

**Report of the OECD Pesticide Risk Reduction Steering Group Seminar  
on Compliance and Risk Reduction**

**ANNEX 2 – PART A**

**SEMINAR PRESENTATIONS AND PAPERS**

(Available on the Pesticide Risk Reduction Steering Group Password Protected Web Page for the  
Compliance Seminar)


**Government Experience and Perspectives**

European Commission Food and Veterinary Inspection Office  
United States Environmental Protection Agency  
Australian Department of Agriculture, Fisheries and Forestry  
Netherlands Ministry of the Environment

**Stakeholder Experience and Perspectives**

Pesticide Action Network  
CropLife International  
National Farmers' Union, UK  
Working Group on Integrated Crop Management, Germany  
Co-op Supermarket, UK  
BEUC, the European Consumers' Union

**European Commission Food and Veterinary Inspection Office**




**Control of marketing and use of  
plant protection products in EU  
Member States**

Outcome of FVO pesticides missions

OECD Pesticide Risk Reduction Steering Group  
Seminar on Compliance, 10 March 2003, Paris

24-Mar-2004 Denis de Froidmont FVO 1



**European Commission**

- Health and Consumer Protection Directorate-General
  - Food and Veterinary Office (**FVO**)
    - Food of Plant Origin, Plant Health; processing and distribution (unit 4)

<b>pesticides</b>	GMO
contaminants	organic farming
food hygiene	plant health

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**FVO statement**

to promote effective control systems in the food safety and quality, veterinary and plant health sectors

- + to check on compliance with the requirements of EU food safety and quality, veterinary and plant health legislation within the European Union and in third countries exporting to the EU
- + to contribute to the development of EU policy in the food safety and quality, veterinary and plant health sectors
- + to inform stakeholders of the outcome of evaluations

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## The FVO's missions

(carried out following a Manual of Procedure)

- **Planning** (formal letter, evaluation plan, pre-mission questionnaire)
- **Performance** (meeting with CA's, participation to inspection visits, visit of laboratories, collection of evidences)
- **Reporting** (draft + CA comments = final report, publication)
- **Follow-up** (action plan, closeout note)

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## Objectives of FVO Pesticides missions

To **evaluate control systems**  
**for the placing on the market and use** of plant  
 protection products  
 and for residues in foodstuffs of plant origin

From 1998 to date: all Member States visited including 4 missions  
 on specific pesticide residue problems.  
 Reports published on  
[http://europa.eu.int/comm/food/fs/inspections/fnaoi/reports/  
 pesticides/index\\_en.html](http://europa.eu.int/comm/food/fs/inspections/fnaoi/reports/pesticides/index_en.html)

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## Directive 91/414/EEC

concerning the placing of plant protection products on the  
 market

**Control measures : Article 17**

- Member States shall make the **necessary arrangements** for plant protection products which have been placed on the **market and for their use to be officially checked** to see whether they comply with the requirements of this Directive and **in particular** with the requirements of the **authorisation** and information appearing on the **label**.


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### Control activities evaluated by FVO

- registration of wholesalers and retailers
- licences for retailers / users + training
- records keeping at retailer and user levels
- authorisation of the product, label
- authorisation of the use (sampling)
- storage conditions, packaging
- formulation
- pesticide residues in foodstuffs

01-Apr-2004                      DdeF                      FVO                      7 / 14




### Various Member States in EU

**crop, climate, number of retailers,  
number of farms....**

- PPP authorised: between **300** and **8000**.
- a.s. authorised: between **150** and **500**.
- PPP used: 232 377 tonnes of a.s. in EU-15,

France: <b>35.6</b> %	UK: 4.9%	Denmark: 0.8 %
- Italy: 21.9 %	- Portugal: 3.4%	- Sweden: 0.4 %
- Spain: 13.6 %	- The Netherlands: 1.8 %	- Finland: 0.3 %
- Germany: 9.4 %	- Belgium: 1.3 %	- Ireland: <b>0.2</b> %
- Greece: 5.5 %	- Austria: 0.9 %	- Luxembourg: n/a

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## Purposes and types of controls carried out by MS

<ul style="list-style-type: none"> <li>• <b>Worker safety</b></li> <li>• <b>Environment protection</b></li> <li>• <b>Consumer protection</b></li> </ul>	<ul style="list-style-type: none"> <li>* protective clothes</li> <li>* water / soil samples</li> <li>* sprayers</li> <li>* risk mitigation measures</li> <li>* <u>authorisation of the product,</u></li> <li>* <u>labels</u></li> </ul>	<ul style="list-style-type: none"> <li>* <u>license,</u></li> <li>* <u>training</u></li> <li>* <u>packaging</u></li> <li>* <u>storage / disposal</u></li> <li>* <u>formulation</u></li> <li>* <u>pesticide residues</u></li> </ul>
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## Competent Authorities for control

Ministry of / Agency for:

<ul style="list-style-type: none"> <li>– Agriculture...</li> <li>– Health</li> <li>– Environment</li> </ul>	<ul style="list-style-type: none"> <li>– Consumer Protection, Food and Agriculture</li> <li>– Finances</li> <li>– Customs officers</li> </ul>
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## Control activities carried out by MS

- Control of **retailers**, of **users** (licences, records, storage conditions).
- Control of plant protection products
  - **label**
  - **authorisation** (+ or - list)
  - **sampling** for formulation analysis
- Control of **use** (samples from the field)


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## Control materials of MS inspectors

- Check list (storage conditions, ...)
- Approved labels (for comparison)
- **Database / list** of authorised / banned products and uses
- Sampling material (for formulation analyses)


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## Major non compliances identified by MS

- non authorised uses
- recently banned products
- presence of obsolete products
- storage conditions
- label in a foreign language (direct import from outside EU)
- label: risk + safety phrases
- formulation ([a.s.]< level mentioned)

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## Major non compliances identified by FVO

- communication between CA's
- limited scope of control activities
- follow up (seizure)

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## **PESTICIDE USE COMPLIANCE IN THE UNITED STATES**

### **Environmental Protection Agency**

#### **Office of Pesticide Programs**

#### **I. Introduction**

Each year nearly a billion pounds of conventional use pesticides are applied in the United States (U.S.). All new pesticides must go through an extensive pre-marketing registration process to ensure that their use will not pose an unreasonable risk to people or the environment. In addition, all old pesticides registered before November 1, 1984 must undergo reassessment to ensure that these pesticides are registered based on data that meet up-to-date scientific standards. If a product review concludes that the product can be used without posing excessive risk to the user, the environment or to the public, labelling statements are devised to reduce or remediate potential risks, and the product is registered or reregistered as applicable.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and its accompanying regulations set out the registration requirements for pesticides in the U.S., and include specific labelling requirements. Each registered pesticide must bear a label which clearly and prominently displays the use directions and warning or precautionary statements as well as other label requirements. Section 12(a)(2)(G) of FIFRA states, "It shall be unlawful for any person to use any registered pesticide in a manner inconsistent with its labelling."

That statement is, in fact, the cornerstone of pesticide use compliance in the U.S.; it is a violation for any person to use, ship, store or dispose of any pesticide contrary to label directions. It is commonly said that "the label is the law." In the U.S., most farmers and commercial applicators undergo professional training in the safe use of pesticides and are aware that they are required to follow label directions. Others in the general public or in businesses that rarely use pesticides may be unaware, however, that not only should they read the labels on the pesticides they use, but they are required by law to comply specifically with the directions for use.

This paper presents a brief overview of pesticide use compliance in the United States as it relates to pesticide use and management in the field. It discusses factors that can lead to non-compliance and summarizes the practices and programs the U.S. employs to manage use compliance.

#### **II. Factors Influencing Use Compliance**

For purposes of this paper, use compliance is defined as the handling and application of pesticides in full and complete accordance with all precautions and use directions on the pesticide product label. It may seem that compliance with label directions should be relatively simple and straightforward. This is not always the case, unfortunately. For some pesticides, the use directions and precautions can be very specific and restrictive. Applicators can be required to perform a number of steps to ensure correct applications. For example, the label may include instructions such as : shake well before using; wear personal protective equipment; wash soiled clothing in a prescribed manner; flush exposed skin immediately with water; do not apply within x feet of wells or bodies of water. Labels may also include different instructions for different soil types, different crop/pest combinations and different application equipment. Strict compliance with the label can require careful attention to detail.

Factors that can affect whether or not a pesticide is applied in compliance with the label include:

### *Labelling*

The complexity of product labelling is a big factor in use compliance. The trend is for labels to become more specific, and therefore more detailed and complicated. For example, chemicals that are biologically active at very low rates require very specific precautions to prevent damage to non-target organisms. They may also require prescriptive safety equipment for the applicator to wear at different stages of handling or use. Compliance with these new labels often requires more attention than to older more generic labels.

### *Weather*

Weather-created circumstances can make it challenging for applicators to apply pesticides correctly. Poor weather conditions can mean that growers have to perform field operations in conditions they normally would avoid. For example, applying pesticides in high wind is usually prohibited, yet some years experience windy conditions throughout the normal spraying season, making it difficult to adhere to label directions and precautions. Unusual weather conditions can also create exceptional pest pressures on growing crops. Under these circumstances, producers may be tempted to go beyond permitted applications on a pesticide product's label in order to save their crop. Producers may be tempted to apply pesticides for uses or at rates not specified on the label.

### *Economics*

Similarly, when profit margins are very slim, commercial applicators and growers may be tempted to use less-expensive products that may not be labelled for the use intended by the applicators. Applicators may be aware that the active ingredients in the cheaper product are the same as those in a fully approved product, or they simply may have heard that the cheaper product will control the pest, so they decide to try it. In other cases, growers may decide because of price differences to buy pesticides from outside the U.S. that are not labelled for use in the US. They may think the economic savings are worth the risk of being caught or that any illegal residue on a food product will have dissipated by the time the crop goes to market.

### *Equipment / Technology*

Pesticide application equipment and applicator techniques change constantly. Applicators may find a new method, or a new diluent, carrier or rate of application that works well with one product, but has not been approved for all the products the applicators use or the crops they grow. Applicators may adapt equipment or experiment with applications in a way that can lead to label violations.

Technological gaps can also make detection of use violations challenging, in some cases. New active ingredients are required to have valid laboratory analytical methods available for food residues prior to registration. Methods may not be available for environmental samples, such as samples from foliage, soil, water, clothing or others.

### *Industry Practice*

Often pest control practices are established through years of successful application based on using certain chemicals at specified rates, with standardized equipment. When new products or revised labelling with new application instructions are introduced, applicators may be reluctant to change their established practices. When the applicator industry does not have sufficient information about new practices or is unwilling to adapt and change to new methods, they can find themselves in non-compliance.



### III. Inspections / Investigations

FIFRA allows EPA to give the primary responsibility for monitoring pesticide use compliance to the States. States train and certify pesticide applicators, and are better positioned to regulate end users of labelled products. EPA provides grant money to states to assist them in inspections, investigations and enforcement. Most states add funding from state appropriations and fees, often making EPA funds a relatively small part of their program funding. This relationship between state and federal regulators regarding pesticide use compliance is unique compared to other EPA programs. Federal authority to enforce pesticide misuse is limited compared to what the states can do. EPA funds and works cooperatively with tribal governments to enforce FIFRA, as it does for states and territories. Tribes with EPA-approved pesticide programs work to ensure compliance with pesticide laws by conducting inspections and recommending enforcement actions to EPA. In some cases, tribal code permits direct enforcement by the tribe.

The majority of regulatory resources for compliance monitoring are spent on what are called “follow-up inspections.” Essentially, these are any pesticide use investigations that originate from a complaint. Some states are bound by law to investigate every complaint that comes to their attention. Others have such heavy workloads that they send an inspector out only on the more significant complaints, and try to resolve the minor or frivolous ones over the phone. Follow-up inspections that involve personal property damage can take several days to investigate and can consume considerable inspection and laboratory resources.

In fiscal year 2001, states conducted 2546 agricultural follow-up inspections and 6415 non-agricultural follow-up inspections. Enforcement action was taken on 45% of the agricultural inspections and 53% of the non-agricultural inspections. These enforcement actions ranged from warning letters, to monetary penalties and all the way up to criminal convictions. The majority of the violations detected during these inspections involved the use of pesticides contrary to label directions. Most states have newsletters or other mechanisms to report serious enforcement cases back to the applicator industry to help them avoid further misuse.

States also conduct use inspections that are planned in advance so that regulators can establish a “presence in the field.” Much like a policeman walking down the sidewalk, having pesticide inspectors routinely observe and collect information on applications raises awareness of the need to follow label directions. In fiscal year 2001, state inspectors conducted “planned use inspections” i.e., inspections that were not in response to complaints, at 8670 agricultural sites and 18,324 non-agricultural sites. Planned use inspections benefit both applicators, by pointing out minor problems and making recommendations for improvement, and regulators, by keeping them informed about new techniques and practices and highlighting labelling problems.

Both planned use inspections and follow-up use inspections are a critical part of the government’s effort to enforce pesticide use in strict accordance with labelling. Pesticide inspections can serve as a deterrent to purposeful pesticide misuse. Inspections can also serve as educational tools that help applicators avoid mistakes and stay in compliance. Inspections alone, however, cannot ensure compliance. The regulated universe is very large, with approximately 693,000 private applicators (farmers) and 42,100 commercial applicators (essentially persons applying pesticides for hire). It is not possible for state and tribal agencies, even with assistance from the federal government, to conduct enough inspections to ensure total compliance. The objective is to create and maintain a culture of compliance where compliance with the label becomes the expected norm for pesticide users.

#### **IV. Managing Use Compliance - Creating a Culture of Compliance**

In the U.S., one of the biggest advantages to regulators in managing use compliance is that most people want to do the right thing. The American public is very concerned about risks from pesticide residues in their food, homes, and public places. They are especially concerned about risks to their children. Most people who use pesticides generally try to use them correctly.

Also, most professional applicators know that they face extensive financial liability if they cause an illegal residue on food, or misapply a chemical on a lawn, near a stream or any place else that may eventually impact man or the environment. The majority of applicators are reluctant to knowingly violate pesticide laws and regulations. They are aware that widespread misuse and increased risks can result in the cancellation of popular pesticide products.

Aided by these general public and pesticide user concerns, preventing pesticide misuse continues to be a priority for federal and state regulators. Efforts to manage use compliance include:

##### ***Strengthened National Pesticide Program Partnership***

Effective use compliance depends on a strong partnership among the regulatory compliance/enforcement agencies and offices responsible for pesticides in the U.S. Within EPA, the Office of Pesticide Programs (OPP) and the Office of Enforcement and Compliance Assurance (OECA) work closely with pesticide staff in the ten regional offices. OPP registers all pesticides and approves labels. OECA provides overall guidance on compliance and enforcement. EPA regions work directly with state and tribal partners. EPA's partnership with states and tribes supports uniform compliance and enforcement practices focused on national and state priorities. Feedback from EPA regions, states and tribes is essential for OPP to learn about label and user concerns. The State FIFRA Issues Research and Evaluation Group (SFIREG) and the Tribal Pesticide Program Council, funded by OPP, provide an opportunity for dialogue and problem resolution among national pesticide program partners. OPP and OECA jointly issue cooperative agreement guidance in consultation with other partners, that is the foundation for annual cooperative agreement negotiations between EPA regions and state and tribal pesticide lead agencies. These partners are committed to mutual accountability to ensure steady improvement in program delivery.

##### ***Applicator Training and Certification***

Applicator training and certification programs are an important part of compliance. In the US, all farmers and commercial applicators who use Restricted Use Pesticides (RUPs), must be certified to purchase and use these chemicals. Most states exceed federal certification regulations which require general training for applicators, and require that applicators attend training classes developed specifically for the types of pesticide applications they plan to conduct. Applicators must pass a written exam, as well. Generally, the training is conducted by the State Land Grant University Extension Service and the exams and certification are the responsibility of the state agency designated as the State Lead Agency (SLA) for pesticide regulatory administration. These SLAs are also responsible for enforcing use compliance. By incorporating examples of noncompliance into their annual training courses, states try to ensure that applicators know what use violations have been committed and how to avoid them.

##### ***Worker Safety and Training***

Use compliance also involves worker safety and training regulations. All agricultural pesticide labels reference worker protection standard requirements and make it a violation of FIFRA if worker protection regulations are not complied with. Requirements can include pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, and the presence of decontamination supplies and emergency medical equipment. EPA has

established a comprehensive program to educate pesticide users regarding worker protection requirements and to help users comply with the standards.

### ***Compliance Assistance***

Other types of education are important, as well. The regulated industry needs regular information on label changes, policy changes, and new rules to help them understand what needs to be done. Government and state agencies take the opportunity to promote use compliance through outreach and education activities. For example, EPA and its state and tribal regulatory partners often make presentations on issues affecting compliance at grower/applicator meetings. They also use direct mailings, e-mail, bulletins and web sites to keep the regulated industry informed. One of the key resources available to farmers and agricultural applicators is the National Agricultural Compliance Assistance Center, which provides a wide variety of information and technical assistance to all interested parties, including a comprehensive Web site: ([www.epa.gov/agricultural/news/index/html](http://www.epa.gov/agricultural/news/index/html).)

Generally, when regulatory changes are made regarding a pesticide's use, the applicator industry is afforded a transition period to adopt the new practices. Regulators try to use this transition to reach out and help industry learn how to get themselves into full compliance by the implementation date of the new regulation.

### ***State Tracking***

Most states and tribes keep track of the numbers and types of complaints they work on each year. If in a given growing season, they have an unusually high number of incidents related to a specific product on a specific site, they will highlight that during their next years' training sessions. Additional planned use inspections can then be targeted in the problem areas.

### ***Incident Reporting***

FIFRA requires that pesticide registrants notify EPA of adverse effects resulting from the use of their companies' products. Although the data that come to EPA are often generic (specific sites are not required and incidents do not require verification), they do allow EPA to identify the most serious incidents as well as general trends of negative impacts. This information can be used to identify use patterns that may need additional compliance monitoring, or products that may need specific label changes to improve safety.

### ***National Database***

EPA has recently completed and is assessing the results of a pilot to determine the feasibility of creating a National Pesticide Field Database that will enable states and tribes to download use and violation information from a myriad of software systems into a centralized database. The goal is for regulators to be able to access up-to-date real world information collected by hundreds of pesticide inspectors throughout the country. Having access to this information would make it easier for EPA to develop policies to remediate individual product risks, using actual field data. Additionally, the database would assist the enforcement program in targeting field activities in future years and in setting overall priorities based on real need.

## **V. Conclusion**

Pesticide regulators face a number of challenges to preventing pesticide misuse. State and federal resources for monitoring use compliance are limited and the regulated industry is very large. It is possible to inspect only a fraction of the huge number of applications made each day. Many factors can contribute to misuse including difficult weather conditions, economics, changes in use patterns or equipment and

increases in the complexity of labelling. The need to educate and train pesticide applicators increases as pesticide labels and use become more complex.

To meet these challenges, the U.S. has established a comprehensive use compliance program. The strong working relationship between EPA and its state and tribal regulatory partners is a great advantage in managing pesticide misuse. Established communication networks help to ensure that all regulators are made aware of any widespread compliance problems that occur so they can adjust their programs accordingly. Routine inspection activities conducted by state regulators maintain a “field presence” that keeps applicators constantly aware that label compliance is important to both regulators and the public at large. The most effective compliance tool the US relies upon is the longstanding program to educate and certify pesticide applicators. Enforcing violations against one individual is very resource intensive compared to training a classroom full of applicators. Lastly, EPA and its state and tribal partners make use of every opportunity to disseminate information about using pesticides correctly. As citizens become more informed about pesticides and the need to follow label directions carefully, they become better able to make decisions about using pesticides correctly in their homes, on their farms and in their communities.

## Agricultural and Veterinary Chemicals Compliance in Australia

### Introduction

The overarching goal of compliance activities for agricultural and veterinary (agvet) chemicals within Australia is to ensure that there is no harm to humans, animals, plants or the environment or prejudice trade or commerce between Australia and places outside Australia.

Responsibility for managing compliance within Australia is divided between Federal and State/Territory jurisdictions. The Australian Pesticides and Veterinary Medicines Authority (APVMA) which was established under Federal legislation (the *Agricultural and Veterinary Chemicals Code Act 1994* [Agvet Code Act]) is responsible for compliance to the point of retail sale. The State and Territory Governments regulate the second area encompassing the control of use of agvet chemicals. Control of use compliance is enabled through the various State and Territory Governments control of use legislation. Although there is a division of powers, the APVMA and the State and Territory Governments work closely together to ensure a sound interface between the division of responsibilities.

### Compliance to the Point of Retail Sale

Pre-market activities are an integral component within Australia's regulatory risk framework. This framework supports many of the post registration activities and, to some degree, assists in targeting post-regulatory activities. Activities under this area are generally directed towards prevention and quality assurance. The basis of most post-registration activities is focused on the monitoring and surveillance of agvet chemical products and active substances. Here the focus is on manufacturers, importers and suppliers of agvet chemicals including distributors and retailers.

The role of the APVMA in compliance is to ensure that manufacturers, importers and suppliers of agricultural and veterinary chemicals are aware of, and exercise, their responsibilities with regard to compliance requirements of Australia's agricultural and veterinary chemicals legislation to the point of retail sale. The APVMA's compliance regime focuses on three primary strategies including, *prevention, quality assurance and surveillance and enforcement*.

#### 1. Preventative Measures

The APVMA's prevention strategy is based on the principle that education deters acts of non-compliance and provides assurance to those who do comply. This preventative strategy includes a variety of activities aimed at improving the awareness and understanding of the National Registration Scheme and compliance obligations by the various stakeholders. An emphasis is placed on:

1. industry liaison through general consultative and subject or program specific committees and groups;
2. the publication and dissemination of targeted information and educational material for key stakeholder groups (chemicals industry, retailers, wholesalers, agricultural and livestock industry, the public);
3. providing an educational forum through seminars and training sessions, in partnership with other agencies and industry;
4. working with industry to achieve desired outcomes through co-regulation and control of the promotion and advertising of agricultural and veterinary chemicals;
5. selected promotion of enforcement outcomes; and
6. enhanced border control of imports and management of interfaces with other regulatory authorities such as Australian Customs Service, Therapeutic Goods Administration (TGA), and Australian Quarantine and Inspection Services (AQIS).

## ***2. Quality Assurance***

Quality assurance of agricultural and veterinary chemicals in the marketplace is facilitated through the publication of various standards, codes and guidelines. The purpose of these activities is two fold, firstly to satisfy regulatory requirements for registration of agvet chemicals ensuring an acceptable level of quality in the regulatory process and, secondly, they provide for the basis of post-market compliance giving a reference standard against an approval. Having this approach enables the focus on quality using a 'whole of system approach', from pre-registration, during manufacture and post-registration.

In addition, programs such as the Manufacturers Licensing Scheme (MLS) and the Adverse Experiences Reporting Program (AERP) are operated by APVMA in respect of veterinary chemical products. An AERP for agricultural products is currently being developed. The MLS is designed to ensure chemical products are manufactured consistently, by reproducible methods, under appropriate supervision and with effective quality control procedures. For veterinary chemical products, the APVMA has prescribed 'Manufacturing Principles' that include Codes of Good Manufacturing Practice (GMP). The Codes of GMP are the standards against which Australian-based manufacturers of veterinary chemical products are licensed under the APVMA's MLS. Overseas-based manufacturers of veterinary chemical products must, as a pre-requisite to product registration, demonstrate that their product is manufactured to a standard comparable to the relevant Australian Code of GMP.

The AERP is a post-registration quality assurance program for identifying corrective action necessary to assure continued safety, quality and effectiveness of registered veterinary chemical products in the Australian marketplace. Reporting under the Program includes a mandatory obligation on the Registrants under Section 161 of the Agvet Codes and voluntary reporting is encouraged for veterinarians, animal owners, farmers and other users of veterinary chemical products. Reports received are evaluated in consultation with the registrant and the manufacturer to determine whether the adverse experience is related to the product formulation, manufacturing processes, use practices or product labelling. The program also looks at whether any changes to the registration status of the product involved are necessary.

## ***3. Surveillance and Enforcement***

Routine surveillance is currently conducted by the APVMA only in respect of Hormonal Growth Promotants (HGP) as part of the National Monitoring and Control Scheme managed by AQIS in support of Australia's beef exports to the European Union. This takes the form of audits of importer and retailer premises and records. The NRA also conducts surveillance campaigns in respect of specific chemical products. These are generally undertaken in partnership with the relevant State/Territory control-of-use agencies.

Compliance enforcement action is targeted using intelligence gathered from reports of non-compliance submitted by industry, the general public, other agencies such as Australian Customs Service, AQIS, TGA and police, and APVMA and State field officers. Industry is by far the greatest source (constituting some 70%) of reports of non-compliance received by the APVMA. After acknowledging receipt of the report, the APVMA assesses the actual and potential risk posed by the non-compliance bearing in mind APVMA's legislative obligations for public health, the environment, trade and product efficacy, by examining the:

- validity of the report's claims (status of registration/approval/permit/consent to import, conditions of registration and approved label details etc);
- potential or actual severity of the consequences of the product's presence in the marketplace (for example, animal deaths, harm or pain and suffering, crop damage etc);
- history of the matter (for example, previous non-compliances or responses to previous requests for compliance action); and

- completeness of the information provided and the potential to obtain relevant evidence that is legally admissible.

Depending on the assessed risk and the resources available and required to pursue the matter, the APVMA may take one of a number of actions in pursuit of compliance:

- administrative action,
- investigation with a view to prosecution, and/or
- recall of the product in question.
- The matter may also be referred for consideration of whether it would be appropriate to suspend or cancel the registration and/or approvals for the relevant product.

### **Control of Use**

The States and Territories are responsible for the control of use of agvet products beyond the point of retail sale. The legislative basis underpinning control of use of chemicals varies in each State and Territory due to differing agricultural production systems and of climatic conditions.

Areas where non-compliance may differ include things such as off-label use of chemicals. Off-label use essentially refers to the use of a chemical for purposes other than those for which it is registered. Some States and Territories, there may be differences regarding the conditions under which off-label use can occur. In almost all jurisdictions, chemicals must be used only in accordance with the conditions specified on the label. Some variations to label use conditions may be allowed by permit (or by legislation) but these generally apply to low risk uses only.

Control of use compliance activities presently include licensing of pest control operators, spraying and aerial spraying operators and pilots, the investigation of adverse incidents, the monitoring programs for the detection of violations against residues standards and veterinarian's rights to prescribe and use veterinary drugs. Increasingly, the definition of control of use is also being extended to include control over use in respect to user safety (OH&S) and environmental protection.

### **Conclusion**

Regulators face a variety of challenges in ensuring compliance of agvet chemical products, from the importation, manufacture and sale of unregistered chemicals to the off-label use of chemicals. Government resources for agvet chemical compliance are limited by other competing regulatory obligations and Australia's market size. With this in mind, the focus of compliance activities is predominantly on minimising risk by maximising the impact of activities undertaken within a minimal resource base. The integrity of Australia's compliance program relies heavily on education/training and upfront strategies to reduce risk and to educate the importers, manufacturers and users of agvet chemicals, complemented by quality assurance systems and, to a lesser degree, monitoring.

### **Introduction to Documents on the Certification System of the Dutch Auction of Vegetables**

Based amongst others on the demand of retailers with regard to product quality standards, the Dutch auctions have joined an international program called Eurep GAP (Euro Retailer Produce Working Group Good Agricultural Practice), launched by “Food plus”. The system was introduced 3 years ago and is now used in more than 10 countries.

The program constitutes a system between retailers and producers. The producers demonstrate to retailers their commitment and ability to produce safe and clean food. To do so, the producers use the system of Good Agricultural Practise, which incorporates Integrated Crop Management and Integrated Pest Management practices in their daily routine.

To enforce the system, each producer is visited once a year by a controller. This is a person from an independent company, certified by a national certification authority. A number of producers will receive a second, surprise visit. Besides these “control” visits, there is also the possibility to have visits from advisors, for example to address questions on how to deal with certain plagues.

The system is made up of an extensive number of rules and requirements. A part of these is dealing with use of pesticides.

Although based on the same system, the interpretation may be different from country to country. On top, some requirements refer to the demand to comply with national law which is different from country to country. For example, the pesticides allowed to be used for a certain crop differ within European countries.

The two documents are both linked to Eurep GAP. The first one is to be used by the farmers. It defines the way they are supposed to handle pesticides. The first two pages contain general information, the next pages focus on the specific demands on crop protection and the use of pesticides, and finally there is information on audits and sanctions.

The second document is a checklist that controllers have to complete during a visit of a company. It consists of a long list with different qualifiers. “Should” is recommended but not required, “minor must” is obliged but it is allowed to have a maximum of five times no. “Major must” is a must.

The document is a pdf file of all items to be checked, the pages 13-21 refer to pesticides.



## **Self-audit relating to the EUREPGAP components of The Greenery UK Standard**

Each grower must perform an audit at least once a year, using The Greenery UK Standard checklist. This self-audit must be performed before the external audit. If the self-audit reveals that some points have not been put into effect correctly, you must take appropriate measures.

### **Registration**

Registration forms the basis of The Greenery UK Standard. The system includes the following types of registration:

#### ***Daily and frequently updated registration:***

- daily registration of pesticides;
- registration of fertilizer application;
- registration of chemical vermin control;
- registration of daily glass inspection in sorting room;
- registration of weekly inspection of glass in glasshouse;
- registration of glass breakage;
- harvest record form;
- registration of equipment maintenance;
- registration of cleaning;
- registration of complaints and emergencies;
- registration of harvesting instruments;
- registration of temperature of cold rooms;
- registration of reservoir water
- registration of use of blue plaster.

#### ***Non-recurring registration***

- registration of waste flows;
- accident procedure.
- new property risk analysis form;
- nature conservation action plan;
- nature policy plan;
- record of the inventory of all pesticides;
- record of the inventory of fertilizers;
- registration of initial stock of pesticides;
- registration of initial stock of fertilizers;
- cleaning schedule;
- maintenance schedule.

#### ***Statements***

- statement on personal hygiene of personnel;
- statement by consultant;
- statement on crop protection performed by third parties;
- statement on plant material;
- statement on personnel training course in chemicals and hazardous equipment;
- statement of external carrier

You will also find a number of appendices:

- appendix 1, Personal hygiene rules;
- appendix 2, Visitors rules;
- appendix 3, The Greenery statement on crop protection and food safety (residue);
- appendix 4, The Greenery genetic modification statement;
- appendix 5, Useful addresses;
- appendix 6, Banned Pesticide List;
- appendix 7, HACCP plan and hazard analysis.

Registration must take into account the following;

- Each business must submit its business data annually;
- The records must be updated daily and, if requested, must be presented at The Greenery within 24 hours. The Greenery may use the records for trading purposes, for example;
- In principle, all records must be saved. They must be kept for at least two years;
- You will find registration forms in the enclosed file. You are not obliged to use these forms. You can also use your own (computerized) registration method. In that case, at least the minimum data must be provided, as recorded on the enclosed registration forms;
- Growers who start to use the EUREPGAP/The Greenery UK Standard for the first time must have kept all the required registers, in accordance with the requirements, for at least three months before the first external audit takes place.

### ***Keeping relevant documents***

All relevant documents showing that you work in accordance with The Greenery UK Standard must be filed and kept for at least 2 years.

Amongst other records, this includes:

- All registration forms;
- Purchase receipts for pesticides, disinfectants and fertilizers;
- Reports on maintenance, repairs and equipment inspections;
- Spraying licence(s);
- Purchase receipts for seeds and propagation material.

Auditors are entitled to examine the data. We recommend you to keep these documents (or copies of them) and all the associated records in The Greenery UK Standard folder.

### **Tracking and Tracing**

#### ***External***

- Any product that leaves the business's premises must bear the correct markings, such as telephone number, date code, etc. in accordance with the directions;
- The products must be traceable to the plot/department level;
- The products with various origins (different treatments) must be marked separately.

#### ***Internal***

- Various registration schemes in the business enable any complaints that have arisen in the trade channel to be traced to various business activities and the registrations that have been made (traceability).

## Crop protection

### *General*

Minimum use should be made of chemical pesticides. As far as possible, diseases and pests must be avoided by preventive measures. If action is necessary, non-chemical pest treatments are preferred. If chemical action is required, it must be carried out in a way that minimizes the environmental impact and so that there is no risk to the safety of the product or the operator.

### *Choice of chemical crop protection*

If chemical crop protection is required, your choice of pesticide must take into account the following points, amongst others:

- Only permitted pesticides may be used on the crop;
- You must take into account the harvest intervals;
- The environmental impact should preferably be as low as possible. For more information about this, see the “milieumeetlat” (graduated environmental scale), which is available from the CLM in Utrecht. This information is available at [www.gewasbescherming.nl](http://www.gewasbescherming.nl) (the “milieumeetlat” option);
- Harm to useful organisms, preferably use a selective pesticide;
- Prevent resistance, vary the use of pesticides;  
Temperature, wind speed, humidity and method of application, to achieve the optimum effect.

### *Integrated pest management for fruit & vegetables under glass (incl. strawberries)*

- Integrated pest management of pests in fruit & vegetables is compulsory. All pests for which a common and reliable biological method of management is available are managed using natural enemies;
- Integrated pest management means that certain pesticides must not be used, may only be used subject to restrictions (e.g. site basis) or only at the end of cultivation. Consult your cultivation adviser about this, if necessary;
- Preventive use of chemical agents must be followed within six weeks by the deployment of natural enemies;
- After chemical curative action, biological management remains the basis of pest management.

Assessments are made in relation to this on the basis of biological indicator standards (thresholds). The standards are provided below.

*Amblyseius cucumeris* and *Amblyseius degenerans*: A Thrips mite is present on 75% of the leaves (relevant parts of plant). All stages of development count.

*Gall wasps*: 5% full mummies in the plant louse congregations.

*Plant louse predators*: Larva of the predator present on every plant in the plant louse congregation.

*Encarsia* and *Eretmocerus*: 50% visible in the parasitized pupa on the leaf layer with emerging pupa.

*Macrolophus*: One present on each plant.

*Leaf-miner-fly ichneumon wasps*: 40% parasitizing and/or host feeding on lava of leaf miner fly.

*Orius species*: At least 50 specimens per 100 flowers and/or growing points.

*Phytoseiulus persimilis* and *Amblyseius californicus*: A red spider mite is present on 75% of the leaves with webs. All stages of development count.

### ***Exceptions***

Integrated pest management is the starting point of The Greenery UK Standard. However, there are times (start of cultivation, end of season, etc.) and circumstances during which a biological balance (temporarily) cannot be maintained. In the case of a number of short cultivation periods, it is also difficult to comply with the biological indicator standards. In the event of cultivation temporarily not being integrated and/or the biological indicator not being achieved, it must be possible to provide proper reasons. In such a case, a check will also be made of the deployment of insects in relation to the chemical agents used.

### **Work instruction use of crop protection**

#### ***Activity and result of the activity***

This involves marketing products that comply with the Dutch admission legislation (crop protection), residue legislation and/or supplementary requirements of export destinations or specific requirements of the market.

#### ***Detailed description of the activity***

One person in the business is appointed as the person with responsibility for crop protection. This person's deputy is also appointed. The person with responsibility for crop protection ensures that the product is grown in accordance with the Netherlands Residue and Admission Legislation on the use of pesticides and permitted residues.

#### ***Preparation of spray mix***

- Always read the label;
- Take into account restrictions on a number of specific destinations (including the USA and the United Kingdom). If applicable, written copies of these supplementary requirements must be available at the business. With regard to exports to the United Kingdom, you will find the "banned pesticides list" in the appendices. The pesticides referred to on the list must not be used for exports to the United Kingdom;
- Use the right protective clothing, as indicated on the label;
- The required quantity of spray must be measured accurately using a weighing machine or measuring jug. Properly functioning measuring and weighing equipment must be available;
- At least every six months, the weighing equipment must be checked using calibration weights or on the basis of a service contract with the supplier. The calibration weights or the service contracts must be available. Measuring equipment must be clearly readable. A record must be kept of the inspection of both. You can note the data on the "Equipment maintenance" registration form;
- Empty containers must be cleaned in accordance with the statutory requirements. This entails using a rinsing device, or rinsing at least three times with water. Return the rinsate to the tank;
- Do not place pesticides in the vicinity of products that have been harvested or are awaiting harvesting;
- If a permanent mixing location is used, at least the following emergency facilities must be available for the operator:
  - First aid box;
  - eye washing facilities and running water;
  - absorbent material (for example sand or cat litter);
  - accident procedure.

***Equipment***

- Pesticides must only be used with appropriate equipment designed for that purpose. If possible, this equipment must be calibrated and officially approved (field sprays, for example). If testing is not possible, ensure, in any case, that annual maintenance is performed;
- You must regularly check that the equipment is still working properly. It must be calibrated at least once a year. Proof of calibration must be available and must be registered. A competent person (who at least possesses a spraying licence) must perform the calibration. Also keep a record of repairs, replaced parts, maintenance and cleaning of equipment. The “Equipment maintenance” form is included in the file for this purpose. Keep all invoices of maintenance work.

***Performing crop protection operations***

- Operators of the sprayers (and those who make preparations for this) must have a valid spraying licence;
- Use the right protective clothing;
- The above also applies to third parties who perform spraying operations (including contract workers). This must be demonstrable. To this end, you can use the enclosed standard statement “crop protection performed by third parties”;
- Clean clothing that has been worn. The clothing must be stored neatly and separately from the pesticides;
- Check also during the performance of the operations that the equipment is working properly;
- All activities involving pesticides must be recorded within 24 hours of their performance;
- A record must be kept for all the activities of the actual quantities used and not the quantities per hectare.

***Residues of pesticides, removal of empty containers and other matters***

- Prevent spray residue;
- Store the empty and cleaned containers in a secure place (not in the cupboard containing the pesticides) until their disposal;
- Prevent reuse; make holes in containers;
- Pesticides that are no longer used or permitted to be used must be taken, in accordance with statutory regulations, to recognized firms (information from local authorities) or the supplier. Request a receipt on handing over the containers and keep it.

***Pesticides list and harvest record***

- Growers must have lists of all statutorily permitted pesticides for all the crops normally grown in the business. The list must be regularly updated and show the current situation. The information is usually obtainable on the Internet and in advice books. You can request a list of this kind from The Greenery;
- Growers must have a completed list showing which pesticides they normally have or may have in storage. To this end, please find the enclosed “record of the inventory of all pesticides”;
- You must be able to demonstrate that the harvest interval has been taken into account for all crop protection activities. To this end, you must keep a harvest record. The “harvest record” form is enclosed in the file for this purpose.

### ***Post harvesting treatments using pesticides***

A record must be kept of the following details, if post harvesting treatments are carried out: crop, product, location, date of application, reason for application, trade name, type of treatment, quantity used, equipment used to apply it and the name of the operator.

### ***Advice on pesticide***

Consultants must be competent and qualified. Growers must be able to produce evidence of this. At your request, many consultants will be able to provide you with a statement. In addition, the file also contains a consultant's statement. You can use this, if your consultant is unable to provide you with a statement. Ensure that your consultant correctly completes and signs this statement. Your information official must provide the statement annually.

### ***Inspection activities and frequency***

The person with responsibility for crop protection ensures that the method of working is implemented correctly in the business.

### ***Appendices***

- Record of the inventory of all pesticides;
- Registration of pesticides form;
- Registration equipment maintenance form;
- Consultant's statement.

### ***Storage of pesticides***

Pesticide storage must meet the following requirements:

- The storage place (cupboard) must be clean, fire resistant, well lit, locked and clearly recognizable as a storage place for pesticides;
- The construction material of the storage place (cupboard) must not be absorbent;
- If the storage room is accessible, it must also have proper ventilation and lighting;
- The cupboard or room must only contain pesticides, including spreaders and vermin control agents. Do not keep protective clothing, filters and so forth in this room;
- The pesticides must be stored in the original container;
- The label must be legible;
- Powders must be stored higher than liquids;
- Liquid pesticides must be placed in collection trays;
- Access doors must display signs warning of potential hazards;
- There must be both running water and eye washing facilities within 10 metres of the storage place;
- Absorbent material must be available in the vicinity of the storage place;
- The location of the absorbent material must be clearly indicated;
- Only employees with a spraying licence are allowed access to a key to the cupboard containing the pesticides;
- An accident procedure must be displayed in the direct vicinity of the cupboard. You will find an "accident procedure" appendix in the file. Fill in the appendix for your specific business situation and display the procedure at the required places (possibly make copies);

- A record of the inventory of all pesticides must be hung near the cupboard; a form is enclosed for this purpose;
- There must be a complete first aid box within 10 metres of the storage place;
- Only pesticides may be stored that are permitted for one of the crops that the business normally cultivates.

All other statutory requirements concerning the storage of pesticides must, of course, also be observed.

### ***Storage of disinfectants***

- Disinfectants must be stored in a clean and locked room;
- All contact with the product must be prevented.

### **Audits**

Audits will be conducted to guarantee satisfactory compliance with The Greenery UK Standard. A distinction is made here between site visits and residue tests. All participating businesses will be audited. All businesses will be audited in accordance with the EUREPGAP and the hygiene code protocol, amongst others.

### ***Site visit***

The site visits are made by both an external, accredited organization as well as The Greenery's internal auditors.

### ***External audit***

All businesses will be audited at least once a year by the external audit organization. More audits per year are possible. Audits will usually be announced in advance. The visits will cover all relevant parts of the indicated system.

Moreover, all businesses will receive a visit from one of The Greenery's auditors. The Greenery may also request audit registration forms.

### ***Residue monitoring***

Random samples taken at The Greenery and/or at the cultivation site will be analyzed for residues. In such cases, the business's pesticides register may be requested.

### **Sanctions**

Sanctions will be imposed, if a site visit or residue test reveals a failure to comply with the set requirements. There are three types of failures:

1. minor failures that can be rectified and/or that do not result in an immediate threat to food safety;
2. major failures that cannot be rectified and that affect product safety, such as glass in the product;
3. exceeded residue limits.

In the first case, the grower must rectify the failure.

- In the second case, the grower will no longer be permitted to supply the product. The grower will only be permitted to start supplying the product again after taking action to prevent the failure from occurring. These businesses may possibly be audited again.
- If a sample reveals a failure to comply with the residue legislation, an urgent sample of the product will be taken at the site immediately. If it emerges that the product does not comply with the residue legislation, an immediate (temporary) sale prohibition will be imposed. The grower will only be permitted to start supplying the product again when subsequent samples have shown that the residues that are present have fallen below the statutory limit/detection limit. The business concerned will be charged for the costs of resampling. The Greenery may decide not to further purchase product from the grower concerned, depending on the severity of the failure.

Any failure by a business to comply with the conditions of the system, may prevent the product being sold in certain market segments. This may have consequences for the price paid for the product.

In accordance with the EUREPGAP audit protocol, if an audit reveals that the business has failed to fully comply with the EUREPGAP standards, it will not be possible to certify the business, or any certificate that has been granted will be withdrawn. Besides the EUREPGAP sanction (refusal to certify or withdrawal of certificate), the aforementioned sanctions relating to risks to product safety and breaches of the residue standards will remain fully effective.

A second audit may be required before the EUREPGAP certificate can be issued. The business concerned will be charged the costs of the second audit.