Food Safety AUTHORITY OF IRELAND

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Pesticides in Food

The aim of this document is to provide food business operators (FBOs), enforcement officers and other stakeholders with a concise overview of the regulation of pesticide residues in food. It gives information on methods of sampling and analysis for these contaminants and the legislative control measures in place to control their presence in food. Finally, it provides a short guidance for FBOs on the risk management measures that they should have in place to control residues of pesticides in food and also a bibliography giving sources of further information. The summary below gives a short synopsis of the information, while the following pages provide more technical detail.

Summary

The term 'pesticides' covers plant protection or biocidal products that are either chemical or biological in nature. Pesticides are used to control, repel or prevent the effects of harmful organisms (fungal diseases, weeds, insect pests, or other unwanted organisms) in agriculture, industry, public health and the home. Pesticide active substances are biologically active and prior to being authorised for use must be assessed to ensure that their use will not give rise to any unacceptable risks to man, animals or to the environment. As part of this assessment, pesticides are fully investigated for potential adverse health effects relevant for humans. The endpoints investigated include acute, sub-chronic and long term toxicity, neurotoxicity, genetic and reproductive and developmental effects. Before a pesticide is used, a full risk assessment is always carried out on it, using exposure assessments for infants, toddlers, those occupationally exposed, the elderly or persons whose systems are under stress because of illness and who may be especially vulnerable to possible adverse effects of pesticides. In the case of sensitive individuals, several factors including developing or saturated metabolic systems, and food intake per unit bodyweight, that may make these groups more vulnerable than healthy adults, are taken into account.

For the general population exposure to applied pesticides mainly occurs via residues remaining in food of plant origin. Maximum Residue Limits (MRLs) are put in place to control the use of plant protection products. When these limits are established an assessment is always carried out to ensure that the values set will not pose a risk to consumers. MRLs for food are set out in EU legislation and these are enforced by means of national surveillance programmes. Separate specific legislation is in place to control pesticide residues in commercial baby food products. MRLs are statutory limits for trade in food. They are derived from studies/trials that establish the residues that remain in a commodity following the use of a plant protection product according to specified use conditions (Good Agricultural Practice (GAP)).

EU legislation governs the approval, marketing and use of pesticides as well as the permissible levels of residues in food. Council Directive 91/414/EEC states that active substances cannot be used in pesticides products unless they are included in a positive list. Since 1996, EU Member States have been participating in annual EU Co-ordinated pesticide residue monitoring programmes in addition to implementing their own nationally tailored programmes. The Irish monitoring programme is carried out by the Pesticide Control Service of the Department of Agriculture, Fisheries and Food (DAFF) under service contract to the Food Safety Authority of Ireland (FSAI). When MRLs are exceeded, science-based risk assessments are made to determine the possible health risks for consumers. The results of these checks show that pesticide residues in Irish food are generally at very low levels, and are considered to present little risk to the health of the Irish consumer, although occasional instances of unacceptable levels of contamination are detected.

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Reflecting the overall responsibility placed on FBOs by the General Food Law (Directive 178/2002) to supply safe food, the principal control over the levels of pesticides in food lies in the hands of farmers and growers. If plant protection products are applied in accordance with GAP, e.g. by following the specified label instructions, residues in excess of the established MRLs should not occur.

1. Introduction

A **pest** is any wild animal, plant, fungi, virus, bacteria, insect etc that causes unacceptable damage to man, animals, crops or other objects. The chemical or biological agents used to control and manage these pests are called pesticides and are marketed as plant protection or biocidal products. Biocidal products are not used in crop production and include products used against domestic pests, disinfectants, wood preservatives etc. They are selected because of a known intrinsic property that can be used to control one or more pests. The borderline between biocides and plant protection products is continually being defined and clarified, and about 100 active substances are common to both groups. Within the EU and elsewhere in the world, pesticides are very closely controlled. They are not authorised for use unless they undergo a thorough risk assessment to determine that they are effective in controlling the target pest and, in so doing, do not pose any unacceptable risk to man, animals or the environment.

The active substances contained in pesticides and biocides are a very large and diverse array of chemicals and include many biological agents. Worldwide there may be up to 1,500. The most common classification of pesticides is on the basis of the target organism/function. The major groups are fungicides, herbicides and insecticides in descending order of importance. Of the total tonnage of pesticides used in the EU, fungicides, herbicides and insecticides account for approximately 60%, 34% and 6% of the market respectively.

2. Toxicity of pesticides

Pesticides are a very extensively studied group of chemicals and the toxicological database is therefore comprehensive. They are designed to be biologically active, and exposure to these substances could potentially have adverse effects on the health of consumers and to those applying these products. The EU authorisation process requires that all pesticides are screened for their potential to cause acute, subchronic or long term effects, neurotoxic, genetic or reproductive and developmental effects. There is wide variation within and between the various functional groups/chemical classes of pesticides with respect to the types, severity and reversibility of toxic effects.

Acceptable Daily Intakes (ADIs) of pesticides for the general population are established by expert bodies such as the Joint Expert Meeting on Pesticide Residues (JMPR) of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), by the European Food Safety Agency (EFSA) and by experts in many countries world-wide. The ADI is the amount of a chemical (in mg/kg bodyweight) that can be ingested daily for life without causing appreciable risk to health. This value is based on the results of animal studies with the pesticide and the determination of the level showing no toxicological effect (NOAEL). An uncertainty factor of 100 is normally applied to the NOAEL to derive the ADI, in order to ensure adequate protection of human health. In the same way, an Acute Reference Dose (ARfD) may be established for acutely toxic pesticides. The ARfD is the quantity of a chemical that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risks for the consumer.

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Infants, toddlers, the elderly or persons whose systems are under stress because of illness are considered to be the most vulnerable to the toxic effects of pesticides. This is due to several factors including developing or saturated metabolic systems, and food intake per unit bodyweight.

Debate is ongoing on whether it is possible to assess the cumulative toxic effects of groups of pesticide active substances having a common mode of action (such as the organophospate pesticides) as well as the possible additive and/or synergistic effects of multiple residues in food items. In the national monitoring programme for 2006, residues of more than one pesticide were found in 29% of samples.

3. Exposure to pesticides

Agricultural workers who apply plant protection and biocidal products are the sector of the population who have the highest level of exposure to pesticides. The authorisation process for pesticides (see section 6) requires an assessment to be carried out to ensure that such workers do not suffer an unacceptable level of exposure and, where relevant, instructions will be provided as to how the pesticide product should be handled and applied to minimise the exposure level.

Plant protection products are used in the conventional cultivation of food crops and it is not surprising that pesticide residues are present in many of these crops. The consumption of fruit and vegetables is the primary route by which consumers are exposed to pesticide residues. The authorisation process takes account of this and requires that the quantity of residue remaining on the treated crop is determined routinely at harvest. This information is used to establish standards called 'maximum residue limits' (MRLs) which are used to ensure that plant protection products are applied correctly. An MRL should not be exceeded when food or food products are placed on the market. Pesticide MRLs are established in Regulation (EC) No. 396 of 2005 for all food crop/pesticide combinations and apply in all EU Member States, including Ireland. The established MRLs have been shown to be safe for consumers.

Residues in food items are usually reduced during storage, transport, preparation, commercial processing and cooking - in the EU national monitoring programmes for 2006 there were no MRL exceedances in processed samples while some 2.9% of fresh produce contained residues in excess of an MRL.

4. Establishing MRLs

To protect consumers against possible adverse health effects from pesticide residues maximum residue limits (MRLs) for food are set out in EU legislation (see section 6) and these are enforced primarily via national monitoring programmes. MRLs are trading rather than safety standards and may be regarded as statutory limits for trade in agricultural products. They are derived from studies/trials that establish the residues that remain in a commodity following the use of a pesticide according to specified use conditions (GAP). For an MRL derived in this way to be accepted, consumer intake calculations must show that consumption of all treated products will not lead to an exceedance of the ADI or the ARfD.

When MRLs are exceeded, risk assessments are made to estimate intakes relative to the ADI or the ARfD. In the EU co-ordinated residue monitoring programme for 2006, the dietary intake assessments performed showed no ADI exceedance, while 15 of the pesticides evaluated showed exceedances of the ARfD. These estimates are carried out using worst case assumptions and indicate a relatively small number of theoretical health risks for the consumer, even when worst case assumptions were made.

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5. Sampling and analysis

Directive 2002/63/EC sets out criteria for the taking of samples for analysis of pesticides. Sampling comprises mainly fresh produce, with most samples being taken at wholesale level. The overall numbers of samples taken per country reflect population size as well as laboratory capacity. Criteria for determining commodities/sample numbers in national plans include dietary consumption patterns, results from previous years, findings in other countries as well as notifications under the EU Rapid Alert System for Food and Feed (system for communication of serious health risks associated with food or feed). Across the EU, including the three EEA states Norway, Iceland and Liechtenstein, samples were analysed for on average 241 pesticide active substances in 2006.

Multi residue analytical methods are most commonly used for the analysis of pesticide residues in food. These methods increasingly use a combination of Gas Chromatography (GC) and High Performance Liquid Chromatography (HPLC) in combination with a range of detection systems. In the past ten years the introduction of mass spectrometric universal detectors, particularly in combination with HPLC has led to a doubling of laboratory capacity, with the average number of pesticides being analysed in samples in EU increasing from 126 in 1998 to 241 in 2006. A typical analytical method for the analysis of pesticide residues in food involves the blending of samples in a suitable organic solvent, the clean-up of the solvent extract using chromatographic techniques and the analysis of the cleaned up extracts by the techniques outlined above.

6. Legislation and controls

Within the EU, the authorisation of plant protection products is controlled by Directive 91/414/EEC while biocidal products are controlled by Directive 98/8/EC. This legislation requires companies to generate extensive dossiers to allow the toxicology, environmental fate/behaviour, residue and physical chemical properties of each pesticide to be determined. These dossiers are evaluated by experts from all the EU Member States, EFSA and the EU Commission, and pesticides are authorised only if their use is determined to be safe and effective.

All pesticides used within the EU as plant protection products are reviewed, and those meeting the safety criteria are placed on a positive list of approved pesticide actives. All pesticides used as biocidal products will be fully reviewed by 2014. The review programme for substances used in plant protection products has resulted in the removal from the market of a large number of older pesticides. At present, the existing legislation controlling the authorisation and use of pesticide products is being reviewed and updated as part of an EU environmental action plan. This revision, estimated to be complete by the middle of 2009, will update the procedures for evaluating and authorising pesticide products and will also put measures in place to ensure the sustainable use of these products.

An EU Regulation (Regulation (EC) No. 396 of 2005) controlling pesticide residues in food has been adopted and replaces all of the existing EU pesticide residue Directives [76/895/EEC (Selected Fruit And Vegetable); 86/363/EEC (Cereals And Cereal Products); 86/362/EEC (Products Of Animal Origin); 90/642/EEC (Selected Fruit And Vegetables)] controlling pesticide residues in food. This Regulation came into effect in September 2008 and establishes MRLs for all pesticide active substances in all food of plant and animal origin. MRLs are established on the basis of residue trials, that indicate what residue will remain on a food crop treated in accordance with good agricultural practice, and a dietary intake assessment to ensure that the residues pose no risk to consumers.

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Pesticides residues in baby food are regulated by EU Directives 96/5/EC as last amended by 2003/13/EC on processed cereal based foods and baby foods, and 91/321/EEC as last amended by 2003/14/EC on infant formulae and infant follow-up formulae. Baby food legislation in this area deals with industrially manufactured products and requires that there is no pesticide residue present in processed baby food products. The baby food Directives established MRLs at 0.01 mg/kg or less for all pesticides in industrially processed baby food.

7. Control measures for pesticides in food

Reflecting the overall responsibility placed on FBOs by the General Food Law (Directive 178/2002) to supply safe food, the principal controls over the levels of pesticides in food lie in the hands of farmers and growers. By adhering to GAP, whereby pesticides are used according to the requirements specified on labels, residues in excess of MRLs should not occur. Currently, as outlined earlier, in 95% of samples tested residues are below MRLs. National monitoring programmes (required by EU legislation) are the prime means of ensuring that pesticides are used in accordance with GAP. The Irish monitoring programme is carried out by the Pesticide Control Service of DAFF under service contract to the FSAI.

Since 1996, EU Member States have been participating in an annual EU co-ordinated monitoring programme in addition to implementing their own nationally tailored programmes. The aim of the co-ordinated programme is to estimate actual dietary exposure for European consumers to the most commonly found pesticide residues. The choice of commodities in the co-ordinated programme includes the major components of the Standard European Diet as defined by the WHO. These commodities are tested for a predetermined suite of pesticides.

Under the national programmes in the EU and EEA (European Economic Area) countries for 2006, a total of 65,810 samples were analysed and the average number of actives sought per country was 241. Detectable residues (at or below MRL) were found in 46% of samples while 54% contained no detectable residues. In 4.4% of samples, residues exceeded MRLs. In the national programmes, MRL exceedances ranged from 3% to 5% over the period 1996-2006. In the EU co-ordinated programme for 2006 over 10,906 samples of eight commodities were analysed for residues of up to 55 pesticides and 2.3% of samples had residues in excess of MRLs.

8. Other agencies

The European Food and Veterinary Office (FVO) located in Grange, Co. Meath is responsible for monitoring Member State and third country compliance with European Union legislation in areas such as public, veterinary and plant health. The FVO thus monitors control systems for foodstuffs of both plant and of animal origin in Member States and third countries, including control measures, sampling and analysis. Reports of the outcome of such monitoring inspections are published on the internet at http://ec.europa.eu/food/fvo/index_en.htm.

Since mid-2003, EFSA has been responsible for the EU peer review of active substances used in plant protection products. This task is carried out by EFSA's Pesticide Risk Assessment Peer Review Unit (PRAPeR) following procedures and deadlines set out in the legislation. Moreover, EFSA is setting up a Pesticide Steering Committee to further strengthen its role in reviewing the safety of active substances. The committee, which is fully operational from 1 January 2009, will provide a platform for cooperation and consultation between the different actors involved in pesticide risk assessment. The peer review process is a joint effort by EFSA in cooperation with Member States applying the latest scientific standards and risk assessment methods EFSA's Panel on Plant Protection Products and their Residues (PPR) gives scientific

advice on issues that cannot be resolved within the peer review of active substances, or when further scientific guidance is needed on more generic issues, commonly in the field of toxicology, eco-toxicology, fate and behaviour of pesticides. The European Commission may also request the scientific opinions of the PPR Panel on residues of pesticides in fields outside the remit of the PRAPeR Unit.

The Codex Alimentarius Commission (CAC) sets MRLs at the global level. CAC was established in 1961 and the Codex Alimentarius is a collection of internationally-adopted food standards (see www.codexalimentarius.net). It has a subsidiary Committee, the Codex Committee on Pesticides Residues. This committee determines priorities, establishes maximum limits for specific food items (at global level) and considers methods of analysis and sampling. Account is taken of Codex values when setting MRLs in the EU. Member States of the EU and the EU Commission are all members of the CAC. The Irish Codex Advisory Committee provides a forum to enable all interested parties express their views in a structured manner for consideration. The Codex Secretariat communicates with its member countries through a system of Codex Contact points. DAFF is the Codex Contact point is for Ireland.

Another important international body in the field of pesticides is the Joint FAO/WHO Meeting on Pesticides Residues (JMPR). While not officially part of the CAC structure, the JMPR provides independent scientific expert advice to the Commission.

The Food Safety and Inspection Service of the United States Department of Agriculture is responsible for the monitoring of pesticide residues in America. Again there is a national plan. The plan applies tolerances/residue limits (see www.fsis.usda.gov/OPHS/red2000/appendix3.pdf) which are set by the Food and Drug Administration (FDA).

9. Useful web sites

Pesticide Control Service Department of Agriculture,Fisheries and Food Ireland: http://www.pcs.agriculture.gov.ie/

Food Safety Authority of Ireland: www.fsai.ie

European Food Safety Authority: www.efsa.eu

World Health Organization: www.who.int

Food and Agricultural Organization of the United Nations: www.fao.org

Codex Alimentarius: www.codexalimentarius.net

Joint FAO/WHO Meeting on Pesticide Residues (JMPR): www.who.int/foodsafety/chem/jmpr/en/

U.S. Food and Drug Administration: http://www.cfsan.fda.gov/~lrd/pestadd.html

International Organisation for Standardisation: www.iso.ch

Eurachem: www.eurachem.org

EU Commission Website Plant Health: http://europa.eu.int/comm/food/plant/protection/