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FOD Inspectors dealing with Agriculture

ENFORCEMENT MANAGEMENT MODEL APPLICATION TO RISKS FROM PESTICIDES

This SIM gives guidance to Inspectors on applying the EMM to pesticide related risks. Although much of the Health and Safety Executive's involvement in pesticides is within the agricultural sector, this guidance applies to the storage and use of pesticides in all industrial sectors.

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INTRODUCTION

1 HSE's Enforcement Management Model (EMM) provides a framework to assist inspectors make enforcement decisions in line with the HSC's Enforcement Policy Statement (EPS) which reflects the Cabinet Office's Enforcement Concordat on good enforcement practice. The original EMM works particularly well where there are risks to safety and has been developed to address compliance with Permissioning Regimes and Compliance and Administrative Arrangements.

2 Application of the EMM to general health issues and specifically to the health risks from chemicals has been further addressed in OC130/5 'EMM General Guidance on Application to Health Risks' and OC273/19 'EMM Application to Chemical Risks' respectively.

3 This pesticides enforcement guidance seeks to provide inspectors with a framework to assist in making enforcement decisions with respect to risk to human health, non-target species and the environment – specifically, water.

4 In summary, inspectors should apply:

- The EMM as amplified by OCs 130/5 and 273/19 where risk to human health is at issue; and
- The guidance set out in this SIM where risk to non-target species and the environment is under consideration.

THE LEGISLATION

5 Currently the primary legislation regulating the advertisement, sale, supply, storage and use of pesticide products in GB is The Food and Environment Act 1985 (FEPA) and The Control of Pesticides Regulations 1986 (as amended)(COPR). The aim of FEPA is to secure safe, efficient and humane methods of controlling pests whilst at the same time protecting the health of human beings, creatures and plants, safeguarding the environment, and in particular avoiding pollution of water. The mechanism for achieving this is set out in COPR.

6 The relationship between FEPA and COPR is analogous to that between the Health and Safety at Work etc. Act 1974 (HSWA) and associated health and safety regulations. Progressively this regime will be replaced by two harmonised approval systems throughout the European Union, which separately address plant protection products (most agricultural pesticides) and biocides (which includes all non-agricultural pesticides and certain products not previously covered including disinfectants). Council Directive 91/414/EEC concerning the placing of plant protection products on the market is implemented in GB by the Plant Protection Products Regulations 2005. Similar regulations apply in Scotland. Council Directive 98/8 EEC concerning the placing of biocides on the market has been implemented by the Biocidal Products Regulations 2001.

7 All three regimes work in broadly similar ways. Ultimately, they require products to be approved, and impose conditions on their advertisement, sale, supply, storage and use. Inspectors should be aware that products will increasingly be approved under the new regimes and should be careful to apply the relevant legislation in each case. Further guidance will be issued in due course. In the meantime advice should be sought from the Agriculture and Food Sector.

8 The HSWA, The Management of Health and Safety at Work Regulations 1999 (MHSWR), and in particular The Control of Substances Hazardous to

Health Regulations 2002 (as amended)(COSHH) also apply in relation to the risks to human health from the storage and use of pesticides. Inspectors should select the most appropriate legislation when considering enforcement action.

ENFORCEMENT RESPONSIBILITY

9 The HSC/E enforce FEPA under an Agency Agreement between the Commission and Ministers. Under the agreement, HSE enforces the provisions of Part III of the Act in respect of those premises and activities for which it is the enforcing authority by virtue of the Health and Safety (Enforcing Authority) Regulations 1998. HSE does not have any direct responsibility for enforcing the provisions of the Act in respect of pesticide residues in foodstuffs nor for the disposal of pesticides, which is not within the scope of the legislation.

POWERS OF AUTHORISED OFFICERS

10 Inspectors may only perform their functions under FEPA if they hold a valid certificate of authorisation: a FEPA Warrant. The delegated functions arising from the Agency Agreement permit HSE to authorise staff to exercise the powers contained in Section 19 and Schedule 2 of the Act as amended by the Pesticides (Fees and Enforcement) Act 1989 and the Pesticides Act 1998. A person so authorised may:

- Enter any land or vehicles;
- Require information on formulations and the effects or use of a substance;
- Order to leave undisturbed;
- Issue an enforcement notice;
- Require answers to questions; and
- Take photographs and samples

11 N.B. The power to seize or dispose of pesticides or anything treated with a pesticide set out in regulation 7 of COPR has not been delegated to authorised inspectors. It has been retained by the Executive and their written authority is required before such action can be taken. Inspectors should contact the Agricultural and Food Sector if they require authorisation to seize pesticides.

12 Inspectors also have the power to prosecute in Magistrates Court for FEPA cases. Most offences under FEPA are triable either way and prosecution is initiated and pursued in the same way as under HSWA.

13 Although broadly similar to an Inspector's powers under s20 HSWA there are significant differences and Inspectors should read and familiarise themselves with the specific legislation before taking action.

ENFORCEMENT NOTICES

14 Unlike under health and safety legislation, there is only one type of Enforcement Notice under FEPA. Issued under S19, this notice is flexible and can be used in the same way as HSWA notices i.e. to immediately prohibit activity, to prohibit activity after a predetermined period or to effect improvement over a flexible, agreed period.

15 Inspectors should note that 'improvement type' Enforcement Notices are not restricted to a 21day minimum period as there is no appeal process in FEPA. However recipients have the right to seek a Judicial Review of an inspector's decisions and actions.

16 Issuing Enforcement Notices under FEPA is a broadly similar process to that of issuing notices under HSWA. Form FEPA 23 should be used.

ENFORCEMENT ACTION

17 HSE is only one of a number of enforcing authorities under FEPA. Certain DEFRA departments and every Local Authority in GB are also authorised to enforce the FEPA/COPR regime.

18 For clarity this guidance has been separated into the following sections:

- General
- Serious Risks
- Compliance and Administrative Arrangements
- Human Health and COSHH
- Environmental Issues

19 Where inspection or investigation highlights problems with both risk-based and compliance/administrative elements, inspectors should decide on action principally in relation to the control of risk. However, all the factors will need to be considered in reaching a final enforcement decision.

GENERAL

Introduction

20 Pesticides can only be advertised, sold, supplied, stored and used in GB if they are approved for the purpose(s) by Ministers, acting on the advice of the independent, expert Advisory Committee on Pesticides (ACP). The approval process is managed by the Pesticides Safety Directorate (PSD) in respect of products for agricultural use and by HSE's Biocides and Pesticides Unit (BPU) in respect of non-agricultural pesticides.

21 As part of the approval process, certain statutory conditions of use are laid down for every pesticide product and each is given a unique approval number. A list of approved agricultural products can be found either on the PSD website (<http://www.pesticides.gov.uk/>) or by telephoning the PSD Infoline on 01904 455775. Similarly, details of approved non-agricultural products can be found on the BPU web pages at

(<http://www.hse.gov.uk/pesticides/index.htm>) or directly by telephoning BPU (VPN: 523 3535).

22 Each product is approved for advertisement, sale, supply, storage and use in GB in specific, limited ways. These restrictions are known as the product's 'Conditions of Approval' and are printed on the product label in a boxed "statutory area". The approval number and further information, including advice on known health risks and control measures will also be printed on the product label. More detailed instructions will be found in a separate leaflet or in the product's Material Safety Data Sheet.

Product Labels

23 The information in the "statutory area" will include:

	MAFF/ HSE or MAPP No. 00000
The phrase "compliance with the following conditions of use is a legal requirement"	
The approved "Field of Use" of the product e.g. agriculture, home garden, vertebrate control	
The crops or situations for which treatment is permitted	
The maximum individual dose/maximum concentration	
The maximum number of treatments/maximum total dose	
The latest time of application or harvest interval	
Any other specific restrictions relating to a particular pesticide	
The phrase "Read all other safety precautions and directions for use before use"	

24 N.B. Inspectors should note that pesticide products are now subject to the provisions of the Chemicals (Hazard, Information and Packaging for Supply) Regulations 2002 (CHIP3).

General Consents

25 In addition to product approval conditions, there are also General Consents contained in the schedules of COPR. These are in effect the conditions, which need to be complied with by those seeking to advertise, sell, supply store or use any approved product. Failure to comply with a relevant General Consent condition is an offence under the regulations.

Off-Label Approvals

26 A pesticide can only be used in accordance with its conditions of approval (including its approved use(s)) as set out on the label. However, Inspectors need to be aware that there is a scheme in place whereby users can obtain approval to use a product approved for agricultural use in a different way e.g. on a different crop from that stated on the label. This is known as a “Specific Off Label Approval” or “SOLA”. Users should be able to provide documentary evidence of any off label approval, which should be verified with PSD. N.B. BPU does not operate a similar arrangement for non-agricultural pesticides.

SERIOUS RISKS

27 Inspectors should always deal first with matters which give rise to a serious risk to human health or of damage to the environment. They have power to prohibit the work activity or to make safe the substance(s), which are creating the risk using their powers under HSWA and/or FEPA.

28 Inspectors should deal with these matters in accordance with Chapter 2 paragraphs 9-12 of the EMM.

29 Inspectors are advised to consult the Environment Agency (EA) when assessing risks to the environment.

COMPLIANCE AND ADMINISTRATIVE ARRANGEMENTS

The Initial Enforcement Expectation

30 Compliance and Administrative arrangements are those legal requirements which are not in themselves risk based i.e. do not directly result in the control of risk. These arrangements are generally defined by law or supporting approved codes of Practice and include risk assessments and the keeping of records etc.

31 In practice there is no difference in dealing with these issues under pesticide legislation than under other health and safety law. Inspectors should refer for guidance to the EMM and in particular to paragraphs 5, 14, 33, 52, Table 4 ‘Compliance and Administrative Arrangements’ and Table 5.2 ‘Compliance with Administrative Arrangements: Initial Enforcement Expectation’ to determine the initial enforcement expectation.

HUMAN HEALTH AND COSHH

32 Given the wide variety of types of pesticide products and their various additional chemical co-formulants (constituents) it is very difficult to give generic guidance relating to human health risk.

Risk assessment

33 The FEPA/COPR regime is based on a system of product approval. As part of the approval process, applications are subjected to a rigorous evaluation covering a range of matters including risk to operators (users), bystanders (members of the public) and the environment.

34 Given this evaluation, the regime is predicated on the assumption that an approved product, used in accordance with specified Conditions of Approval and the relevant General Consent (conditions) applicable to the activity e.g. storage or use, set out in the Schedules to COPR should not pose significant risk to the health of human beings, creatures or plants (other than the target species) or to the environment

35 Whilst the generic risks to human health from a product have been assessed and guidance on control measures generated by the approvals process, the particular circumstances under which a pesticide is to be used still needs to be considered as part of a suitable and sufficient assessment of the risks to health under COSHH. Compliance with the Conditions of Approval and the General Consents should not be accepted as proof of adequate control but together with other relevant information such as that contained in Material safety data Sheets (MSDS) will inform the COSHH assessment, which should address the risk from the specific way(s) in which the product is being handled and used.

36 Inspectors should note the product label will contain much of the information required to assess the quality of a COSHH assessment

37 The COSHH assessment in conjunction with the advice given in OCs 130/5 and 273/19 will lead to a judgement on the actual risk to health.

38 N.B. Generally, the risk to human health from the storage or use of pesticides will be minor. However, in some cases the risk may be significant and in exceptional cases, serious.

Benchmarks

39 The defined standard for an activity involving an approved pesticide product is that it should be used in strict accordance with its Conditions of Approval and the appropriate General Consent. Additionally the ACOP guidance on the storage and use of both agricultural and non-agricultural pesticides in the DEFRA Code 'Code of practice for using plant protection products' and the advice in HSE's ACOP under COSHH on 'The safe use of pesticides for non-agricultural purposes' are both defined standards.

40 Inspectors need also to be aware of the relevance of specified 'Harvest Intervals' in ensuring the protection of workers' and consumers' health. Many products have a stipulated harvest interval as a Condition of Approval, which will be printed on the label. This interval, often several days, is the period that should be left between the last date of application of a product and the harvesting of the treated crop. Bad weather and commercial pressures can influence a grower's decisions.

41 Established and interpretative standards include HSE Guidance Note MS17 'Medical aspects of work-related exposures to organophosphates', HSG251 'Fumigation – Health and safety guidance for employers and technicians carrying out fumigation operations' and Agriculture Information Sheets 16 'Guidance on storing pesticides for farmers and other professional users' and 31'Safe use of rodenticides on farms and holdings'.

42 In practice, if duty holders are complying with relevant guidance, the residual risk from the storage and/or use pesticides will lie within the Nil / Negligible range of the EMM.

The Initial Enforcement Expectation

43 Inspectors should refer to the EMM to assess the risk gap (Table 2.1) and then determine the initial enforcement expectation (Table 5.1) in the usual way. Determination of enforcement action arising from the risks to human health from pesticides is no different to that of any other substance hazardous to health.

44 Inspectors are reminded to refer to the guidance in OC's 130/5 and 273/19 in coming to a decision.

ENVIRONMENTAL ISSUES

45 Generally, inspectors are neither expert nor experienced in environmental toxicology, assessing environmental risk or determining the appropriate enforcement level for environmental protection matters. HSE's EMM cannot be applied directly and fully to environmental risks because the "consequence" definitions in the EMM are based on the effects on humans. However, the principles of proportionality to risk and to the extent of any breach that are contained in the EPS and the EMM, are applicable generally to all our enforcement activities, including those in the environmental area.

46 For practical purposes, environmental protection and enforcement can be subdivided into the following areas each of which is dealt with separately in the following sections:

- Animal Health
- Plants and Land
- Water

Animal Health

47 The Wildlife Incident Investigation Scheme (WIIS), is managed by DEFRA, the Scottish Executive for the Environment and Rural Development (SEERD) and the National Assembly of Wales's Agricultural Affairs Department in England, Scotland and Wales respectively who are responsible for incidents e.g. complaints, illness or fatalities involving wildlife species, including bees and other beneficial insects, livestock and pets, where there is

suspicion of pesticide poisoning. Whilst any incident involving animals may become a matter for HSE, inspectors should avoid accepting complaints into any animal incident, pending discussion with the respective managers of the WIIS scheme who have greater technical and forensic expertise.

48 Conclusions from a WIIS investigation however, may provide evidence of other breaches and the significance of their evidence may support action being used to define the risks in terms of human health, plant and water environmental effects and suitable enforcement.

49 HSC/E priorities will not normally allow detailed forensic examination of animals in isolation.

Plant and Land

50 As indicated, inspectors are not expert in assessing risks to the environment. HSE has therefore adopted the guidance of the Environment Agency (EA) to assist inspectors with making enforcement decisions. The guidance is reproduced at Appendix 1. Inspectors who require an enforcement steer on environmental factors are encouraged to liaise and consult with the EA when risks are predominantly or significantly environmental.

The initial enforcement expectation for plants, land and environmental damage is set out in the EA's enforcement policy at Appendix 1.

Water

51 The EA is responsible for enforcing the Groundwater Regulations 1998. These regulations place a duty upon the EA to protect groundwater by prohibiting discharges of certain substances to that water. This is enacted by authorising discharges of certain substances including organophosphate (OP) substances and biocides in general. Discharge of pesticides including waste water from washing down pesticide equipment to the ground is likely to require authorisation under this legislation. However, pesticides applied in accordance with FEPA/COPRA conditions will not normally require authorisation. Inspectors should refer complaints relating to such discharges to the EA.

52 In the case of spraying pesticides near to watercourses, the initial enforcement action should be determined by assessing the level of compliance with the DEFRA guidance 'LERAP: Horizontal Boom Sprayers' and 'LERAP: Broadcast Air-assisted Sprayers'. These are defined/established standards for the protection of water courses in connection with the application of pesticides to arable crops and orchards/hops respectively. Reference should also be made to the ACOP requirements of the DEFRA Code in any case in which water has been threatened.

53 Decisions should be based on the instructions in the EMM for dealing with Compliance and Administrative Arrangements.

THE FINAL ENFORCEMENT DECISION

54 Inspectors should first consider duty holder factors that may vary the initial enforcement expectation and then the strategic factors, which may influence the final enforcement conclusion in line with Section 5 of the EMM in order to reach a final enforcement decision.

55 When considering strategic factors inspectors should be aware of the high level of interest, from members of the public, pressure groups, politicians, Ministers, the media and other interested parties, about the use of pesticides generally and more particularly, the use of organophosphate (OP) insecticides. Pesticide products classified as carbamates also give rise to concern both in respect of risks to the environment and to human health.

APPENDIX 1

ENVIRONMENT AGENCY ENFORCEMENT FACTORS AND COMMON INCIDENT CLASSIFICATION SCHEME

APPLICATION TO PLANTS / LAND

The following guidance issued by the EA is intended to assist HSE Inspectors to decide the most appropriate enforcement action in response to environmental incidents.

ENVIRONMENT PROTECTION ENFORCEMENT GUIDANCE

The magnitude of the environmental effect is an indicator of the degree to which the offender has failed to put in place, maintain, adhere to/or foresee the consequences of not having, suitable procedures or systems to prevent the incident. Generally, the greater the effect or potential effect, the greater the probability of prosecution.

Where the offence arises out of an incident, which falls within the scheme, reference should be made to the Environmental Impact Category. Where:

- the impact or potential impact falls within Category 1, prosecution will normally result;
- if it is within Category 2, prosecution or formal caution will be the normal course of action - the choice being determined by reference to other factors set out below. (HSE Inspectors should apply dutyholder factors to make this judgement); and
- if it is within Category 3, a warning will usually be sufficient, unless other dutyholder factors determine a more severe course of action, e.g., a repeated offence.

Offences that do not fall within the scheme but affect or have the potential to affect the environment should be judged using the same criteria.

COMMON INCIDENT CLASSIFICATION SCHEME (CICS)

Serious: Category 1 - A major land pollution incident which involves one or more of the following criteria:

- (a) Persistent and extensive contamination of land due to a discharge, spillage or illegal deposit from a site and/or substance controlled by the Agency, which has a major impact on the use or quality of that land and is likely to require extensive decontamination measures.
- (b) Major damage to terrestrial ecosystem i.e. destruction or major damage to a Site of Special Scientific Interest (SSSI) or other important wildlife habitat and Widespread destruction or major impact on terrestrial fauna or flora.
- (c) An explosion and/or large-scale fire, or other incident involving a site, process or substance under the control of the EA, which causes serious

damage or destruction to the site, residential housing and/or commercial buildings.

(d) Major adverse effect on an important recreational activity/event or public space, prohibiting the normal range of activities e.g. the cancellation of a national sporting event following the fly tipping of toxic materials.

The need to evacuate persons/and or restrict access over a wide area, e.g. the build up of landfill gas above trigger levels in property.

(e) Major damage to agriculture activity e.g. extensive contamination of crops/soil rendering them unfit for use and/or the death of livestock, due to fly tipping, the land spreading of waste or build up of landfill gas etc. or commercial interests, e.g. extensive closure of an industrial site, serious interruption of production, due to fly tipping, a build up of landfill gas etc.

Significant: Category 2 - A significant land pollution incident which involves one or more of the following criteria:

(a) Significant but localised contamination of land due to discharge, spillage or illegal deposit from a site and/or substances controlled by the EA which has a significant impact on the use or quality of that land.

(b) Significant but localised damage to an SSSI or other important wildlife habitat or effect on terrestrial fauna and flora e.g. loss of trees or vegetation dieback due to fly tipping of waste.

(c) Significant Impact on property e.g. localised explosion or significant fire, or other incident involving a site, process or substance under the control of the EA which causes superficial damage to the site, residential housing or commercial buildings.

(d) Significant adverse effect to recreational activity, event or restriction of the public's normal range of amenity activities. Includes:

- Significant infestation by insects/rodents;
- Significant effect on the amenity of the locality e.g. deposition of dust over a wide area; and
- Need to issue public warnings, inform residents to avoid areas, e.g. closure of a footpath.

(e) Significant but localised damage to agricultural activity, e.g. loss of crops due to fly tipping and significant damage to commercial activity, e.g. short-term closure of a site, limited loss of production.

Minor: Category 3 -A minor land pollution incident which involves one or more of the following criteria:

(a) Minimal and temporary contamination of land having no overall effect on the use or quality of that land.

(b) Minor damage to local ecosystem i.e. very limited effect on terrestrial fauna and flora.

(c) Amenity value only marginally affected i.e. minor impact on aesthetic quality.

(d) Minimal impact to agriculture or commerce i.e. site temporarily affected, but not declared unfit for agricultural or commercial activity.

CONTACT

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