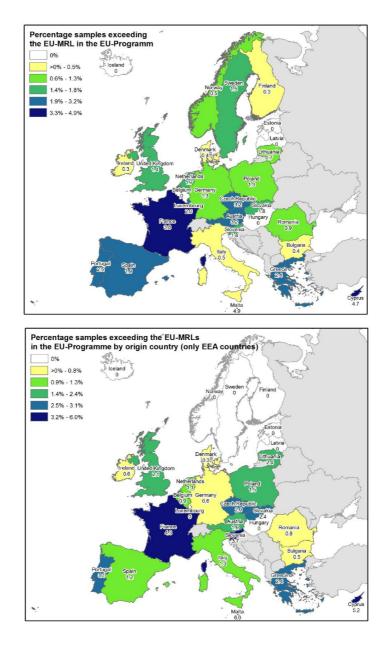


Figure 2. The percentage of MRL-exceeding samples. The upper panel shows the percentage of all tested samples in each reporting country with residues above MRL. The lower panel shows the percentage of exceeding samples originating from the respective reporting country. The figures are from the EU-coordinated programme 2010 (EFSA, 2013a).

Organic food samples

In EU-coordinated programme a total of 3,571 samples of organic origin were analysed in 28 countries in 2010. The rates of MRL exceeding samples for organic and other production types are compared in Figure 3. In this figure, "other production" means anything but organic production, and consists mainly of conventional products.

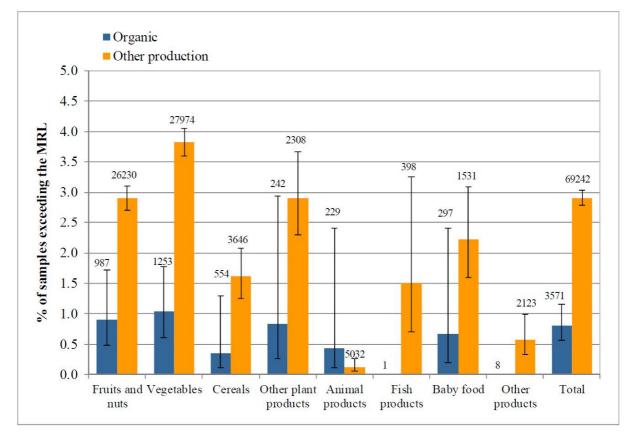


Figure 3. Percentage of organic (blue bars) and other type of products (orange bars) exceeding the MRL values. The number of analysed samples in each food group is shown on top of the bars indicating confidence intervals. The figure is based on the total number of surveillance samples in the 2010 EFSA report (EFSA, 2013a).

For fruit and nuts, an MRL exceeding rate of 0.9% was found in organic products compared to 2.9% for conventionally grown fruit and nuts. For vegetables, the MRL exceeding rates were 1.0% and 3.8%, respectively, for organic and conventionally grown products. Altogether, the MRL exceeding rate for organic food was 0.8% compared to 2.9% of the surveillance samples of conventional food, including milk and swine meat in addition to plant products. In total, 131 different pesticides were found in the organic products in measurable concentrations. It was noted that out of 26 pesticides, each of them found in more than 5 organic samples, only one is permitted in organic farming according to Regulation (EC) No 834/2007 and Regulation (EC) No 889/2008; several other pesticides were related to environmental contamination (e.g. hexachlorebenzene and DDT), to naturally occurring substances (e.g. bromide ion, dithiocarbamates measured as carbondisulfide) or to pesticides not allowed in organic production in Europe.

The fraction of samples from fruit, vegetables and other plant products without detected pesticide residue, below or equal to the MRL value, or above the MRL value is shown in Table 1. The samples shown in Table 1 are surveillance samples taken from the EU coordinated and national programmes and, represents as far as we know a reliable dataset for comparison between organic and conventionally grown fruit, vegetables and other plant products.

Table 1. Pesticide residues in organic and non-organic surveillance samples from the EU coordinated and national programmes of fruit, vegetables and other plant products. The data are from Table I in Annex III of the 2010 EFSA report (EFSA, 2013a).

Fruit, vegetables and other plant products	No. of samples	Samples without residues (≤ LOQ)	Samples with residues ≤ MRL	Samples with residues > MRL
Organic	2482	2189 (88.2%)	269 (10.8%)	24 (1.0%)
Non-organic	24204	12723 (52.6%)	10455 (43.2%)	1026 (4.2%)

Table 1 shows that pesticide residues below or equal to the MRL value is observed in 269 (10.8%) of 2482 analysed organic surveillance samples from fruit, vegetables and other plant products. In 24 or 1% of the samples the pesticide residue levels was found to exceed the MRL values. The corresponding ratios for conventional products were 43.2% and 4.2% for residues below and above MRL, respectively.

The EFSA report does not quote the individually measured levels of pesticide residues in organic samples.

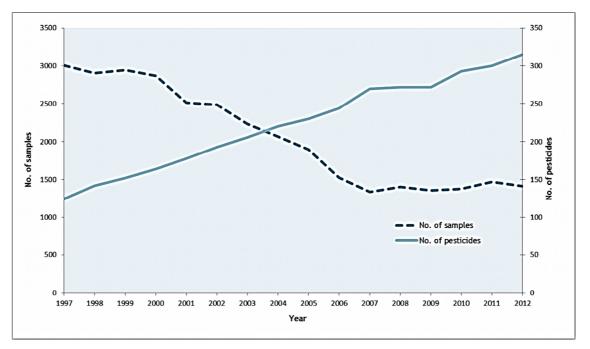
It should be noted that the fraction of fruit, vegetables and other plant products exceeding MRL is 4.2% for conventional products, and therefore higher than for the total number of food commodities tested in the 2010 EU-coordinated control programme, where the number is 1.6%. This difference is due to different food commodities included, and illustrates the importance of care taken when comparing values from different groups of samples. For such a comparison to be valid it is essential that the groups are similar with regard to which types of samples they contain, how the samples are selected, which pesticides that are analysed for and with which sensitivity analysis is performed.

2.2 PESTICIDE RESIDUES IN FOOD SAMPLES COLLECTED IN NORWAY

The Norwegian monitoring programme for pesticide residues in fruit and vegetables, cereals, baby food, animal products and some other food products has the last years included approximately 1400 samples. The EU-coordinated programme is included in the national programme. The Norwegian Food Safety Authority and Bioforsk present the results of the monitoring programme in annual reports. The results are also reported to EFSA. In addition, Norway reports to EFSA on pesticide residue results from controls on the import of certain feed and food of non-animal origin, EU-regulation No. 669/2009 (border control samples). Such samples represent targeted selection and are not included in the present report.

The sampling in the national control programme includes products, which are important in the Norwegian diet, but less eaten products are included as well. The number of each commodity and the percentage of imported vs. domestic samples are based on Norwegian statistics of food consumption rates, the risk for residues and previous RASFF notifications.

The criteria for taking organic grown samples are dependent on their market share and the availability on the market. Samples from organic products in the national monitoring programme have in previous years been around 6-7% of the total number of samples analysed.



The increases in the number of pesticides in the analytical scope, and the change in the number of samples in the monitoring programme from 1997 - 2012 is shown in Figure 4.

Figure 4. Number of pesticides analysed for and the total annual number of samples in the Norwegian monitoring programme from 1997 to 2012. Right scale and solid line show the number of pesticides analysed. Left scale and dotted line show the number of samples analysed annually. The figure is from the national report "Rester av plantevernmidler i næringsmidler 2012"(Mattilsynet, 2013b).

In 2012, a total of 1168 surveillance samples (64% imported and 36% domestic produced) of fruit, vegetables and some samples of animal origin were analysed in the national pesticide residues monitoring programme. In total, 1.9% of the samples had findings above the MRL values, while 53% of the samples had measurable residue levels above the LOQ, but below or at the MRL. Thus 45% of the samples were without measurable pesticide residues. The results from 2012 are, in general, comparable to that observed in previous years.

Direct comparison between the Norwegian data from 2012 and results from EFSA 2010 EUcoordinated programme is not possible due to large differences in the sample matrices and the target number of pesticides analysed for. The EFSA data from 2010 is based on 12 selected commodities and a target list of 178 pesticides while the Norwegian data from 2012 includes 111 different commodities analysed for more than 315 compounds. The LOQ's also differ. However, the results are in the same range. The EFSA data 2010 showed 1.6% of samples with pesticide residues above the MRL, 47.7% had measurable levels above the LOQ and 50.7% were without measurable pesticide residues.

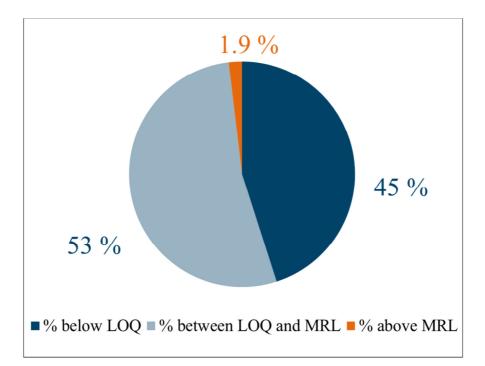


Figure 5. Surveillance samples in the 2012 Norwegian monitoring of fruit, vegetables, and samples of animal origin. In total 1168 samples were analysed. The figure is from the national report "Rester av plantevernmidler i næringsmidler 2012" (Mattilsynet, 2013b).

Organic food samples

In the years from 2007 to 2012, a total of 624 organic samples were analysed in the Norwegian monitoring programme. Of these, 205 samples were of domestic origin. Pesticide residues were detected in 12 of the 624 samples. The types of substances and residue levels detected, as well as the relevant MRL when the products were sampled, are shown in Table 2.

Table 2. Pesticide residues detected in organic samples analysed in the Norwegian monitoringprogramme 2007 - 2012. *Valid MRL when the product was sampled.

Commodity	Pesticide	Residue (mg/kg)	MRL	Origin
			$(mg/kg)^{\#}$	country
Apple	Thiabendazole	0.02	5	Argentina
Lemon	Biphenyl	0.03	70	Italy
Cucumber	Abamectin	0.03	0.02	Bulgaria
Cucumber	Fenamiphos	0.013	0.02	Spain
Orange	Imazalil	0.02	5	Spain
Orange	Imazalil	0.026	5	South Africa
Potato	Chlorpropham	0.02	10	Norway
Squash	Endosulfan	0.02	0.05	Italy
Tomato	Chlorpropham	0.01	0.05	Spain
Tomato	Spinosad	0.053	1	Israel
Tomato	Spinosad	0.022	1	Spain
Tomato	Bromide	0.2	50	Norway

In one organic sample, cucumbers from Bulgaria, abamectin was found to exceed the MRL value. Two samples were found to contain low levels of spinosad whose use is allowed in

organic production in EU (when produced from micro-organisms). Bromide can occur naturally in fresh plant materials at levels below 5 mg/kg. The reported finding of 0.2 mg/kg may therefore have a natural cause.

The results are shown in Figure 6. In total, 0.2% (one out of 624 samples) of the organic samples had findings above the MRL values, while 1.8% of the samples had measurable residue levels above the LOQ, but below the MRLs. Thus 98% of the samples were without measurable pesticide residues. The residue levels found were in most cases very low and close to LOQ (normally set at 0.01 mg/kg).

The low number of Norwegian organic samples with pesticide residues makes it difficult to make a quantitative comparison with levels observed in conventional samples.

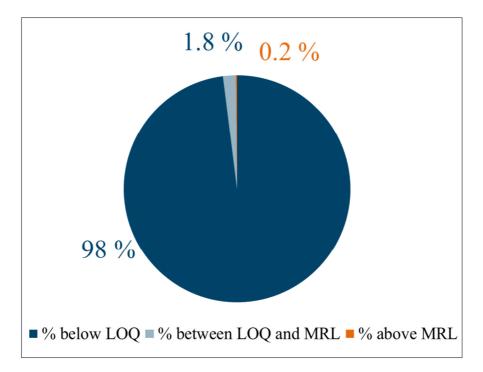


Figure 6. Results of organic samples in the national monitoring from 2007-2012 in fresh fruit and vegetables. In total 624 organic samples were analysed. The figure is prepared on the basis of data from annual reports 2007 - 2012, "Rester av plantevernmidler i næringsmidler" by Mattilsynet and Bioforsk (Mattilsynet, 2013a).

Pesticide residues in organic and conventional food samples

We have focused on five commodities from the Norwegian monitoring programme over the time period from 2007 to 2012, namely - apples, tomatoes, carrots, strawberries and lettuce. During this period, the number of pesticides analysed and the analytical sensitivity has increased due to improved instrumentation and methods. Direct comparison of results between different years may, therefore, be difficult to perform.

The frequencies of samples with pesticide residues related to LOQ and MRL are shown in Figure 7. Although the numbers of organic samples from each commodity are low, the data may be taken to indicate reduced amounts of pesticide residues in organic food samples compared to the conventional samples, in line with what is illustrated by Figure 5 and 6. All commodities showed reduced frequency of samples with pesticide residues above LOQ in organic compared to conventional products. For strawberries, pesticide residues were found in

more than 90% of the conventional samples, however in low concentrations compared to MRL. No organic samples contained residues exceeding the MRLs, while 0.4 - 0.5% of conventionally grown tomatoes, strawberries and lettuce contained pesticide residues above the MRL values.

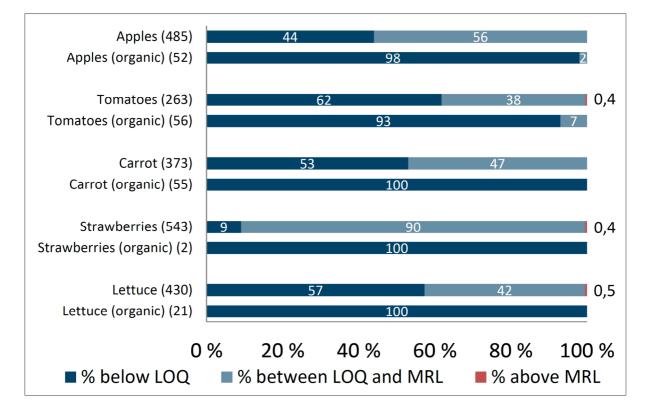


Figure 7. Percentage of samples collected in Norway without detected pesticide residues (dark blue), residue levels below MRL (light blue) and levels above MRL (red). The figure is prepared on the basis of data from annual reports 2007 to 2012, "Rester av plantevernmidler i næringsmidler", by Mattilsynet and Bioforsk (Mattilsynet, 2013a).

2.3 PESTICIDE RESIDUES IN ORGANIC AND CONVENTIONAL FOOD IN PEER-REVIEWED LITERATURE AND REPORTS FROM GOVERNMENTAL AGENCIES

In addition to the EFSA reports, other international studies and reports of pesticide residues in organic and conventional food have also been conducted. Several monitoring programs for contaminants in the diet have concluded that a large proportion of commercially available food items contain low levels of residues of agricultural pesticides. Since the use of synthetic chemicals is not permitted in organic farming, most studies have shown that their presence in organic crops is considerably lower than for conventional ones, although differences in some instances were small and the reported findings of pesticide residues show considerable variation between studies (Andersen and Poulsen, 2001, Poulsen and Andersen, 2003, Woese et al., 1997, Baker et al., 2002, Corrales et al., 2010, Dani et al., 2007, Gonzalez et al., 2005, Harcz et al., 2007, Hoogenboom et al., 2008, La Torre et al., 2005, Mansour et al., 2009a, Mansour et al., 2009b, Tasiopoulou et al., 2007, Tsatsakis et al., 2003, Turgut et al., 2011). This variation may reflect on how the studies were conducted, such as the selection of samples and number and type of pesticides that were analysed for, and assay sensitivity. There has been report on a shift from about 80 - 10% of wine samples without pesticide

residues when the detection level was lowered from 0.01 to 0.001 mg/kg (Tamm, 2001). Thus, the sensitivity of the analytical method used should always be considered when comparing the frequency of pesticide residue detection in both conventional and organic products in different studies. Several other observations taken together suggest that the frequency of observed food contamination by pesticides is remarkably stable, and that the residue levels in conventional food are generally well below established tolerance levels. A time dependent increase in relative amounts of pesticide residues in conventional compared to organic olive oil over a 3-year observation period was mainly due to a gradual reduction of pesticide concentrations in organic olive oils, rather than an increase in conventional ones (Tsatsakis et al., 2003).

The occurrence of pesticides and other synthetic chemicals used in conventional farming in organic foods have been suggested to be caused by different reasons, such as the cultivation on soil previously used for conventional production, unauthorized use of pesticides, cross-contamination via air and water, or during transport and storage of food products. Regulations in many countries demand that organic farms should have been free from the use of unauthorized substances for several years prior to the use for cultivation of organic products. In some instances, concerning particularly persistent pesticides, even longer time periods may be necessary. Organo-chlorine pesticide (OCP) residues have been reported to be surprisingly abundant in food samples, despite being off the market for more than twenty years (Schafer and Kegley, 2002). The organic certifiers are usually responsible for the control of the land used for organic production. A trend towards lower levels and less frequent presence of pesticide residues in organic vegetables and fruits with time was suggested (Bourn and Prescott, 2002).

Pesticide residues were analyzed in a comparative large-scale study of close to 100.000 samples of organic and conventional fruits and vegetables, showing that organically grown fruits and vegetables contained pesticide residues about one-third as often as that observed for conventional ones (Baker et al., 2002). The difference seemed to be stable over time, and the data were later reviewed by Magkos and colleagues (Magkos et al., 2006). Figure 8 is taken from this publication.

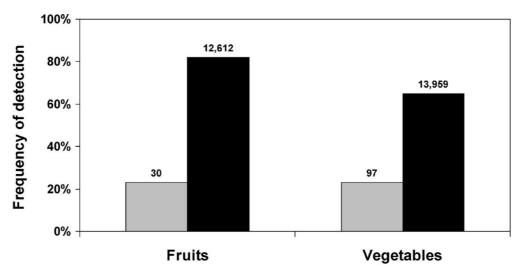


Figure 8. Frequency of detecting pesticide residues in organic (grey bars) and conventional fruits and vegetables (black bars). The number of samples tested is shown on top of the respective bars. The data have been collected from the Pesticide Data Programme of the US Department of Agriculture, and the figure is from (Magkos et al., 2006).

Organic crops have been found to contain multiple pesticide residues (two or more), but with lower frequency than conventional ones. Generally, the pesticide residue levels in organic fruits and vegetables were considered lower than in conventionally grown products (Baker et al., 2002).

When 9 different studies were reviewed, pesticide residues were detected in about 7% of organic produce samples (95% confidence interval (CI): 4% to 10%; 3041 samples) and 38% of conventional produce samples (95% CI: 32% to 45%; 106 755 samples) (Smith-Spangler et al., 2012).

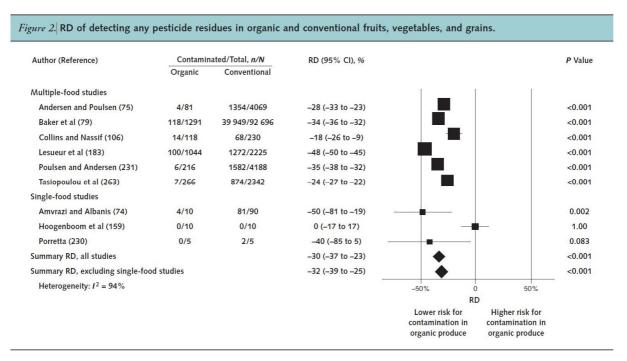


Figure 9. Frequency of pesticide residue detection in organic and conventional fruits, vegetables and grains in nine separate studies. The combined data comprise 3041 organic and 106755 conventional samples. (Taken from a review article by (Smith-Spangler et al., 2012).

The authors stated that organic produce had about 30% lower probability for being contaminated with detectable pesticide residues compared to conventional produce ("Risk Difference" (RD), 30% [CI, 23% to 37%]; P< 0.001; 9 studies) (Figure 9). It can be argued that the reduction from 38 to 7% actually means a reduction in probability of 82%, and not 30%.

In a report, "10 Years of Organic Monitoring", from the Ministry of Rural Affairs in Baden-Württemberg (MLR), the analyses of 4481 organic samples of plant-based foods during the years from 2002 to 2011 were presented (Table 3) (MLR, 2012).

No. of samples	Samples with residues	Samples with Residues > 0.01 mg/kg ¹	Irregular samples ²	Samples with multiple
				residues
4481	1308 (29%)	375 (8%)	218 (5%)	473 (11%)

Table 3. Pesticide residues in plant-based food samples from organic production analysed during the years 2002 to 2011 in Germany.

The table is taken from a report of The Ministry of Rural Affairs and Consumer Protection (MLR, 2012). ^{1"}Residues of substances not authorized for organic production." ^{2"}Samples with amount and type of substance that was considered not to comply with organic farming."

Pesticide residues were found in 29% of the samples, and levels above 0.01mg/kg in 8% of the samples. Of the samples analysed, 5% were found to contain pesticide residues in amounts that were considered not in compliance with organic farming. The criteria for consideration of the samples as "irregular" were that the samples had levels exceeding the 0.01 mg/kg by 50% of the analytical variation, i.e. 0.02 mg/kg or higher. In the report, it is stated that these 218 samples are considered likely to result from either illegal use of pesticides or mixing with conventional goods. On the other hand, it was estimated that on average, conventionally produced fruit and vegetables contain about 180 times higher amounts of pesticides than organic products (MLR, 2012).

The data presented in the EFSA report, the German report and the review article by Smith-Spangler et al. is relatively consistent with regard to the frequencies of pesticide residues detected in organic and conventional products.

On the other hand, the situation in Norway and Denmark regarding pesticide residues in organic food seems comparable. The Danish monitoring of pesticide residues in food in 2012 comprised a total of 2338 samples of fruit, vegetables, cereals, baby food, processed food and animal products (Fødevarestyrelsen, 2012). This included 217 organic samples (9.3%) of which 72 of the products were produced in Denmark and 145 were imported. The samples were analysed for about 300 compounds with reporting level of 0.01 mg/kg for most of the substances. Pesticide residues were detected in three samples (1.4%); lettuce from Denmark (boscalid 0.017 mg/kg), orange juice from Italy (chlorpyrifos 0.04 mg/kg and imazalil 0.014 mg/kg) and in pear from Italy (spinosad 0.013 mg/kg). All the findings were low in concentration and none exceeded MRL. Thus, the Norwegian data from 2007-2012 show that 98% of the organic samples are without measurable pesticide residues, while the corresponding finding in the Danish data from 2012 is 98.6%.

3 Multiple pesticides in each type of food

3.1 PESTICIDE RESIDUES REPORTED BY EFSA

Several different pesticides are observed in each type of food. To illustrate this, a chart showing the pesticides found in apple samples sorted according to the frequency of detection (blue boxes/upper x-axis scale) is shown in Figure 10.

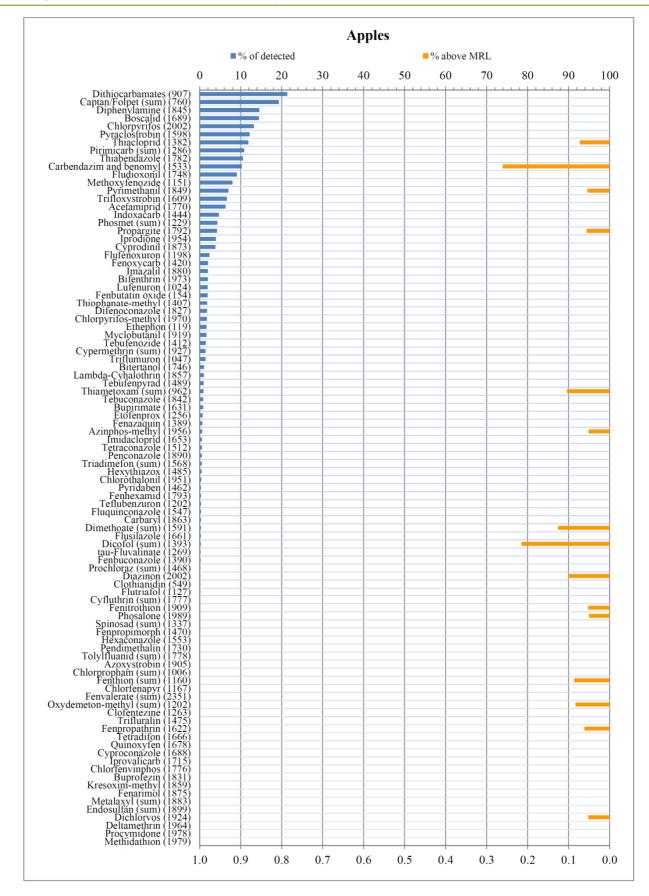


Figure 10. Percentage of apple samples with measurable residues (upper x-axes scale/blue boxes), and residues above the MRL (lower x-axis scale/yellow boxes). The number of apple samples tested for the specific pesticide is given in brackets after the pesticide name. The figure is from the EU-coordinated programme 2010 (EFSA, 2013a).

In the same chart, the percentage of residues exceeding the MRLs (yellow boxes/lower x-axis scale) is also included, and the number of samples tested for each pesticide is shown in brackets next to the pesticide name.

A total of 94 different pesticides were detected in apples. The most frequently found active substances were dithiocarbamates (21.4% of samples analysed), captan/folpet (19.3%) and diphenylamine (14.6%). Residues above MRL were detected for 15 active substances in 27 samples. The samples exceeding MRL originated in Portugal (5), Chile (3) and Romania (3).

One important reason for the large number of available pesticides is to avoid the development of pesticide resistance. Such development of resistance is more likely to develop when the same pesticide is used continuously.

Figure 11 shows the distribution of the measured residue levels in apples expressed in percentage of the MRL value for each specific pesticide.

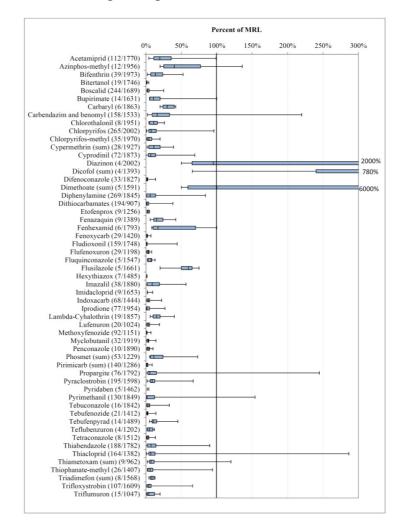


Figure 11. Measured residues in apples expressed as % of the MRL. Data are given for samples exceeding LOQ. The lower and upper edges of the blue box represent the 25th and the 75th percentile, respectively, and the line within the box shows the mean value. The whiskers of the bar lines show the minimum and the maximum residue level obtained among all samples analysed for each pesticide. The figure is from the EU-coordinated programme 2010 (EFSA, 2013a).

Most of the samples are well below the MRL value as shown in Figure 10. Some of the pesticides such as diazinon, dicofol and dimethoate, exceeded up to 60 times the MRL value. It should however be noted that this relates to less than 0.3% of a total of close to 5000 samples. The origin of these highly MRL exceeding samples was not given in the EFSA report, but it should be noted that for instance the use of dicofol is no longer allowed in Europe.

For the other food commodities tested, the situation is similar although not identical to this example shown for apple samples.

In tomatoes, altogether 84 different pesticides were detected and the MRL values were exceeded for eight different residues in 1.2% of the samples analysed. The samples where the tomato MRL was most frequently exceeded were from Spain (6), Turkey (4) and the Netherlands (3). In cabbage, 49 different pesticides were detected and MRL violation was observed for 8 substances in 10 samples. The exceeding samples came mainly from France, The Czech Republic and Thailand with two samples from each country. In leek, 45 different pesticides were detected and 9 substances in 12 samples exceeded the MRL value. The exceeding samples came mainly from Portugal (3), Denmark (2), France (2) and Spain (2). In lettuce, 68 different pesticides were detected and levels above MRLs were observed for 25 substances in samples mainly from France (20), Germany (6), Cyprus (4), Greece (4) and Romania (4).

The highest exceeding MRL value was reported for seven lettuce samples where residues of chlorothalonil were observed to exceed MRL 40 times. The highest residue level was 3.28 mg/kg, while the MRL for lettuce is set to the LOQ of 0.01 mg/kg. This finding was notified to the RASFF (The Rapid Alert System for Food and Feed). The reason for this very high value is that chlorothalonil is only authorised for use in land cress with a MRL value of 5 mg/kg, but not in other types of lettuce. If not authorized, the MRL is set to the quantification level of 0.01 mg/kg, as in this case for lettuce.

No information is given in the EFSA report on the finding of multiple pesticides in organic samples.

3.2 MULTIPLE PESTICIDES IN NORWEGIAN FOOD SAMPLES

As for the results from the EFSA report, the Norwegian analysis also showed that a relatively large number of different pesticides are observed in each type of food. While the data from EFSA showed a total of 94 different pesticides detected in apples, the apple samples analysed under the Norwegian national programme from 2007 to 2012 detected 53 different pesticide residues. Part of the explanation for this difference in number of detected pesticides is that fewer pesticides are approved for use on apples in Norway and that 39% of the samples are of Norwegian produce.

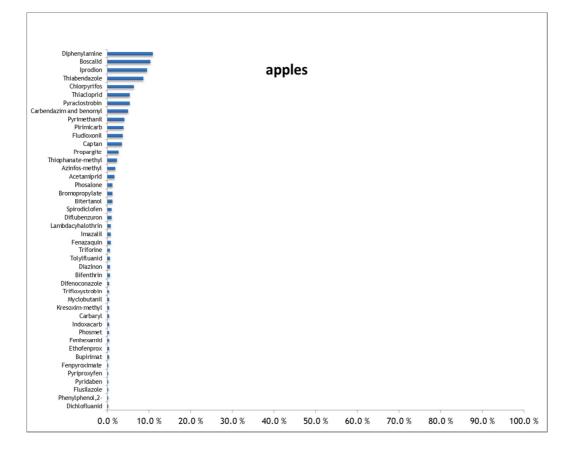


Figure 12. Apple samples collected in Norway with measurable pesticide residues in percentage of MRL. In total 485 samples of which 190 (39%) were of domestic produce. None of the samples contained pesticide residues above the MRL. The figure is based on data from reports "Rester av plantevernmidler i næringsmidler", 2007 to 2012, prepared by Mattilsynet and Bioforsk (Mattilsynet, 2013a).

Diphenylamine was the most frequently detected pesticide residue in apples in the Norwegian monitoring programme from 2007 to 2012, and was found in 53 (10.9%) of 485 analysed samples (Figure 12). Diphenylamine is a plant growth regulator; used for post-harvest treatment of pome fruit against scald. Since May 2010, diphenylamine is no longer authorized in the EU or Norway. Boscalid was the second most frequently found pesticide, observed in 50 (10.3%) of the samples. Boscalid is a systemic fungicide used to control fungal diseases in a wide range of fruit and other crops. Iprodion is a non-systemic fungicide used to control plant diseases in a wide range of fruit and other crops. Iprodion was found in 46 (9.5%) of the samples. Data for nine additional detected pesticides are not included in figure 12 because the number of samples analysed was small. The three most frequently observed pesticides in EU (Figure 10).

Levels of diphenylamine, boscalid and iprodion in the apple samples expressed in percentage of MRL is shown in Figure 13. The highest residue level of diphenylamine was 4.2 mg/kg and the mean value was 0.77 mg/kg, while MRL is 5 mg/kg. The highest residue observation of boscalid was 0.23 mg/kg, the mean value 0.06 mg/kg while MRL is 2 mg/kg. Iprodion was detected with residue up to 1.6 mg/kg with a mean level of 0.23 mg/kg. The MRL for iprodion in apples is 5 mg/kg.

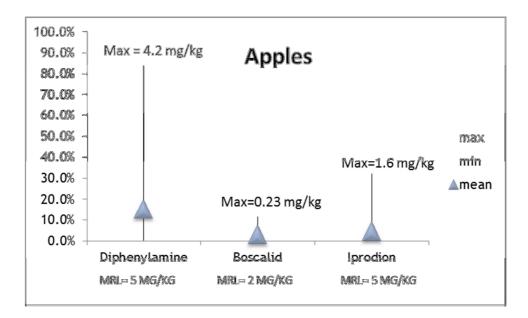


Figure 13. Levels of diphenylamine, boscalid and iprodion in apple samples analysed in Norway, expressed in percentage of the MRL values. The triangle indicates the mean level of residues in samples with detected pesticide, and the line illustrates the degree of variation of observed residues. The figure is based on data from reports "Rester av plantevernmidler i næringsmidler", 2007 to 2012, prepared by Mattilsynet and Bioforsk (Mattilsynet, 2013a).

The number of detected pesticide residues varies among the food commodities. For instance, the number of pesticides detected in 373 analysed carrot samples in the period from 2007 to 2012 was 13 (Figure 14). Most of the carrot samples (89%) were produced in Norway.

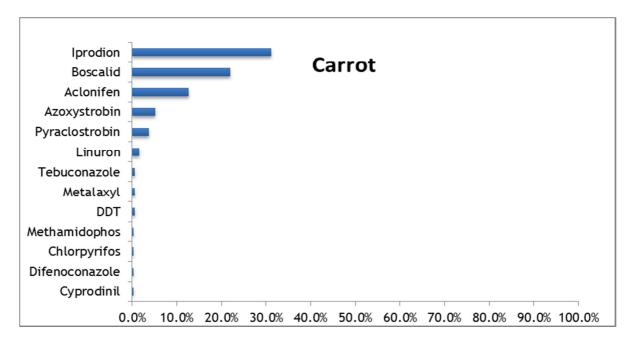


Figure 14. Carrot samples collected in Norway with measurable pesticide residues in percentage of MRL. In total of 373 samples of which 332 (89%) were of domestic produce. The figure is based on data from reports "Rester av plantevernmidler i næringsmidler", 2007 to 2012, prepared by Mattilsynet and Bioforsk (Mattilsynet, 2013a).

3.3 MULTIPLE PESTICIDES IN ONE SAMPLE

Data from EFSA

The relative proportion of samples with detectable multiple number pesticides within the same sample is shown in Figure 15.

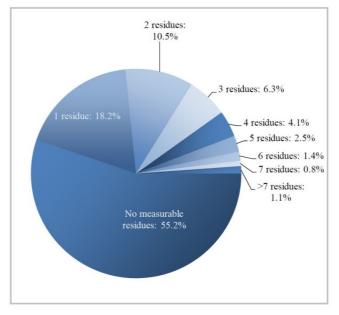


Figure 15. Percentage of samples containing none or increasing number of different pesticides in the same sample. The figure is based on the total number of surveillance samples in the 2010 EFSA report (EFSA, 2013a).

The figure is taken from the EFSA report and is based on the total number of surveillance samples from both the national and the EU-coordinated programmes in 2010. The figure shows that residues of two or more pesticides were detected in 26.6% of the samples; that is 19,382 of altogether 72,813 surveillance samples.

All reporting countries observed multiple residues, and citrus fruits (62.8% of 4,363 samples) and strawberries (60.5% of 2,479 samples) had the highest frequency of samples with multiple residues.

The presence of multiple residues in one sample does not, according to current legislation affect the way the sample is evaluated as long as the individual residues do not exceed the individual MRLs. Legal actions are imposed by national authorities when one or more MRLs are exceeded. In 2010, 338 samples (or 0.5% out of the 72,813 surveillance samples), were found to exceed two or more MRL values, and the highest number of exceeding MRL in one sample was 11, measured in processed grape leaves. The commodity with the highest number of samples with multiple exceeding MRL observations was peppers (including chili pepper), with 46 out of 1,633 samples (2.8% of the samples).

No information is given in the EFSA report on the finding of multiple pesticides in individual organic samples.

Data from Norway

Figure 16 is based on apples, tomatoes, carrots, strawberries and lettuce samples from the 2007-2012 national monitoring. Residues of two or more pesticides were detected in 37% (778 samples) of the analysed samples. The figure is influenced by a large number of strawberry samples with multiple residues (Mattilsynet, 2012a).

None of the 624 organic samples had multiple findings of pesticide residues.

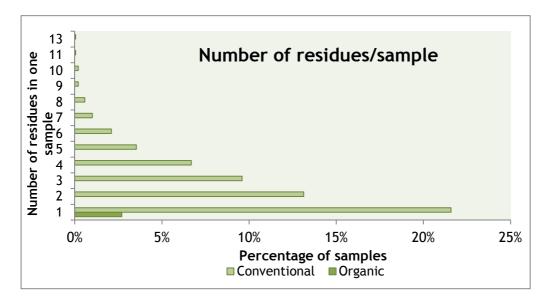


Figure 16. Percentage of samples (apples, tomatoes, carrots, strawberries and lettuce) collected in Norway containing one or more different pesticides in the same sample. The figure is based on data from reports "Rester av plantevernmidler i næringsmidler", 2007 to 2012, prepared by Mattilsynet and Bioforsk (Mattilsynet, 2013a).

4 Dietary exposure to pesticide residues

Description of the Norwegian dietary surveys

The estimated dietary exposure to pesticides presented in this report is based on data from Norwegian food consumption surveys for adults. The food consumption data are the most complete, detailed and currently available in Norway, and was computed by using the food database software system, KBS, developed at the Institute of Basic Medical Sciences, Department of Nutrition, University of Oslo.

Norkost 3 is based on two 24-hour recalls by telephone at least one month apart. Food amounts were presented in household measures or estimated from photographs (Totland, 2012). The study was conducted in 2010/2011, and 1787 adults (925 women and 862 men) aged 18-70 participated.

Consumption data from Norkost 3 has been used to calculate both acute and chronic exposure of pesticides.

Table 4. Mean and 97.5 percentile intake (g/day) of five commodities in Norkost 3, adults 18-70 year	
(n=1787).	

	Carrot	Tomato	Apple	Strawberry	Lettuce
Mean	11	13	38	2	6
97.5 percentile	75	71	250	24	47

The exposure to pesticides depends on many different aspects. The EFSA report (EFSA, 2013a) on pesticide residues includes Norwegian occurrence data on pesticides, but Norwegian dietary data are not included in the report. To be able to compare the Norwegian level of exposure of pesticides with the European level, the Norwegian calculations for exposure have been performed in a similar way.

Dietary exposure is basically calculated according to this simplified equation:

Dietary exposure =
$$\frac{\sum (residue \text{ concentration x food consumption})}{body weight}$$

However, the input values for residue levels and food consumption varies depending on acute or chronic exposure.

Acute exposure

A model for short-term (acute) risk assessment is referred to in the EFSA report (EFSA, 2013a). Dietary intake calculations have been performed for five commodities in the Norwegian monitoring programme (2012) in a comparable way to that of the EFSA report. The lower number of Norwegian samples for each pesticide/commodity pair increases the uncertainty compared to the EFSA calculations (EFSA 2013a).

The following input values were used to calculate the acute exposure:

- Highest residue concentration measured per pesticide in each commodity was used as input for the acute exposure calculation (Table 5).
- Food consumption data were retrieved from 2 x 24-hour recalls in the Norkost 3 study. The fruit and vegetable intake are given in edible weight, and both raw and processed foods were added together (eg. strawberries eaten raw were added to strawberries in jam). The 97.5 percentile food intake reported during 24-hours is used in the calculations (see Table 4).
- Mean body weight in Norkost 3 was 77.5 kg.
- A variability factor of 7 was used for commodities between 25-250 g. For commodities below 25 g (e.g. strawberries and lettuce), a variability factor of one is used.

Table 5. Highest residue (mg/kg) measured per commodity/pesticide, used as input values for the short-term
calculations. The data is based on conventional samples from the Norwegian monitoring programmes 2007 -
2012.

Pesticide	Carrot	Tomato	Apple	Strawberry	Lettuce
Acetamiprid		0.04	0.06		0.3
Aclonifen	0.14				
Acrinathrin	-			0.031	0.00
Alpha-cypermethrin Amitraz		0.02			0.08
Anntraz Azinphos-methyl		0.02	0.21	0.02	
Azoxystrobin	0.11	0.22	0.21	0.55	0.52
Benalaxyl	0.11	0.22		0.55	0.01
Bifenazate				0.097	
Bifenthrin		0.16	0.11	0.08	0.8
Bitertanol		0.1	0.04		
Boscalid	0.13	0.1	0.23	2.4	11.3
Bromide Ion		11.6			3.4
Bromopropylate Bupirimate		0.05	0.011 0.031	0.26	
Buprofezin		0.05 0.08	0.031	0.20	
Captan		0.08	1.2	0.68	
Carbaryl			0.02	0.00	
Carbendazim		0.03	0.14	0.37	
Chlorantraniliprole			0.034		0.24
Chlorothalonil		0.29			
Chlorpyrifos	0.08	0.3	0.35	0.02	0.08
Chlorpyrifos-methyl		0.02		0.01	
Clofentezine				0.22	0.12
Cyfluthrin Cymoxanil		0.011			0.12
Cypermethrin		0.07			0.15
Cyproconazole		0.07		0.01	0.15
Cyprodinil	0.023	0.32		1.1	1.2
DDT	0.01				0.02
Deltamethrin					0.21
Diazinon			0.15		
Dichlofluanid			0.16		0.07
Dicloran	0.02	0.042	0.01		0.07
Difenoconazole Diflubenzuron	0.03	0.043	0.01 0.03		0.73
Dimethoate			0.03		0.4
Dimethomorph		0.04		0.012	0.16
Diphenylamine			4.2		
Dithianon			0.026		
Dithiocarbamates		0.48		1	3.82
Dodine		0.05	0.55		
Endosulfan	-	0.35	0.02		0.12
Etofenprox Famoxadone		0.04	0.03		0.12 0.34
Fenamiphos		0.04			0.54
Fenazaquin		0.15	0.05		
Fenhexamid		0.56	0.02	2	1.4
Fenpropathrin				0.05	
Fenpropimorph				0.06	
Fenpyroximate			0.01		
Fludioxonil		0.04	0.74	0.66	1.8
Flusilazole Flutriafol		0.014	0.01		
Folpet		0.014	0.01		0.34
Glyphosate			0.02		0.34
Hexythiazox		0.02		0.078	
Imazalil		0.02	0.72		0.02
Imidacloprid		0.014		0.15	1.8
Indoxacarb		0.053	0.014		0.97
Iprodion	0.38	0.18	1.6	0.77	2.1
Kresoxim-methyl		0.011	0.04	0.2	0.03
Lambda-Cyhalothrin	0.05	0.011	0.06	0.06	0.25
Linuron Lufenuron	0.05	0.012			
Malathion		0.012			0.07
	I				35

Pesticide	Carrot	Tomato	Apple	Strawberry	Lettuce
Mandipropamid					0.93
Mepanipyrim		0.045		0.59	
Metalaxyl	0.02	0.031			0.69
Methamidophos	0.04				
Methiocarb				0.33	
Methocyfenozide		0.02	0.053		
Metomyl/tiodikarb					0.02
Myclobutanil		0.02	0.03	0.39	
Omethoate					0.01
Oxadixyl					0.07
Oxamyl		0.09			
Penconazole				0.12	
Pencycuron					0.68
Pendimethalin					0.02
Phenmedipham				0.03	
Phenylphenol-orto			0.04		
Phosalone			0.46		
Phosmet			0.03		
Pirimicarb			0.1	0.24	2.9
Procymidone		0.27		1.1	0.32
Profenofos				0.05	
Propamocarb		2.8			94
Propargite			0.36		
Propyzamide					0.03
Pymetrozine		0.032		0.029	0.3
Pyraclostrobine	0.02	0.04	0.13	0.53	1.3
Pyridaben		0.03	0.03		
Pyrimethanil		0.22	2.6	0.66	0.06
Pyriproxyfen		0.14	0.02		
Quinoxyfen				0.19	
Quizalofop					0.02
Simazine					0.017
Spinosad		0.014		0.13	2
Spirodiclofen			0.03	0.29	
Tau-Fluvalinate		0.06			0.46
Tebuconazole	0.014	0.03	0.02		0.03
Tebufenpyrad				0.074	
Teflubenzuron			0.02		
Tetraconazole		0.04		0.09	
Thiabendazole			3.7		0.016
Thiacloprid		0.06	0.07	0.18	0.01
Thiamethoxam					0.075
Thiophanate-methyl		0.06	0.1		
Tolclofos-methyl					3.2
Tolylfluanid			0.19	0.23	0.03
Triadimefon/-menol		0.15		0.9	
Trifloxystrobin		0.03	0.03	0.26	
Triflumuron			0.04		
Triforine			0.05		
Vinclozolin					0.24
Zoxamide		0.01			

Acute exposure for each pesticide/commodity per kg body weight and day are shown in table A1in the Appendix.

Chronic exposure

A model for long-term (chronic) risk assessment is referred to in the EFSA report (EFSA, 2013a). Dietary intake calculations have been performed for five commodities in the Norwegian monitoring programme (2012) in a comparable way to that of the EFSA report. The lower number of Norwegian samples for each pesticide/commodity pair increases the uncertainty compared to the EFSA calculations (EFSA 2013a).

The following input values are used to calculate the Norwegian chronic exposure:

- Residue concentration to which the consumer is exposed (Table 6). For each pesticide/food combination, an overall mean value was calculated. The actual values in the individual samples exceeding the LOQ and the LOQ-value for the samples with no quantification of pesticides were used to calculate the mean. This is a conservative assumption, and for most pesticide/food combinations the LOQ values gives the main contribution to the residue concentration.
- Mean food consumption from Norkost 3. The mean intake of the five fruits and vegetables chosen as examples were used in the calculations. The fruit and vegetables intakes are given in edible weight, and both raw and processed foods were added together.
- Mean body weight in Norkost 3 was 77.5 kg.

		Ca	rrot	Ton	nato	Ар	ple	Straw	berry	Lett	tuce
Pesticide	LOQ	>LOQ	Mean n=373	>LOQ	Mean n=263	>LOQ	Mean n=485	>LOQ	Mean n=543	>LOQ	Mean n=430
Acetamiprid	0.01			3	0.01	8	0.01			9	0.011
Aclonifen	0.01	47	0.013								
Acrinathrin	0.01							1	0.01		
Alpha- cypermethrin	0.01									3	0.01
Amitraz	0.01			1	0.01						
Azinphos-methyl	0.01					9	0.011	1	0.01		
Azoxystrobin	0.01	19	0.011	7	0.012			65	0.02	10	0.012
Benalaxyl	0.01									1	0.01
Bifenazate	0.01							12	0.01		
Bifenthrin	0.01			9	0.012	3	0.011	4	0.01	17	0.016
Bitertanol	0.01			1	0.01	6	0.01				
Boscalid	0.01	82	0.018	15	0.012	50	0.015	287	0.087	27	0.042
Bromide Ion	0.1			10	0.160					12	0.120
Bromopropylate	0.01					6	0.011				
Bupirimate	0.01			1	0.01	2	0.01	8	0.013		
Buprofezin	0.01			7	0.011						
Captan	0.01					15	0.026	2	0.012		
Carbaryl	0.01					2	0.01				
Carbendazim	0.01			3	0.01	29	0.012	3	0.011		
Chlorantraniliprole	0.01					6	0.01			2	0.01
Chlorothalonil	0.01			7	0.013						
Chlorpyrifos	0.01	1	0.01	3	0.011	31	0.013	1	0.01	2	0.01
Chlorpyrifos-methyl	0.01			2	0.01			1	0.01		
Clofentezine	0.01							5	0.011		
Cyfluthrin	0.02									5	0.021
Cymoxanil	0.01			1	0.01						
Cypermethrin	0.01			1	0.01					11	0.011
Cyproconazole	0.01							1	0.01		
Cyprodinil	0.01	1	0.01	12	0.014			279	0.046	24	0.022
DDT	0.01	2	0.01							2	0.01
Deltamethrin	0.01									3	0.011

Table 6. Number of samples exceeding LOQ, and calculated mean pesticide concentrations (mg/kg) in carrots, tomatoes, apples, strawberries, and lettuce. The data is based on conventional samples from the Norwegian monitoring programmes 2007 – 2012.

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Phenylphenol-orto 0.01 1 0.01	0.01
Phosmet 0.01 2 0.01 14 Pirimicarb 0.01 19 0.011 11 0.011 14	0.025
Procymidone 0.01 5 0.012 2 0.013 11	0.023
Profenofos 0.01 1 0.01	5.015
Propamocarb 0.01 11 0.043 12	0.25
Propargite 0.01 13 0.013	
Propyzamide 0.01 3	0.01
Pymetrozine 0.01 1 0.01 1 0.01 1 Public 0.01 1 0.01 2 0.01 1 0.023 4	0.011
Pyraclostrobine 0.01 14 0.01 3 0.01 26 0.011 149 0.023 4 Pyridaben 0.01 7 0.01 1 0.01 4	0.013
Pyridaben 0.01 7 0.01 1 0.01 9 Pyrimethanil 0.01 14 0.012 20 0.026 10 0.013 2	0.01
Pyrimethanii 0.01 14 0.012 20 0.026 10 0.015 2 Pyriproxyfen 0.01 6 0.011 1 0.01 1 1	0.01
Quinoxyfen 0.01 9 0.011	-
Quizalofop 0.01 2	0.01
Simazine 0.01 1	0.01

		Car	rrot	Ton	nato	Ар	ple	Straw	berry	Lett	uce
Pesticide	LOQ	>LOQ	Mean n=373	>LOQ	Mean n=263	>LOQ	Mean n=485	>LOQ	Mean n=543	>LOQ	Mean n=430
Spinosad	0.01			1	0.01			7	0.011	11	0.018
Spirodiclofen	0.01					5	0.01	6	0.011		
Tau-Fluvalinate	0.01			1	0.01					4	0.011
Tebuconazole	0.01	2	0.01	4	0.01	1	0.01			1	0.01
Tebufenpyrad	0.01							1	0.01		
Teflubenzuron	0.01					1	0.01				
Tetraconazole	0.01					2	0.01	4	0.01		
Thiabendazole	0.01					42	0.066			1	0.01
Thiacloprid	0.01			6	0.01	26	0.011	66	0.013	1	0.01
Thiamethoxam	0.01									5	0.01
Thiophanate- methyl	0.01			3	0.01	11	0.011				
Tolclofos-methyl	0.01									3	0.018
Tolylfluanid	0.01					3	0.01	5	0.011	2	0.01
Triadimefon/- menol	0.01			10	0.011			5	0.013		
Trifloxystrobin	0.01			1	0.01	2	0.01	27	0.013		
Triflumuron	0.01					3	0.01				
Triforine	0.01					3	0.01				
Vinclozolin	0.01									3	0.011
Zoxamide	0.01			1	0.01						

Long-term exposure to each pesticide/commodity per kg body weight and day are shown in table A2.

Intake calculations were not performed for Norwegian organic samples due to the low number of samples and few findings of pesticides. It seems however clear that the corresponding values for organic products are even lower than those calculated for conventional products.

5 Health risk of single pesticide residues

In this chapter, we will assess the potential human health risk following exposure to single pesticides in fruits and vegetables. For short-term (acute) and long-term (chronic) human health risk assessment, the estimated dietary exposure to a certain pesticide is compared to its toxicological reference values i.e. the ARfD and ADI, respectively. The toxicological reference values are derived following a full hazard identification of a pesticide.

5.1 EFSA AND NORWEGIAN DATA OF CONVENTIONALLY GROWN PRODUCTS

Health risk following short-term (acute) exposure

EFSA data (2010): EFSA studied the risk following acute exposure to 134 pesticides in conventional fruits and vegetables and compared the levels to their respective ARfD (ADI) values. When an ADI value was used instead of an ARfD value, this was because these pesticides have not been evaluated with regard to the setting of an ARfD and/or the setting of an ARfD was not finalized. The residue levels of the 134 different pesticides were measured in the following fruits and vegetables: apples, head cabbage, leek, lettuce, peaches, strawberries and tomatoes. For 20 pesticides, no residues were detected in quantifiable concentrations in any of the samples. For 30 pesticides, at least, one sample that contained residues in concentrations that could be of a potential acute human health risk was identified.

In Table 7, the conventionally grown fruits and vegetables where the ARfD (ADI) was exceeded is shown (EFSA, 2013a).

For 0.4% (79 out of 18243 samples) of conventionally grown fruit and vegetable samples, short-term acute consumer health effects could not be excluded based on the estimated exceeding of the ARfD/ADI values.

Table 7. Type of commodity and pesticide where ARfD is exceeded following short-term dietary exposure assessment. Exposure is expressed as % of ARfD. The figures in brackets show the number of samples exceeding the toxicological reference level. The data is taken from Table 5-3 in the EFSA report (EFSA, 2013a).

Pesticide	Apple	Head cabbage	Leek	Lettuce	Peach	Straw- berry	Tomato
Bifenthrin				112 (2)		•	
Bitertanol					190 (1)		333 (5)
Carbensazim/benomyl	216 (4)				190 (1)		
Carbofuran				323 (1)			
Chlorfenvisphos	196 (1)						
Delthametrin							128 (2)
Dichlorvos	392 (1)						
Dimethoate ¹	1176 (1)			188 (2)	754 (2)		
Dimethoate ²	5878 (5)	234 (2)		942 (13)	3768 (2)		129 (2)
Dithiocarbamates ³				106 (1)			
Dithiocarbamates ⁴	465 (18)	395 (10)	296 (7)	901 (55)	191 (3)	273 (1)	161 (7)
Endosulfan							116 (1)
Ethephon							442 (5)
Ethion						250(1)	
Fenthion	108 (1)						
Folpet ³	133 (3)			229 (6)			
Imazalil	221 (6)						163 (1)
Lamda-Cyhalothrin	114 (1)			237 (6)	158 (1)		
Methamidophos	196 (1)					780(1)	
Methiocarb					187 (1)		
Methomyl/		116(1)				271.2 (1)	
Thiocarb							
Oxamyl		1316(1)				156 (1)	2210 (4)
Oxydemeton-methyl	169 (1)						
Procymidon				157(2)			228 (3)
Pyraclostrobin				108 (1)			
Tau-Fluvalinate				151 (1)			
Tebuconazole	327 (2)				119 (1)		
Thiacloprid	281 (1)						
Thiophanate-methyl					131 (1)		

ARfD used for: ¹dimethoate, ²omethoate, ³mancozeb, ⁴ziram.

Norwegian data (2007-2012): The acute intake of pesticide residues was determined for 117 different pesticides in 635 Norwegian conventional samples of the following fruits and vegetables: carrot, tomato, apple, strawberry and lettuce. For 39 of the 117 different pesticides, the assessment of acute toxicity was not considered relevant. The results are given in Table 8 as percentage of ARfD. None of the samples exceeded the ARfD. For 81 samples the estimated intake of pesticide residues in fruit and vegetables was below 1% of the ARfD.

For 40 samples the intake was between 1 and 10% of ARfD, and in 20 of the samples it was estimated to be between 10 and 100% of the ARfD. It is concluded that the acute human consumer health risk related to the intake of fruit and vegetables on the Norwegian marked is minimal.

Table 8. Summarized results of short-term dietary exposure assessment expressed in % of ARfD.

Yellow: between 1 and 10% of ARfD, Orange: between 10 and 100% of ARfD

Pesticide	ARfD ¹	Source	Carrot	Tomato	Apple	Strawberry	Lettuce
	(mg/kg bw)						
Acetamiprid	0.1	04/99/EC		0.3	1.4		1.3
Aclonifen	na	Dir 08/116				0.1	
Acrinathrin	0.01	EFSA 2013				0.1	0.0
Alpha-cypermethrin	0.04	Dir 04/58		1.2			0.9
Amitraz	0.01	SCoFCAH 4.7.03		1.3	15	0.04	
Azinphos-methyl	0.01	SCoFCAH Mar 06		-	47	0.06	
Azoxystrobin	na	EFSA 2010					
Benalaxyl	na	Dir 04/58					
Bifenazate	na	05/58/EC		2	0	0.00	11
Bifenthrin	0.03	EFSA 11		3	8	0.08	11
Bitertanol	0.01	EFSA 10		6	9		
Boscalid	na	08/44/EC					
Bromide Ion	na	JMPR					
Bromopropylate	na	JMPR					
Bupirimate	na	EFSA 10		0.1			
Buprofezin	0.5	EFSA 10		0.1	0	0.07	
Captan	0.3	SCoFCAH July 08			9	0.07	
Carbaryl	0.01	EFSA 06		0.00	5	0.6	
Carbendazim	0.02	Dir 06/135		0.96	16	0.6	
Chlorantraniliprole	na	EFSA 13		0.2			
Chlorothalonil	0.6	SCoFCAH Septh 06	0.5	0.3	0	0.01	0.2
Chlorpyrifos	0.1	Dir 05/72	0.5	2	8	0.01	0.3
Chlorpyrifos-methyl	0.1	Dir 05/72		0.1		0.003	
Clofentezine	na	Dir 08/69					2
Cyfluthrin	0.02	Dir 03/31		0.1			3
Cymoxanil	0.08	EFSA 08		0.1			0.2
Cypermethrin	0.2	Dir 05/53		0.2		0.02	0.3
Cyproconazole	0.02	11/56/EU				0.02	
Cyprodinil	na	Dir 06/64					
DDT	na	JMPR 2000					0
Deltamethrin	0.01 0.025	Dir 03/5 EFSA 06			14		9
Diazinon					14		
Dichlofluanid	na 0.025	Codex EFSA 10					1
Dicloran			0.1	0.2	0.1		1
Difenoconazole Diflubenzuron	0.16	Dir 08/69 EFSA 2010	0.1	0.2	0.1		
	na						17
Dimethoate Dimethomorph	0.01 0.6	EFSA 2013 Dir 07/25		0.04		0.0007	<u>17</u> 0.1
Diphenylamine	na	EFSA 08		0.04		0.0007	0.1
Diphenylamine	0.012	11/41/EU		}	5		
Dithiocarbamates	na	Codex		}			
Dodine	0.1	EFSA 10			12		
Endosulfan	0.02	JMPR 2006		11	12		
Etofenprox	1	EFSA 08		- 11	0.07		0.05
Famoxadone	0.2	02/64/EC	<u> </u>	0.1	0.07		0.05
Fenamiphos	0.0025	Dir 06/85		13			0.7
Fenazaquin	0.0025	EFSA 2013		0.9	1		
Fenhexamid	na	01/28/EC		0.7			
Fenpropathrin	0.03	JMPR 2012				0.05	
Fenpropimorph	0.03	EFSA 08		1		0.06	
Fenpyroximate	0.02	EFSA 2013			1	0.00	
Fludioxonil	na	Dir 07/76					
1 IduloAviiii	iia	DI 0///0		1	I	1	1

Colour codes: Light yellow: less than 1% of ARfD,

Pesticide	ARfD ¹	Source	Carrot	Tomato	Apple	Strawberry	Lettuce
	(mg/kg bw)	~				~	
Flusilazole	0.005	Dir 06/133			5		
Flutriafol	0.05	11/42/EU		0.2	0.5		0.7
Folpet Glyphosate	0.2 na	SCoFCAH July 08 Dir 01/99					0.7
Hexythiazox	na	11/46/EU					
Imazalil	0.05	EFSA 10		0.3	33		0.2
Imidacloprid	0.08	Dir 08/116		0.1		0.06	9.6
Indoxacarb	0.125	06/10/EC		0.3	0.3		3
Iprodion	na	Dir 03/31					
Kresoxim-methyl	na	99/1/EC		0.0	10	0.2	14
Lambda-Cyhalothrin Linuron	0.0075	Dir 00/80 Dir 03/31	1	0.9	18	0.3	14
Lufenuron	na	Dir 09/77	1				
Malathion	0.3	EFSA 06					0.1
Mandipropamid	na	EFSA 12					
Mepanipyrim	na	04/62/EC					
Metalaxyl	0.5	2010/28/EU	0.03	0.04			0.6
Methamidophos	0.003	Dir 06/131	9			0.0	
Methiocarb Methoayfonozida	0.013	Dir 07/5 0.5/3/EC		0.06	0.6	0.8	
Methocyfenozide Metomyl/tiodikarb	0.2	0.5/3/EC EFSA 06		0.06	0.6		3
Myclobutanil	0.0025	EFSA 00 EFSA 10		0.04	0.2	0.04	
Omethoate	0.002	EFSA 2013		0.01	0.2	0.0.	2
Oxadixyl	0.012	11/49/EU No					3
		authorisation					5
Oxamyl	0.001	Dir 06/16		58			
Penconazole	0.5	Dir 09/77				0.007	
Pencycuron Pendimethalin	na na	1/49/EU Dir 03/31					
Phenmedipham	na	Dir 04/58					
Phenylphenol-orto	na	Codex (1999)					
Phosalone	0.1	EFSA 06			10		
Phosmet	0.045	Dir 07/25			2		
Pirimicarb	0.1	SCoFCAH April 06			2	0.07	12
Procymidone	0.012	DAR 07 JMPR 2007		14		3	11
Profenofos Propamocarb	1	Dir 07/25		2		0.002	40
		No authorisation,		2	0.1		τυ
Propargite	0.012	EFSA 14			81		
Propyzamide	na	Dir 03/39		0.0		0.01	
Pymetrozine Pyraclostrobine	0.1	01/87/EC 04/30/EC	0.5	0.2	9.8	0.01 0.5	1 18
Pyridaben	0.05	EFSA 10	0.5	0.9	9.8	0.5	10
Pyrimethanil	na	Dir 06/74		0.4	1		
Pyriproxyfen	10	Dir 08/69		0.01	0.01		
Quinoxyfen	na	04/60/EC					
Quizalofop	0.1	EFSA 08					0.1
Simazine	0.012	No authorisation, EFSA 14					0.7
Spinosad	na	07/6/EC					
Spirodiclofen	na	EFSA 09					
Tau-Fluvalinate	0.05	EFSA 10		0.8			4
Tebuconazole	0.03	EFSA 08	0.3	0.6	2	0.1	0.4
Tebufenpyrad Teflubenzuron	0.02	Dir 09/11 EFSA 08				0.1	
Tetraconazole	na 0.05	EFSA 08 EFSA 08		0.5		0.06	
Thiabendazole	na	Dir 01/21		0.5		0.00	
Thiacloprid	0.03	04/99/EC		1	5	0.2	0.1
Thiamethoxam	0.5	07/6/EC					0.06
Thiophanate-methyl	0.2	Dir 05/53		0.2	1		
Tolclofos-methyl	na	Dir 06/39			2	0.02	0.07
Tolylfluanid Triadimaton/monol	0.25	Dir 06/06		1	2	0.03	0.05
Triadimefon/-menol Trifloxystrobin	0.08 na	JMPR 2004 03/68/EC		1		0.4	
Triflumuron	na	EFSA 11	<u> </u>				
		No authorisation,			11		
Triforine	0.012	EFSA 14			11		
Vinclozolin	0.06	SCoFCAH Mar 06		0.02			2
Zoxamide 1 na – not applicable	0.3	03/119/EC		0.02			

 1 na = not applicable.

Health risk following long-term (chronic) exposure

EFSA data (2010): The estimated human long-term exposure to pesticides from fruit and vegetables did not exceed the ADI for any pesticides included in the EU-coordinated monitoring programme (EFSA, 2013a). Therefore, based on the current scientific knowledge, no long-term consumer health risk was expected for these compounds. It should be noted that for 105 of the substances (60% of the surveyed substances) the exposure was negligible or accounted for less than 2% of the ADI. For 3 substances the exposure was between 50 - 100% of the ADI (Figure 17). This was for diazinon (93% of ADI), dimethoate/omethoate (87% of ADI) and dithiocarbamate/ziram (86% of ADI).

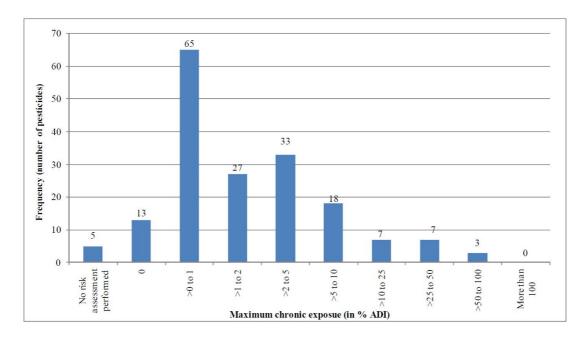


Figure 17. Comparison of the estimated chronic dietary intake of pesticide residues and the respective ADI value. The figure shows the grouping of pesticides according to their exposure expressed in percentage of ADI. The figure is from the EU-coordinated programme 2010 (EFSA, 2013a).

Norwegian data (2007-2012): The calculated chronic intake of pesticide residues was found to be low compared to the ADI values, as shown in Table 9, where the intake for each conventional sample and pesticide is given in percentage of ADI. In addition the intake of each individual pesticide is given as a sum for the five fruit and vegetable commodities studied. The highest value was obtained for diazinon in apples, where the intake was found to be as low as 2.5% of the ADI value. All the other estimated intakes of pesticide residues from carrots, tomatoes, apples, strawberries and lettuce were found to be below 0.3% of ADI, which strongly suggest that chronic health risk from the intake of pesticide residues in fruit and vegetables obtained in Norway is minimal. It is however, important to notice that the five commodities that have been chosen as examples contributes to only about 15% of the total fruit and vegetable intake, based on weight.

Pesticide	ADI	Source	Carrot	Tomato	Apple	Strawberry	Lettuce	% of ADI
	(mg/kg bw)		Currot			Strawberry		(sum)
Acetamiprid	0.07	04/99/EC	0.002	0.002	0.007		0.001	0.011
Aclonifen Acrinathrin	0.07	Dir 08/116 EFSA 2013	0.003			0.003		0.003
Alpha-						0.003		
cypermethrin	0.015	Dir 04/58					0.005	0.005
Amitraz	0.003	SCoFCAH 4.7.03		0.056				0.056
Azinphos-methyl	0.005	SCoFCAH Mar 06			0.108	0.005		0.113
Azoxystrobin	0.2	EFSA 2010	0.001	0.001		< 0.001	< 0.001	0.003
Benalaxyl	0.04	Dir 04/58					0.002	0.002
Bifenazate Bifenthrin	0.01	05/58/EC EFSA 11		0.012	0.026	0.003	0.000	0.003
Bitertanol	0.015 0.003	EFSA 11 EFSA 10		0.013 0.056	0.036 0.163	0.002	0.008	0.059 0.219
Boscalid	0.003	08/44/EC	0.006	0.005	0.105	0.006	0.008	0.219
Bromide Ion	1	JMPR	0.000	0.003	0.010	0.000	0.001	0.004
Bromopropylate	0.03	JMP 1993		01002	0.018		0.001	0.018
Bupirimate	0.05	EFSA 10		0.003	0.01	0.001		0.014
Buprofezin	0.01	EFSA 10		0.018				0.018
Captan	0.1	Dir 07/5			0.013	< 0.001		0.013
Carbaryl	0.0075	EFSA 06		0.00-	0.065	A 444		0.065
Carbendazim	0.02	Dir 06/135		0.008	0.029	0.001	10 001	0.039
Chlorantraniliprole Chlorothalonil	1.56 0.015	EFSA 13 Dir 05/53		0.015	<0.001		< 0.001	<0.001 0.015
Chlorothalonii Chlorpyrifos	0.015	Dir 05/53 Dir 05/72	0.014	0.015	0.064	0.003	0.008	0.015
Chlorpyrifos-			0.014		0.004		0.000	
methyl	0.01	Dir 05/72		0.017		0.003		0.019
Clofentezine	0.02	Dir 08/69				0.001		0.001
Cyfluthrin	0.003	Dir 03/31					0.054	0.054
Cymoxanil	0.013	EFSA 08		0.013				0.013
Cypermethrin	0.05	Dir 05/53		0.003			0.002	0.005
Cyproconazole	0.02	11/56/EU	0.005	0.000		0.001	0.000	0.001
Cyprodinil DDT	0.03	Dir 06/64 JMPR 2000	0.005	0.008		0.004	0.006	0.022 0.022
Deltamethrin	0.01	Dir 03/5	0.014				0.008	0.022
Diazinon	0.001	EFSA 06			2.452		0.009	2.452
Dichlofluanid	0.3	JMPR 1983			0.002			0.002
Dicloran	0.005	EFSA 10					0.015	0.015
Difenoconazole	0.01	Dir 08/69	0.014	0.017	0.049		0.009	0.089
Diflubenzuron	0.1	EFSA 2010			0.005			0.005
Dimethoate	0.001	EFSA 2013		0.000		0.001	0.085	0.085
Dimethomorph	0.05	Dir 07/25		0.003	0.061	0.001	0.002	0.006
Diphenylamine Dithianon	0.073	EFSA 08 11/41/EU			0.001		0.015	0.001
Dithiocarbamates	1	JMPR		< 0.001		< 0.001	<0.013	<0.001
Dodine	0.1	EFSA 10		101001	0.005	101001	101001	0.005
Endosulfan	0.006	JMPR 2006		0.059				0.059
Etofenprox	0.03	EFSA 08			0.016		0.003	0.019
Famoxadone	0.012	02/64/EC		0.014			0.007	0.021
Fenamiphos	0.0008	Dir 06/85		0.21	0.000			0.21
Fenazaquin	0.005	EFSA 2013		0.04	0.098	0.001	0.001	0.138
Fenhexamid Fenpropathrin	0.2	01/28/EC JMPR 1993		0.001	0.002	0.001	0.001	0.006 0.001
Fenpropatirin	0.003	EFSA 08				0.001		0.001
Fenpyroximate	0.005	EFSA 2013			0.049	5.007		0.009
Fludioxonil	0.37	Dir 07/76		< 0.001	0.002	< 0.001	< 0.001	0.003
Flusilazole	0.002	Dir 06/133			0.245			0.245
Flutriafol	0.01	11/42/EU		0.017				0.017
Folpet	0.1	Dir 07/5					0.001	0.001
Glyphosate	0.3	Dir 01/99		0.007	0.002	0.001		0.002
Hexythiazox	0.03	11/46/EU		0.006	0.024	0.001	0.002	0.007
Imazalil Imidacloprid	0.025	EFSA 10 Dir 08/116		0.007 0.003	0.024	<0.001	0.003	0.033 0.006
Indoxacarb	0.006	06/10/EC		0.003	0.082	<0.001	0.003	0.006
Iprodion	0.000	Dir 03/V92	0.008	0.028	0.082	0.001	0.005	0.120
Kresoxim-methyl	0.4	99/1/EC	0.000	0.000	0.025	<0.001	<0.001	0.002
Lambda-Cyhalothrin	0.005	Dir 00/80		0.034	0.098	0.005	0.017	0.154
			·					44

Table 9. ADI for each pesticide, and exposure calculations expressed in % of ADI for each food, and the exposure from the five example fruits and vegetables together.

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Destiside	ADI	Sauraa	Carrot	Tomoto	Annlo	Strawberry	Lattuce	% of ADI
Pesticide	(mg/kg bw)	Source	Carrot	Tomato	Apple	Strawberry	Lettuce	(sum)
Linuron	0.003	Dir 03/31	0.047					0.047
Lufenuron	0.015	Dir 09/77		0.011				0.011
Malathion	0.03	EFSA 06					0.003	0.003
Mandipropamid	0.15	EFSA 12					0.001	0.001
Mepanipyrim	0.02	04/62/EC		0.008		0.002		0.011
Metalaxyl	0.08	2010/28/EU	0.002	0.002			0.001	0.005
Methamidophos	0.001	Dir 06/131	0.142			0.002		0.142
Methiocarb	0.013	Dir 07/5		0.000	0.005	0.002		0.002
Methocyfenozide	0.1	0.5/3/EC EFSA 06		0.002	0.005		0.021	0.007
Metomyl/tiodikarb	0.0025			0.007	0.02	0.001	0.031	0.031
Myclobutanil Omethoate	0.025	EFSA 10 EFSA 2013		0.007	0.02	0.001	0.259	0.028
Omethoate	0.0003	No authorisation,					0.258	0.258
Oxadixyl	0.011	EFSA 14					0.008	0.008
Oxamyl	0.001	Dir 06/16		0.185				0.185
Penconazole	0.03	Dir 09/77				0.001		0.001
Pencycuron	0.2	11/49/EU					< 0.001	< 0.001
Pendimethalin	0.125	Dir 03/31				0.001	0.001	0.001
Phenmedipham	0.03	Dir 04/58			0.001	0.001		0.001
Phenylphenol-orto	0.4	Codex (1999)			0.001			0.001
Phosalone	0.01	EFSA 06			0.064			0.064
Phosmet	0.01	Dir 07/25		-	0.049	0.001	0.007	0.049
Pirimicarb	0.035	Dir 06/39		0.072	0.015	0.001 0.012	0.006	0.022
Procymidone	0.0028	DAR 07		0.072			0.036	0.12
Profenofos	0.03 0.29	JMPR 2007 Dir 07/25		0.002		0.001	0.007	0.001 0.009
Propamocarb		No authorisation.		0.002			0.007	
Propargite	0.012	EFSA 14			0.064			0.064
Propyzamide	0.02	Dir 03/39					0.004	0.004
Pymetrozine	0.03	01/87/EC		0.006		0.001	0.003	0.009
Pyraclostrobine	0.03	04/30/EC	0.005	0.006	0.018	0.002	0.003	0.034
Pyridaben	0.01	EFSA 10		0.017	0.049			0.066
Pyrimethanil	0.17	Dir 06/74		0.001	0.007	< 0.001	< 0.001	0.009
Pyriproxyfen	0.1	Dir 08/69		0.002	0.005	0.001		0.007
Quinoxyfen	0.2	04/60/EC				< 0.001	0.000	< 0.001
Quizalofop		EFSA 08 No authorisation,					0.006	0.006
Simazine	0.011	EFSA 14				0.001	0.008	0.008
Spinosad	0.024	07/6/EC		0.007		0.001	0.006	0.014
Spirodiclofen	0.015	EFSA 09		0.024	0.033	0.002	0.015	0.035
Tau-Fluvalinate	0.005	EFSA 10	0.005	0.034	0.016		0.017	0.051
Tebuconazole Tebufenpyrad	0.03	EFSA 08 Dir 09/11	0.005	0.006	0.016	0.003	0.003	0.029 0.003
Teflubenzuron	0.01	EFSA 08		-	0.049	0.005		0.003
	0.004	EFSA 08			0.123	0.006		0.129
Tetraconazole Thiabendazole	0.004	Dir 01/21			0.032	0.000	0.001	0.033
Thiacloprid	0.01	04/99/EC		0.017	0.052	0.003	0.001	0.082
Thiamethoxam	0.026	07/6/EC		0.017	0.054	0.005	0.003	0.002
Thiophanate-	0.020	Dir 05/53		0.002	0.007		0.005	0.009
methyl				0.002	0.007		0.002	
Tolclofos-methyl	0.064	Dir 06/39			0.007	0.001	0.002	0.002
Tolylfluanid	0.1	Dir 06/06			0.005	< 0.001	0.001	0.006
Triadimefon/- menol	0.03	JMPR 2004		0.006		0.001		0.007
Trifloxystrobin	0.1	03/68/EC		0.002	0.005	< 0.001		0.007
Triflumuron	0.014	EFSA 11			0.035			0.035
Triforine	0.02	JMPR 1997		1	0.025			0.025
Vinclozolin	0.005	SCoFCAH Mar 06					0.017	0.017
Zoxamide	0.5	03/119/EC		< 0.001				< 0.001

5.2 EFSA AND NORWEGIAN DATA OF ORGANIC PRODUCTS

Risk following short- and long-term exposure

EFSA data (2010): None of the organic samples in the 2010 EU-coordinated monitoring programme were found to contain pesticide residue levels that exceeded toxicological reference values (ADI/ARfD).

Norwegian data (2007-2012): The number of Norwegian organic samples analysed for pesticide residues was low, which made it difficult to perform risk assessment calculations. The measured levels of the few findings of pesticide residues in organic food were however close to LOQ, and far from exceeding any toxicological reference values.

The human health risk following short-term and long-term exposure to pesticide residues from intake of organic fruit and vegetables is considered minimal.

5.3 OTHER PUBLISHED RESULTS OF HEALTH RISK RELATED TO PESTICIDES IN CONVENTIONALLY AND ORGANIC PRODUCTS

In a Danish study from 2012, a total of 2338 surveillance samples were analysed and 1447 of these were from conventional fruit and vegetables (Fødevarestyrelsen, 2012). Furthermore, 112 samples were from organic fruit and vegetables. The Danish study concluded that with regard to pesticide residues there was no human acute or chronic health risk associated with intake of conventional or organic fruit and vegetables in Denmark.

In an Italian study, 3508 samples of food from plant origin were analysed between 2002 and 2005 (Tasiopoulou et al., 2007). Of these samples, 266 (7%) were from organic products. Only one out of 266 organic samples contained a pesticide residue (dicofol in potatoes) above the MRL. Risk assessment was performed both for acute and chronic exposure to dicofol, although an ARfD value was not available for dicofol. A "worst case scenario" using the ADI value as ARfD was used, and the calculated intake of pesticide residues related to short-term consumption of potatoes was found to be below the toxicological reference value (63.9 and 97.6% for adults and children, respectively). For chronic exposure the intake was estimated to be far below the ADI, for adults 3.5% and for children 5% of ADI (Tasiopoulou et al., 2007). It should be noted that the use of dicofol is no longer allowed in Europe.

6 Combined exposure and cumulative assessment

6.1 **BASIC PRINCIPLES**

As people may be exposed to more than one pesticide either within one meal, in one type of food or by consuming different types of food over a longer period of time, it is of importance to assess whether combined exposure to different pesticides may pose a health risk.

An extensive summary of the principles for combined toxic effects of multiple chemical exposures has been presented by VKM (VKM, 2008, VKM, 2013). Distinction was made between chemicals that act by similar mode of action (similar mechanism) and chemicals that

act by different modes of action, in the evaluation of combined toxic effects of chemical mixtures. If chemicals act by a similar mode of action, dose addition is assumed and adverse effects of the mixture may be expected even if the individual chemical is present at doses below their effect level. If chemicals act by different modes of action effect addition is assumed, and, hence, adverse effects are considered unlikely, if each chemical in the mixture is present at doses below their respective zero effect level.

Toxic interactions (synergy, antagonism and potentiation) between chemicals in a mixture are reported. In a recent review, it was shown that in most of the studies, interactions were observed at doses above their respective point of departure (BMDL/NOAEL) (Boobis et al., 2011). This supports the conclusion drawn by EFSA that significant toxic interactions are "-much less likely to occur at doses below the effect level for individual component compounds than at higher doses" (EFSA, 2008). Based on current knowledge, synergistic interactions (i.e. effects greater than additive) are not considered likely to occur at the low exposure levels that are typical of pesticide residues present in food (EFSA, 2013b).

It should be noted that in the following text cumulative risk refers to risk resulting from exposure to more than one pesticide via the diet per day, and the principle of dose-addition, when relevant for a group of chemicals, is applicable for evaluation of combined toxicity.

6.2 STRATEGIES FOR GROUPING INTO COMMON ASSESSMENT GROUPS

There are no internationally agreed criteria for how to group pesticides into common assessment groups (CAGs), but grouping based on similar mechanism/mode of action or grouping by common toxic effect is discussed as applicable.

Grouping approach by EFSA

According to the WHO methodology and risk assessment approach used at EU level in the framework of pesticide authorisations and MRL setting, the dietary exposure to pesticide residues is calculated for each individual active substance separately (FAO/WHO, 2009). However, Regulation (EC) No 396/2005 acknowledges that consumers are expected to be exposed to multiple residues present in food eaten within one meal, during one day or over a longer period which may lead to cumulative (additive or synergistic) effects on human health.

Based on this, EFSA recently published a scientific opinion on the identification of pesticides to be included in CAGs on the basis of their toxicological profile (EFSA, 2013b). This opinion describes a stepwise methodology specifically developed for grouping of pesticides based on common toxic effects and it was developed on the basis of oral toxicity studies in order to take cumulative effects into account in the MRL settings. The methodology comprises four main steps (Identification of the specific effects, Characterisation of the specific effects, Data collection and Grouping of pesticides into CAGs) and its application to pesticides with effects on the nervous and thyroid system. It is recommended that the methodology for developing CAGs of pesticides should be implemented for all major organs/organ systems (EFSA, 2013b).

The method for grouping pesticides into CAG was based on the assumption that pesticides producing the same toxic effects in tissues, organs and physiological systems have the capability to produce joint, cumulative toxicity. The proposed grouping methodology results

in a sufficiently conservative approach, which is agreed upon by the European Commission and EFSA: when insufficient or no information is available, it is assumed that chemicals with similar effects may have a similar mode of action, even though they exhibit a wide range of chemical structural features. This view is based on empirical evidence that chemically unrelated substances may have a common joint effect in target organs/organ systems, which can be well approximated by dose addition (Kortenkamp A., 2009). Chemicals may be excluded from a CAG provided their modes of actions are different.

Grouping approaches by other international bodies

In contrast to a hazard related methodology described by EFSA, The French Agency for Food, Environmental and Occupational Health and Safety (ANSES) has chosen an approach that is based on exposure and defining the major combinations of chemical mixtures to which the French population is exposed to through their diet. The first approach is to use exposure data to make subgroups of individuals with similar exposure profile, and then the correlations between chemicals are used to define the mixture (Crepet et al., 2013b, Crepet and Tressou, 2011). A second approach is to first define subgroups of individuals from their consumption patterns, and then combine consumption patterns with residue levels. A third approach is to add hazard information in the process of mixture identification. These approaches will be used on a data set of 79 pesticides in the PERICLES research program where food combinations forms the basis for clustering of diets, and then identify main mixtures of pesticides associated to these food combinations (Crepet et al., 2013a).

The US Environmental Protection Agency (US EPA) currently conducts cumulative risk assessment (CRA) on five groups of pesticides: Organophosphates, N-methyl carbamates, s-triazines, chloroacetanilides and, pyrethroids and pyrethrins (EPA, 2012). In all these cases, pesticides that induce a common toxic effect by a common mechanism of toxicity are grouped together. A common toxic effect is defined to exist if chemicals act in a similar way in the body, i.e. the same toxic effect occurs in the same organ or tissue by essentially the same sequence of chemical events.

National Institute of Environmental Health Sciences, USA (NIEHS), is engaged in diverse research initiatives to evaluate toxicity of mixtures, ranging from epidemiological studies that intrinsically consider complex environmental exposures to toxicological studies of defined mixtures including pesticides/fertilizers. As a result of a workshop in 2011, NIEHS is focusing on improved exposure assessment, application of systems biology approaches in mixture research, tools and methodologies for prioritisation of mixtures for toxicological evaluations, and further development for determining sufficient similarity of complex mixtures (NIEHS, 2011).

Grouping of multiple pesticide residues – an approach by the Norwegian Food Safety Authority

The Norwegian Food Safety Authority is responsible for the annual monitoring programme of pesticides in Norway. They are now in the process of establishing a system where combined effects are considered if several substances from the following groups are found in one food sample: Triazoles, carbamates, pyrothroids, neonicotinoids and organophosphates. For the time being, only samples with residues above MRL are subject to further evaluation in order to identify residues within the abovementioned groups. When several substances from the defined groups are found in one sample, the possibility of combined toxic effects is included

in the hazard characterisation. The principle of dose-addition is used, and the levels of the selected residues are added. The total level is then compared to the lowest acute reference dose (ARfD) of the substances included in the mixture.

6.3 CUMULATIVE RISK ASSESSMENT OF PESTICIDES

The EU-funded ACROPOLIS project

Several reports and meetings have highlighted the ongoing research and the need for methods to assess the risk of combined exposures (Kortenkamp A., 2009, SCHER, 2012, WHO, 2009). The ongoing EU-financed project ACROPOLIS specifically aims to improve risk assessment strategies in Europe and has developed a framework for cumulative and aggregate risk assessment of pesticides. Cumulative risk assessment is based on dietary exposure, whereas aggregate risk assessment combines dietary and non-dietary sources (e.g. occupational farming activities). Furthermore, the project intends to provide an adequate tool for risk assessment and risk management so that future consumers might gain confidence in the regulatory process and the legislation on pesticide safety evaluations and also connect innovation in the area of complex model development to practical needs and expectations of the European Commission (ACROPOLIS, 2013).

Cumulative risk assessment by EFSA

No internationally agreed methodology is available to assess cumulative exposure. Therefore, EFSA has worked intensively on this subject. In a previous opinion on risk assessment of combined pesticide residues in food, EFSA recommended that a tiered approach should be adopted both for hazard and exposure assessments and proposed criteria for grouping active substances into CAGs, based on chemical structure, mechanism of pesticide action, mode/mechanism of mammalian toxicity and common toxic effects (EFSA, 2008). In a second opinion, the proposed approach was carried out on a cumulative risk assessment (CRA) of a group of triazole pesticides (EFSA, 2010).

In a more recent report, EFSA presented a pilot CRA (chronic and acute) to multiple pesticide residues (EFSA, 2013a). It should be noticed that this assessment was performed to explore potential deficiencies resulting from the monitoring data generated by the reporting countries and other limitations that may impede the practical use of methodologies currently under development. The modelling approach was based on dose addition of compounds belonging to the organophosphates and N-methyl carbamates which cause a common toxic effect, and residue data reported in the EU-coordinated monitoring programme and in the national framework. The results of three suggested scenarios showed a large variation in the estimated chronic consumer exposure (see short summary below). Comparison of the outcome of the three scenarios demonstrated that the estimated level of exposure is greatly influenced by the values used for residues that are not detected/below LOQ, thus the non-detects represent a main uncertainty.

Short summary of the modelling approach

The overall chronic exposure from 42 pesticides (32 organophosphates and 10 carbamates), covering a total of 27 food commodities, was calculated. The monitoring data showed that a high percentage of the food samples did not contain measurable residues of pesticides belonging to the CAG (below LOQ), and one of the main reasons for doing this model calculation was to investigate the impact of such non-detects on the exposure estimates. Three

scenarios with different strategies for how to deal with this were chosen. In an unrealistic and most conservative worst-case scenario, all samples without detected residues were considered to contain residues at the LOQ. It was also assumed that each individual food commodity contained residues of each pesticide at least up to this level. In a second scenario, the LOQ for non-detects were set to zero for the pesticide/crop combinations for which MRLs are set to LOQ. In the third scenario, all samples with no detected residues were set to zero. Depending on how the non-detects were dealt with, the estimated overall exposures ranged from 46% to a maximum of 354% of the ADI in the most conservative and unrealistic scenario, a maximum of 150% in the second scenario and in the third scenario were non-detects were set to zero the estimated maximum exposure was reduced to 16% of ADI.

For the acute situation, EFSA chose to estimate the exposure resulting from consumption of a single food containing residues of multiple pesticides during a single meal. Lettuce samples were chosen, and the exposure from a single sample was estimated by summing up all the individual compounds present and dose addition was assumed by default. In this exercise, all residues were grouped together without taking into account whether they belonged to a CAG. EFSA reports that under these very conservative assumptions, acute combined exposure accounted for less than 10% of the ARfD for the majority of the samples.

EFSA concludes that it is not possible to draw a conclusion on whether the exposure to the pesticides present in the CAG represents a potential long-term consumer health risk. Based on the outcome of the pilot cumulative risk assessment, EFSA is of the opinion that exposure calculations are affected by significant uncertainties, mainly related to the analytical results reported as non-detect (EFSA, 2013a). The work with establishing CAGs and the methodology is not completed. Therefore, the results of the estimated exposure assessments should be regarded as indicative only. EFSA concluded that before cumulative risk assessment with monitoring data, the following steps are to be taken:

- Definition of common assessment groups and establishment of adjusted hazard indices or relative potency factors
- Agreement on the risk assessment tools for screening and for refined combined exposure calculations
- Development of an approach to deal with pesticides below LOQ (non-detects)
- Improvements of monitoring data/data reporting

Combined exposure and cumulative risk assessment based on Norwegian data

Data from the Norwegian monitoring programme shows that residues of several pesticides were detected in single samples of conventionally grown food collected in Norway, but not in organic samples (Figure 16).

In order to make a tentative estimate of an acute combined exposure based on Norwegian data, apple was chosen as an example of a food item with several pesticide residues in one sample. In 69 out of 485 samples one or more findings at or above LOQ was found and a maximum of 7 different pesticide residues were found in one apple. However, for more than 99% of the detected pesticide residues the exposure levels represented less than 10% of their respective ARfDs when an intake of 250 g apples per day was assumed. Exposure levels

between 10% - 25% of their respective ARfD were only demonstrated in six samples (representing four different pesticides). These results indicate that an estimated combined exposure of several pesticides present in one apple is below the ARfD, even if all pesticides present are grouped together, irrespective of their mode of action. An acute health risk will therefore not be expected. With respect to a chronic combined exposure to pesticides, the EFSA model assessment demonstrated clearly the large uncertainty in exposure assessments caused by the non-detects, and suggests several steps to reduce this. An estimate based on Norwegian data has therefore not been performed.

In summary, no accepted methodology is presently established for a cumulative risk assessment of pesticide residues. However, based on the frequency of occurrence and levels of the reported pesticide residues found in samples collected in Norway, it is not expected that the combined exposure to multiple pesticide residues should pose a human health risk.

7 Uncertainty, data gaps

There are limited amounts of data available on pesticide residues in organic samples.

There is an inherent challenge in the quantitative comparison of data with large variation in measured values of a large number of substances and commodities.

Comparison between different datasets is further complicated by different types of products analysed, the number of pesticides analysed for, the way the samples were selected and the analysis sensitivity.

Accepted and validated methods for determination of combined exposure and cumulative risk assessment are not established.

Dietary assessments are associated with uncertainties. The dietary assessment method used in Norkost 3 is two times 24-hour recalls. This method used in a large sample will give a fairly good estimate of large portions used in the acute exposure assessment. However, underreporting is known to be a challenge in dietary assessment, and this is also the case among the larger portions (eg. 97.5 percentile). For the long-term exposure assessment, it might be that 24-hour recall will give a low estimate, but the overall mean is more robust than the higher percentiles.

There is limited mechanistic understanding to perform cross species extrapolation from high dose experimental animal studies to low dose human exposure and therefore difficult to determine the human relevance.

Epidemiological studies are challenging because of many confounding factors and difficulties with the determination of exposure. An aim for the future is to combine new methods for determination of actual exposure and/or the establishment of useful biomarkers for exposure with prospective epidemiological studies, supplemented with mechanism based assays.

8 Conclusion

The present report on pesticide residues in organic and conventional food is based on data collected by EFSA, the Norwegian monitoring programme and other reported data. The main conclusion to be drawn is that the general levels of pesticide residues in both conventional and organic food are low, and well below what is likely to result in adverse health effects. This conclusion is based on the comparison of estimated dietary exposure with toxicological reference values i.e. ADI for chronic effects, and ARfD for acute effects. The finding of pesticide residues that exceeds established regulatory limits in a minority of tested samples is not considered to represent a health risk. Although the data, in part, is insufficient to perform quantitative comparisons of residue levels between conventional and organic products, it is concluded that organic food contains far lower numbers and amounts of pesticides than conventional food. No generally accepted methodology is at present established for cumulative risk assessment of combined exposure to pesticide residues. Available data suggest however that combined exposure is not likely to result in increased human health risk.

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Appendix

Pesticide Carrot Tomato Apple Strawberry Lettuce Actinniprid 0.000257 0.001355 0.001274 Actinathrin 0.000948 0.00001 0.00001 Alpha.cxpernethrin 0.000128 0.000010 0.000074 Anireze 0.000128 0.000172 0.000017 0.000017 Aniphos.methyl 0.000745 0.001411 0.000017 0.000001 Brenarete 0.00126 0.002444 0.000032 0.000003 Bifentrin 0.00026 0.002444 0.000031 0.000043 Bromide Ion 0.000261 0.000248 0.000734 0.00173 Bromide Ion 0.00031 0.000041 0.000192 0.0000081 Bupirimate 0.000130 0.000015 0.00115 Carbendzim 0.000192 0.000015 0.000192 Chorpartios 0.000192 0.000003 0.00003 Chorpartios 0.000052 0.000003 0.000003 Chorbandzim 0.0000128 0.0000003<						
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Imazalil 0.000128 0.016258 0.000085 Imidacloprid 0.00009 0.000046 0.007641 Indoxacarb 0.0002574 0.001154 0.036129 0.000238 0.008915			0.000128		0.000024	
Imidacloprid 0.00009 0.000046 0.007641 Indoxacarb 0.00034 0.000316 0.004118 Iprodion 0.002574 0.001154 0.036129 0.000238 0.008915				0.016258		0.000085
Indoxacarb 0.00034 0.000316 0.004118 Iprodion 0.002574 0.001154 0.036129 0.000238 0.008915					0.000046	
	Indoxacarb		0.00034	0.000316		0.004118
	Iprodion	0.002574	0.001154	0.036129	0.000238	0.008915
				0.000903		

 Table A1. Acute exposure for each pesticide/food commodity, mg/kg bw/day.

Pesticide	Carrot	Tomato	Apple	Strawberry	Lettuce
Lambda-Cyhalothrin		0.000071	0.001355	0.000019	0.001061
Linuron	0.000339				
Lufenuron		0.000077			
Malathion					0.000297
Mandipropamid					0.003948
Mepanipyrim		0.000289		0.000183	
Metalaxyl	0.000135	0.000199			0.002929
Methamidophos	0.000271				
Methiocarb				0.000102	
Methocyfenozide		0.000128	0.001197		0.000005
Metomyl/tiodikarb		0.000120	0.000(77	0.000121	0.000085
Myclobutanil Omethoate		0.000128	0.000677	0.000121	0.000042
Ometnoate					0.000042 0.000297
Oxadixyi		0.000577			0.000297
Penconazole		0.000577		0.000037	
Pencycuron		+		0.000037	0.002887
Pendimethalin					0.002887
Phenmedipham				0.000009	0.000003
Phenylphenol-orto			0.000903	0.000009	
Phosalone			0.010387		
Phosmet		1	0.000677		
Pirimicarb			0.002258	0.000074	0.012311
Procymidone		0.001731		0.000341	0.001358
Profenofos				0.000015	
Propamocarb		0.017956			0.399045
Propargite			0.008129		
Propyzamide					0.000127
Pymetrozine		0.000205		0.000009	0.001274
Pyraclostrobine	0.000135	0.000257	0.002935	0.000164	0.005519
Pyridaben		0.000192	0.000677		
Pyrimethanil		0.001411	0.05871	0.000204	0.000255
Pyriproxyfen		0.000898	0.000452		
Quinoxyfen				0.000059	
Quizalofop					0.000085
Simazine					0.000072
Spinosad		0.00009		0.00004	0.00849
Spirodiclofen			0.000677	0.00009	
Tau-Fluvalinate	0.000005	0.000385	0.000450		0.001953
Tebuconazole	0.000095	0.000192	0.000452	0.000022	0.000127
Tebufenpyrad			0.000452	0.000023	
Teflubenzuron		0.000257	0.000452	0.000028	
Tetraconazole Thiabendazole		0.000257	0.083548	0.000028	0.000068
Thiacloprid		0.000385		0.000056	0.000068
Thiamethoxam		0.000385	0.001581	0.000030	0.000042
Thiophanate-methyl		0.000385	0.002258	+	0.000318
Tolclofos-methyl		0.000303	0.002230		0.013585
Tolylfluanid		1	0.00429	0.000071	0.000127
Triadimefon/Triadimenol		0.000962	0.00427	0.000279	0.000127
Trifloxystrobin		0.000192	0.000677	0.0000275	
Triflumuron			0.000903		
Triforine			0.001129		
Vinclozolin					0.001019
Zoxamide		0.000064			

Pesticide	Carrot	Tomato	Annlo	Strawberry	Lettuce
Acetamiprid	Carrot	0.000002	Apple 0.000005	Strawberry	0.000001
Aclonifen	0.000002	0.000002	0.000005		0.000001
Acrinathrin				< 0.000001	
Alpha-cypermethrin					0.000001
Amitraz		0.000002			
Azinphos-methyl			0.000005	< 0.000001	
Azoxystrobin	0.000002	0.000002		0.000001	0.000001
Benalaxyl				0.000001	0.000001
Bifenazate		0.000002	0.000005	<0.000001 <0.000001	0.000001
Bifenthrin Bitertanol	-	0.000002	0.000005	<0.00001	0.000001
Boscalid	0.000003	0.000002	0.000003	0.000002	0.000003
Bromide Ion	0.000005	0.00002712	0.000007	0.000002	0.0000093
Bromopropylate		0.00002712	0.000005		0.0000075
Bupirimate		0.000002	0.000005	< 0.000001	
Buprofezin		0.000002			
Captan			0.000013	< 0.000001	
Carbaryl			0.000005		
Carbendazim		0.000002	0.000006	< 0.000001	
Chlorantraniliprole			0.000005	ļ	0.000001
Chlorothalonil	0.000	0.000002	0.0000		0.0000
Chlorpyrifos	0.000001	0.000002	0.000006	<0.000001	0.000001
Chlorpyrifos-methyl Clofentezine		0.000002		<0.000001	
<u>Clofentezine</u> Cyfluthrin				<0.000001	0.000002
Cymoxanil		0.000002			0.000002
Cypermethrin		0.000002			0.000001
Cyproconazole		0.000002		< 0.000001	0.000001
Cyprodinil	0.000001	0.000002		0.000001	0.000002
DDT	0.000001				0.000001
Deltamethrin					0.000001
Diazinon			0.000005		
Dichlofluanid			0.000005		
Dicloran					0.000001
Difenoconazole	0.000001	0.000002	0.000005		0.000001
Diflubenzuron			0.000005		0.000001
Dimethoate Dimethomorph		0.000002		<0.000001	0.000001 0.000001
Diphenylamine		0.000002	0.000046	<0.000001	0.000001
Dithianon			0.000040		0.000002
Dithiocarbamates		0.000002		< 0.000001	0.000002
Dodine			0.000005		
Endosulfan		0.000004			
Etofenprox			0.000005		0.000001
Famoxadone		0.000002			0.000001
Fenamiphos		0.000002			
Fenazaquin	-	0.000002	0.000005	0.000000	0.000001
Fenhexamid	-	0.000003	0.000005	0.000003	0.000001
Fenpropathrin Fenpropimorph				<0.000001 <0.000001	<u> </u>
Fenpropimorph Fenpyroximate			0.000005	<0.000001	
Fludioxonil		0.000002	0.000003	0.000001	0.000002
Flusilazole		0.00002	0.000003	0.00001	0.000002
Flutriafol		0.000002		1	
Folpet		-			0.000001
Glyphosate			0.000005		
Hexythiazox		0.000002		< 0.000001	
Imazalil		0.000002	0.000006		0.000001
Imidacloprid		0.000002		< 0.000001	0.000002
Indoxacarb		0.000002	0.000005		0.000001
Iprodion	0.000005	0.000002	0.000015	0.000001	0.000003
Kresoxim-methyl	-	0.000002	0.000005	<0.000001	0.000001
Lambda-Cyhalothrin	0.000001	0.000002	0.000005	<0.000001	0.000001
Linuron Lufenuron	0.000001	0.000002			
Malathion		0.000002			0.000001
Mandipropamid					0.000001
manupi opannu		I I		1	0.000001

Pesticide	Carrot	Tomato	Apple	Strawberry	Lettuce
Mepanipyrim		0.000002		< 0.000001	
Metalaxyl	0.000001	0.000002			0.000001
Methamidophos	0.000001				
Methiocarb				< 0.000001	
Methocyfenozide		0.000002	0.000005		
Metomyl/tiodikarb					0.000001
Myclobutanil		0.000002	0.000005	< 0.000001	
Omethoate					0.000001
Oxadixyl					0.000001
Oxamyl		0.000002			
Penconazole				< 0.000001	
Pencycuron					0.000001
Pendimethalin					0.000001
Phenmedipham				< 0.000001	
Phenylphenol-orto			0.000005		
Phosalone			0.000006		
Phosmet			0.000005		
Pirimicarb			0.000005	< 0.000001	0.000002
Procymidone		0.000002		< 0.000001	0.000001
Profenofos				< 0.000001	
Propamocarb		0.000007			0.000019
Propargite			0.000006		
Propyzamide					0.000001
Pymetrozine		0.000002		< 0.000001	0.000001
Pyraclostrobine	0.000001	0.000002	0.000005	0.000001	0.000001
Pyridaben		0.000002	0.000005		
Pyrimethanil		0.000002	0.000013	0	0.000001
Pyriproxyfen		0.000002	0.000005		
Quinoxyfen				< 0.000001	
Quizalofop					0.000001
Simazine					0.000001
Spinosad		0.000002		< 0.000001	0.000001
Spirodiclofen			0.000005	< 0.000001	
Tau-Fluvalinate		0.000002			0.000001
Tebuconazole	0.000001	0.000002	0.000005		0.000001
Tebufenpyrad				< 0.000001	
Teflubenzuron			0.000005		
Tetraconazole			0.000005	< 0.000001	
Thiabendazole			0.000032		0.000001
Thiacloprid		0.000002	0.000005	< 0.000001	0.000001
Thiamethoxam					0.000001
Thiophanate-methyl		0.000002	0.000005		
Tolclofos-methyl					0.000001
Tolylfluanid			0.000005	< 0.000001	0.000001
Triadimefon/Triadimenol		0.000002		< 0.000001	
Trifloxystrobin		0.000002	0.000005	< 0.000001	
Triflumuron			0.000005		
Triforine			0.000005		
Vinclozolin					0.000001
Zoxamide		0.000002			