1. Introduction and Regulatory Background

1.1 General

There is a general requirement under Directive 94/37/EC for the procedures for cleaning of application equipment to be described in detail and for the effectiveness of these procedures to be investigated. PSD Guidelines for the generation of data on the physical, chemical and technical properties of plant protection products, dated July 1999, give further detail. These point out that ‘Data must be submitted to demonstrate that residues of the plant protection product do not remain in the spray tank after cleaning such that there is a risk to the operator or crops’. Although data on cleaning application equipment are needed in order to examine different risks it is considered that in many circumstances one set of data can be generated to address the various concerns. This should examine the expected residues left in the equipment after application and cleaning. The risk caused by these residues can then be assessed and the need for further testing considered.

1.2 Efficacy

With regard to efficacy it is the risk to other crops from residues left in the application machinery after use that is the concern. When the same machinery is used to apply another product, usually to another crop, these residues could then be diluted or resuspended and applied onto this subsequently treated crop or land. If this crop, or a crop that is grown on the contaminated land, is sensitive to the levels of the active substance present then high levels of crop damage can occur. The requirement for efficacy data on this issue is laid out in the ‘Uniform Principles’ (Directive 97/57/EC) under Part C, 2.2.8. ‘The proposed instructions for cleaning the application machinery must be both practical and effective so that they can be applied with ease so as to ensure the removal of residual traces of the plant protection product which could subsequently cause damage.’

This is part of the requirement to address the absence of unacceptable effects on plants or plant products. Directive 93/71/EC, which lays down efficacy data requirements, does not give any indication of the type of data that must be generated to meet this requirement. This Guideline provides PSD’s view on meeting this requirement and when agreed in the UK will be submitted to other Member States and EPPO to try to achieve international consensus.

1.3 Submission of evidence

It is important that any specific cleaning method required is clearly described on the product label and the data submitted support that method.

Data submitted to meet this requirement with regard to Efficacy should be included in a Biological Assessment Dossier under 9.2 ‘Impacts on other plants, including adjacent crops’. (Although it is realised that not only adjacent crops are at risk but any crop that is
subsequently treated using contaminated equipment). The methods described below can be used to design a new method for cleaning application equipment or to test whether an existing method is suitable for a new active substance or product. This guideline mostly refers to application using pesticides diluted in water but the general principles apply to other methods of application. Cleaning methods generally consist of one or more rinses with water and possibly the use of a cleaning agent, such as sodium hypochlorite or a proprietary material.

2. Biological activity of the active substance

Before undertaking any tests in this area it is highly advisable to establish the active substance’s biological activity against plants, usually in glass house or semi-field screens. This information can be considered together with data on the active substance’s physical and chemical properties to decide on the need for further testing.

To examine biological activity the effect on seedlings and established plants should be determined in the first instance, as these are the most likely growth stages of plants to be exposed to a contaminated spray. For soil-acting materials, particularly those that are persistent, it should be considered whether when present in a contaminated sprayer they could be applied to land prior to planting or emergence of a crop. If this is the case then effects on seed germination and seedling emergence should also be examined. This information should be available as part of the consideration of effects on succeeding crops, see EPPO Standard PP 1/207.

Particularly for herbicides, the use of pre- and post-emergence screens of activity, as outlined above, are important in meeting a number of efficacy data requirements, including effects on adjacent and succeeding crops. In these screens a range of doses should be applied to a range of species to establish no observable effect levels or the doses where a low level of effects is seen, e.g. ED$_{10}$.

For insecticides and fungicides, where it is expected that the active substance will have limited biological activity on plants, the initial number of test species could be as low as three. A greater range of species should subsequently be tested where biological activity against plants is detected. For herbicides and growth regulators a wider range of species should initially be tested. The range of crop plants tested should be influenced by the known activity of the herbicide, for example if it is active only or mostly against dicotyledonous species this type of plant should be the major component of the screen.

For active substances, such as some insecticides and fungicides, where there is no activity against plants at label recommended doses then no further testing is required. For active substances that have biological activity against plants then it must be considered whether any level likely to contaminate application machinery could damage subsequently treated crops. The level likely to remain in application machinery can be ascertained by carrying out the tests or calculations described below.

3. Requirements for testing

3.1 Small-scale tests

For the initial examination of the cleaning of application equipment small-scale tests in bottles or jars have proven very informative and they often provide more consistent results
when compared to results from a full-scale test. A full protocol for small scale jar tests is given in guideline 305. In small-scale tests there is a greater surface area to volume ratio, increasing the likelihood that spray residues would adhere to the bottle. The small-scale containers should be of a similar material as used for farm-scale application machinery, such as HDPE. The use of small-plot spray equipment is not recommended as this is commonly made of metal and the spray is often delivered using CO₂ pressure, both of which do not represent normal conditions of application. Small sprayers used in the home garden can be suitable as these may be made of HDPE.

A series of single products and mixtures can be tested, being added to the bottles at their highest label recommended concentration. The bottles can then be washed using the label recommended method and then the final rinsate analysed for residues of the active substance(s) concerned. The solvent to be used in the final rinsate should be considered in light of the chemical properties of the active substances under test and need not necessarily be water. Some active substances are not very soluble in water or water insoluble deposits can be formed. In these cases the final rinse which is analysed should be an organic solvent, such as isophorone, instead of water. (This is not unrepresentative of field conditions as organic solvents can often be found in pesticide formulations). If the product is contained in water-soluble packaging then an appropriately sized piece of the packaging should be added to the container at the beginning of the test.

### 3.2 Larger-scale tests

To further refine the results of small-scale testing then larger scale tests can be carried out using full size or scaled down farm application machinery. It is recommended that these tests are only used to test methods already designed following smaller-scale tests. Products are mixed as recommended in the test apparatus and disposed of by spraying though representative nozzles. The test apparatus is then cleaned according to label recommendations and the tank refilled. The tank’s contents at this stage can either be analysed or can be sprayed on to sensitive crop plants. This method is generally acceptable as long as the large-scale test apparatus is; representative of sprayers that will be used in practice, the recommended cleaning technique is tested, and the crops used in the test can be shown to be those most sensitive to the active substance(s) in question. It allows plots of sensitive crops to be treated so that the extent and duration of any damage can be recorded and if necessary yield measured.

### 3.3 Cases where no testing is required for substances which are active against plants

In some cases it may be considered that due to an active substance’s high solubility in water that no testing will be needed. However, when a sprayer is emptied, dilute spray solution will be retained in the sprayer, for example up to 20 litres of spray solution can remain in the spray lines and pump of a 2000 litre sprayer. If a substance is highly active against certain plant species, even if it is greatly diluted during washing and refilling then damage may still result in subsequently treated crops. For soluble active substances it may be possible to calculate the worse case concentration for application machinery contamination. Take the average amount of the original spray dilution that will be left after application. Then calculate the extent of dilution resulting from the recommended sprayer cleaning regime and

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subsequent refilling of the sprayer before use of the next product. This value can then be compared to the known level of biological activity of the active substance(s) to demonstrate if a sufficient level of tank cleaning has been achieved. It is unlikely that sufficient information would be available to calculate the effect of using a cleaning agent, if this is recommended during the cleaning procedure.

4. Acceptability of the levels of active substance(s) detected

For a cleaning method to be acceptable, the level of the active substance that is predicted might be applied to a non-target crop when the application equipment is reused, *i.e.* after cleaning and refilling, should be an order of magnitude less than the no observable effect level or ED$_{10}$ value for the most sensitive non-target crop. If the levels detected are closer than an order of magnitude to that found to have a biological effect, then further larger-scale tests may be used to refine the assessment of risk to subsequently treated crops. In these tests it can be ascertained if any levels of damage seen are significant and might affect yield. If yield affects are likely, then a revised cleaning method will be required. A revised cleaning method can use extra rinses or additional cleaning agents to reduce the levels of contamination to an acceptable level. The acceptability of this method must be then demonstrated in further tests and it must be included on the product label.

5. Tank-mixtures

Representative tank-mixtures recommended on the label, at first approval or subsequently developed should also be tested. The mixtures tested should include; those with widely used products, worse case mixtures identified by the known attributes of the active substance and related compounds, and those mixtures where problems were seen in physical compatibility testing. Small-scale tests are recommended initially, as a greater range of mixtures can be screened. The final rinsate must be analysed for the presence of any of the mixture components that are biologically active. With an acceptable tank washing method, the levels of both active substances detected should be below that likely to cause an effect on non-target crops and plants. If they both have activity against the same species then additive effects should also be considered. Large-scale tests may again be needed if possibly biologically active levels are discovered in the small-scale test.
6. Flow chart on cleaning application machinery

Does the pesticide have any activity on plants? (i.e. is it a herbicide or pgr, or can the product cause crop effects on any of a range of species when used at the recommended dose?)

OUTCOME
No testing of cleaning method required – make case in the BAD

OUTCOME
Does the pesticide have biological activity at the concentration/dose predicted to be present after dilution when refilling the sprayer to apply the next product?

Does the pesticide have any activity on plants?

OUTCOME
No unacceptable levels of crop damage found or predicted.

OUTCOME
Unacceptable levels of crop damage found or predicted.

What level of crop damage is expected when the level of pesticide found in final rinsate is compared to the activity seen in biological screens?

NO

Low levels of crop damage predicted

YES

Devise (or revise) a tank cleaning method, prevent contamination by inclusion of sufficient rinses or use of a cleaning agent.

OUTCOME
Describe the cleaning method on the product label & include the data that support it in the BAD

Carry out small-scale tests – in bottles or jars, mix at the highest concentration then follow the recommended cleaning method. Analyse the final rinsate (use an appropriate solvent)

Carry out large scale tests – in full size or scaled down application equipment – mix and flush out the product following the cleaning method. Analyse final rinsate or spray out on to susceptible crop species and assess duration of any damage, take yield if required

Carry out screening for biological activity – test a range of crop species post-emergence and pre-emergence at a range of doses to establish no effect levels.

YES

Carry out large scale tests – in full size or scaled down application equipment – mix and flush out the product following the cleaning method. Analyse final rinsate or spray out on to susceptible crop species and assess duration of any damage, take yield if required