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Forest Service Handbook 2109.14 – Pesticide-Use Management and Coordination Handbook

Chapter 20 - Risk Assessment

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Responsible Staff:

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Superseded Document(s): 2109.14,20 Contents, Amendment 2019.14-94-1, December 6, 1994; 2109.14,20, Amendment 2109.14-94-1, December 6, 1994

Digest: Following is an explanation of the changes throughout the directive by section.

20: Makes minor technical, formatting, and editorial changes throughout the chapter. Changes chapter caption from Risk Analysis to Risk Assessment to reflect current usage.

20.06: Establishes code, caption, and sets forth direction on risk assessments: (1) explains why the Forest Service conducts its own risk assessments based on past adverse Court decisions; and (2) describes the availability of current national pesticide risk assessments, and that these can be used in lieu of project-level risk assessments.

21.1: Revises this section to emphasize that key inerts, metabolites, and adjuvants must be considered in a risk assessment, in addition to the active ingredient. Revises direction to show a shift in preferences from the use of LD50 values to NOEL values, if available, in assessing acute hazard.

21.11: Removes obsolete contact information and updates sources of information for conducting hazard assessments.

21.12: In paragraph 3, adds reference to amphibians as a class of aquatic species that should be considered in hazard assessment. Changes paragraph 6 from endangered species to non-target

plants and microorganisms. Renumbers existing paragraph 6 to paragraph 7 and adds reference to Threatened, Proposed for Listing, and Sensitive Species.

21.22: Clarifies the most likely methods of human exposure to pesticides for applicators (dermal) and the public (dermal, oral).

21.25: Changes caption from "Dose Estimation" to "Estimating Doses", removes references to obsolete terms, and describes the methods for estimating doses to animals, insects, and plants.

21.3: Removes direction and caption "Risk Characterization" and replaces with direction and caption "Dose-Response Assessment".

21.4: Establishes new code and recodes to this section direction previously set out in 21.3.

21.41: Establishes new code and recodes to this section direction previously set out in 21.31. Removes references to Margin of Safety (MOS) (and the associated methodology) and replaces with Reference Dose (RfD) since this is the current method of evaluation of exposures being used by the Forest Service. Updates the description of cancer effects analysis in risk evaluation. Adds new reference to evaluating non-human risks.

23: Recodes to this section direction previously set out in section 25 and explains the limitations of the risk assessment process.

25: Removes code, caption, and direction and recodes direction to section 23.

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20.06 - Risk Assessments

All human activities carry some degree of risk. Many risks are known with a relatively high degree of accuracy, because data have been collected on the historical occurrence of related problems (for example; lung cancer caused by smoking, auto accidents caused by impairment resulting from drinking, and fatalities resulting from flying in airplanes). The risks associated with other activities, including voluntary and involuntary exposure to chemicals such as pesticides, cannot be readily assessed and quantified. A process called risk assessment has been developed to help evaluate the risks resulting from these less quantifiable occurrences. In this chapter, we consider all activities associated with the process of estimating, evaluating, and managing those risks posed by pesticides to which people and various other components of the environment are likely be exposed as a result of particular pesticide applications.

Risk is defined as the likelihood that an adverse or negative effect (injury, disease, death, or environmental damage) might result from a specific set of circumstances. It can be expressed in quantitative or qualitative terms.

When evaluating risks from the use of pesticides in a National Environmental Policy Act (NEPA) planning document, reliance on the Environmental Protection Agency's (EPA) pesticide registration process as a demonstration of safety may not be adequate. The Forest Service and Bureau of Land Management were involved in several court cases in the early 1980s that specifically addressed this question (principally *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248 (9th Circuit, 1984) and *Southern Oregon Citizens v. Clark*, 720 F. 2d 1475, 1480 (9th Cir. 1983)). Both cases were decided in the 9th Circuit Court of Appeals, which covers most of the western United States. The Southern Oregon Citizens decision was appealed by the Government to the Supreme Court, which refused to hear it. These court decisions and others affirmed that although the Forest Service can use EPA toxicology data, the Agency is still required to do an independent assessment of the safety of pesticides rather than simply relying on the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration. The Courts found that FIFRA does not require the same examination of impacts that the Forest Service is required to undertake under NEPA.

Risk assessment guidelines are available for use by Pesticide Specialists, Pesticide Project Coordinators, and Researchers. This direction is especially important to technical writers of environmental documents prepared in compliance with NEPA. Follow the additional direction for NEPA compliance in FSM 1950 and FSH 1909.15.

Existing risk assessment documents and worksheets for a number of priority pesticides have been developed for the Forest Service. These are available online at the Forest Service, State and Private Forestry, Forest Health Protection website. Existing risk assessments may be used instead of developing a project-specific risk assessment as outlined in the following sections. If one of these existing risk analyses is used, this chapter can serve as a background document useful in explaining how the risk analysis is developed. In developing a new pesticide risk assessment, utilize these existing risk analysis documents as a template and to help formulate exposure scenarios, if appropriate.

21 - Components of Risk Assessment

Risk assessment can be subdivided into four procedural steps: hazard analysis, exposure analysis, dose response assessment, and risk characterization.

21.1 - Hazard Analysis

Use hazard analysis to identify the toxic properties of pesticides proposed for use. In conducting a hazard analysis, make a thorough review of available toxicological information, including acute, subchronic, chronic, teratogenic, reproductive toxicity, carcinogenicity, mutagenicity, neurotoxicity, and potential for endocrine system disruption and any human epidemiological evidence. The hazard analysis must include information regarding the active ingredients, adjuvants, metabolites, and contaminants as it becomes available. Compile the key information into a format that adequately describes the toxicological characteristics of the pesticide under review. Place emphasis on defining the characteristics of the active ingredient. Evaluate the toxicological characteristics, using the available information, of inert ingredients, such as carriers, stickers, spreaders, and other compounds that facilitate the use of the active ingredient.

Hazard analysis should:

1. Identify the kinds of health effects observed in laboratory studies on animals, noting at what levels and in what route of exposure this effect was elicited.

2. Identify any health effects observed in humans (including whether the material is a mutagen, neurotoxin, reproductive toxin, teratogen, or endocrine disruptor). Also identify health effects of metabolites and any inerts or contaminants.

3. Display the lowest no-observed-effect levels (NOELs) or lowest no-observed-adverse-effect levels (NOAELs) for acute, subchronic, and chronic toxic effects.

4. In lieu of acute NOELs for specific scenarios indicate the median lethal dose (LD_{50} or LC_{50}) for acute effects and how it will be used to estimate risk.

5. Determine whether the pesticide formulation is a carcinogen.

6. Identify data gaps.

21.11 - Sources of Toxicity Information

Consult a wide range of literature to establish the toxicity of a particular pesticide. Check availability of relevant Forest Service Human Health and Ecological Risk Assessments (HHERAs). Conduct literature searches (library and internet).

Much of the data on pesticide toxicity have been generated to comply with FIFRA, and they are available from the EPA. The Environmental Protection Agency uses these data to compile summaries in a variety of formats:

1. Summary tables - “tox one-liners".

2. Chemical Fact Sheets.

3. Registration Science Chapters.

4. Reregistration Eligibility Decisions (RED) and supporting documents.

5. Technical Reregistration Eligibility Decisions (TREDS).

6. Databases such as:

    a. Integrated Risk Information System (IRIS).

    b. ECOTOX Database.

Much of the above information is available on-line at EPA’s website (http://www.epa.gov/pesticides/).

In addition to the EPA’s data, summary documentation is available for many pesticides from other agencies such as the United Nations’ World Health Organization and its Food and Agriculture Organization, the State of California’s EPA, Environment Canada, and many similar science agencies.

21.12 - Hazard Analysis for Other Organisms

In addition to hazard analysis of potential effects on humans, toxicity information for other organisms is also important. At a minimum, the following components of the environment should be considered:

1. Pollinators. Pesticide applications might affect domestic and wild bees and other pollinators. If there is potential for direct application to pollinators, or residual effects during foraging and pollination, then consider data on acute toxicity to local pollinators, including pesticide label guidelines, warnings, and Forest Service HHERAs.

2. Other Insects. Insects, such as beneficial parasites and predators, and non-target species might be adversely affected by pesticides proposed for use. Check the literature to determine if there have been reports of adverse effects, including pesticide label guidelines, warnings, and Forest Service HHERAs.

3. Aquatic Organisms. Aquatic invertebrates, amphibians, fish, and plants might be adversely affected by pesticides proposed for use. Review including pesticide label guidelines, warnings, and Forest Service HHERAs and toxicity studies on the impacts of pesticides on these components of the environment. In most cases, the only studies available are acute toxicity studies that describe the LD_{50}, $EC_{50,}$ or LC_{50} for particular pesticides or specific kinds of organisms. Use the 96-hour, or longer, period of exposure for LC_{50} values when available.

4. Mammals. In assessing the hazards of pesticide use to non-target wild mammals, consider appropriate human toxicity studies, wild animal LD_{50} studies, and simulated and actual field testing. However, in most cases, rat or mice acute, subchronic, and chronic laboratory studies are used to extrapolate to other mammals. Use data on rabbits, dogs, goats, cows, or other mammals if they are available.

5. Birds. Consider birds in risk analyses. Review toxicity studies that determine potential adverse effects of proposed pesticide uses. These include: avian acute oral LD_{50}, avian dietary LC_{50}, or better still, no observed effect levels (NOELs) or no observed adverse effect levels (NOAELs) from toxicity studies, avian reproductive studies, and avian cholinesterase tests. Birds frequently used in these tests are upland gamebirds and waterfowl.

6. Non-Target Plants and Microorganisms. Consider impacts to non-target plants and microorganisms. Review toxicity studies that indicate potential adverse effects of proposed pesticide uses.

7. Threatened, Endangered, Proposed for Listing, or Sensitive (TEPS) Species. Although most threatened, endangered, proposed for listing, or sensitive (TEPS) species fit into the preceding biological classifications, a more in-depth literature review might need to be conducted to review toxicity data for these species. Information gathered here might point to more restrictive safety factors being included to protect these individuals (a discussion of safety factors is in sec. 21.41).

21.2 - Exposure Analysis

The purpose of exposure analyses is to determine the exposures (and eventually the dose) that could occur to various human, animal, and plant populations. Exposure analysis should:

1. Identify people, and other organisms likely to be exposed.

2. Identify routes of exposure.

3. Estimate exposure using realistic exposure and accident scenarios.

4. Calculate the doses.

21.21 - Identification of Exposed People

People potentially at risk due to exposure to pesticides fall into two groups; workers and members of the general public. Workers include Pesticide Handlers (Applicators), Supervisors, Crop Advisors, and other personnel directly involved in pesticide application, and/or those categories defined by the Worker Protection Standard when it applies. The public includes other forest workers, forest visitors, or nearby residents. The public could be exposed through pesticide drift; contact with treated vegetation; by eating forest products such as berries or

mushrooms gathered in or near the treated area; by eating game or fish containing pesticide residues; or by drinking water that contains such residues.

1. Workers. Identify appropriate scenarios of worker exposure from the proposed pesticide application. Scenarios for exposure analysis should include those with the greatest potential for worker exposure to pesticides in forest management operations. These scenarios include:

a. Mixing and loading pesticides into application equipment;

b. Applying pesticides as a backpack applicator, a ground equipment operator, or an aircraft pilot or crew member; and

c. Supervising applications, observing applications, or inspecting contracted applications.

In some pesticide-use situations other employees have the potential to be exposed to pesticides. For example, in forest nursery operations workers involved in weeding, seedling lifting, sorting, packing, and fumigation tarp handling could be exposed.

To simplify analysis, worker exposure scenarios generally focus on the Pesticide Handler (the worker typically at risk of receiving the highest exposures.)

2. Public. Identify appropriate scenarios for members of the general public who might be exposed as a result of pesticide applications in forestry. Although most exposure results from indirect rather than direct contact with a pesticide, calculations of the potential doses received by the public are important in any analysis of risk. Consider the potential exposure of members of the general public who come into contact with pesticides through:

a. Incidentally contacting foliage while walking in treated areas;

b. Inhaling or being contacted by vapors or droplets that move offsite ;

c. Ingesting residues on forest products, such as basket weaving materials, berries, mushrooms, seeds, and nuts;

d. Ingesting game animals or fish containing pesticide residues;

e. Consuming water containing pesticide residues; or

f. Directly contacting herbicides during application (accidental exposure).

Also consider members of the public who might be particularly sensitive to certain pesticides. Included in this category are women of child-bearing age, children, senior citizens, or other persons who are known to be particularly sensitive or who have compromised immune systems.

21.22 - Potential Routes of Exposure

For individuals to be exposed to a pesticide there must be one or more points of entry. Typical occupational exposures might involve multiple routes of exposure (that is, oral, dermal, and inhalation). For workers, the route of exposure is a function of the type of application; however, dermal exposure is generally the predominant route. The public are least likely to be directly exposed, but because of the variability in how they might be exposed, dermal or oral exposure should be considered. Exposure analysis is used to evaluate how humans might be exposed through these primary routes.

The amount of pesticide calculated to exist in a person's immediate environment is the exposure level. The amount of pesticide that actually gets into a human body (through inhalation, ingestion, or dermal absorption) is the dose.

21.23 - Exposure Scenarios

Calculate exposures and doses expected to be received on the basis of several scenarios, focusing on the expected pesticide application rate. In most instances, routine operational conditions are likely to exist. Accidents and extreme case events can occur. In such cases, the exposure to pesticides is generally increased, and these eventualities should be considered. Routine scenarios that are likely to exist and accident scenarios that can occur, such as the unintentional spraying of a person or an animal, are analyzed for their effect on personal or environmental exposure. Where data gaps have been identified, follow direction in 40 CFR 1502.22 (also described in FSH 1909.15, sec. 13).

21.24 - Other Exposure Factors

Other factors to consider at this time are:

1. Can project design features be manipulated to reduce the risk of exposure (for example closing campgrounds or roads to limit non-worker access and expected exposure; or, limiting operating seasons to those when certain wildlife species are absent)?

2. What are label constraints on applied volume of pesticide per unit?

3. Can duration of exposures be reduced?

4. Can frequency of exposure be altered to allow the greatest possible time interval between applications?

It is important with some chemicals and in some situations to know the time during the species life-cycle when exposure might occur. With agents that might act negatively on the reproductive system, for example, it is essential to know if exposure will occur during the reproductive period of non-target animals and plants.

21.25 - Estimating Doses

Estimate doses for each scenario (worker and general public). Calculate doses resulting from exposure using the most appropriate available data, or use mathematical modeling procedures to project dose.

Similar to analysis of potential doses to people, estimates of doses to animals, insects, and plants are based on scenarios that attempt to describe potential range of effects predicted for realistic exposures to pesticides applied for forest management. Direct exposures to animals and insects can be via dermal, oral, or inhalation routes, while indirect exposures can be the result of contact with or ingestion of contaminated water or food such as plants or prey animals. For plants, pesticides might be sprayed directly onto plants, or plants might be exposed via pesticide drift or by pesticide movement through or over the soil. Scenarios should involve both susceptible terrestrial and aquatic species, as mentioned in section 21.12. Calculate doses resulting from exposure using the most appropriate available data or project dose using mathematical modeling procedures.

21.3 - Dose-Response Assessment

The purpose of the dose-response assessment is to describe the degree or severity of risk as a function of dose. This can be done by describing the increasing effects from increased dosing found in experimental studies. Once the exposure analysis is completed, if the expected dose is higher than the adopted reference value (for instance, a chronic RfD), then a dose-response assessment can help to describe the relative seriousness of the dose. A dose-response assessment can become fairly complex depending on the adverse effects and how sensitive the organism is to increases in dose amounts and duration.

21.4 - Risk Characterization

Once hazard and exposure analysis and dose-response assessment have been completed, characterize the risk by comparing toxicity (hazard) information with dose estimates and determine the risk posed to the target organism by the proposed scenario. This process helps to estimate the likelihood and severity of impacts on humans and the environment under the specified conditions.

21.41 - Evaluation

To evaluate human risk using the hazard quotient (HQ) method, characterize the risk of acute or chronic effects by comparing the estimated doses with the appropriate acute or chronic RfD (EPA established reference dose) value. Hazard quotient values that are below one generally represent acceptable levels of risk. Hazard quotient values that exceed one (the dose received exceeds the NOEL or RfD determined for the potentially affected organism) might represent an unacceptable level of risk. These doses should be evaluated to determine the likelihood and potential significance of effects if they were to occur.

Human RfDs are generally calculated by the EPA and published on the internet in their Integrated Risk Information System (IRIS) database. However, where this information is missing for a particular chemical it can be estimated by applying a safety factor of 100 to the lowest acute, subchronic, or chronic NOAEL found in mammalian toxicity tests. This safety factor of 100 is based on a factor of 10 when extrapolating from laboratory animals to humans; and an additional factor of 10 to account for differential sensitivities within the human population, including the difference between children and adults. In some cases, additional safety factors might be used, such as with pesticides that show specific effects to the young, or where toxicity data are deemed to have a higher than average degree of uncertainty.

Risk characterization will also include estimating the potential for a pesticide to cause cancer. This risk is normally estimated on the basis of estimated average daily exposure over a 70-year lifetime. The cancer potency factor is intended to be applied to lifetime daily doses. Many of the exposure assessments involve much shorter periods of time. Following the approach recommended by EPA, assume that the average daily dose over a lifetime is the appropriate measure for the estimation of cancer risk. Thus, the lifetime cancer potency factor is scaled linearly when applied to shorter periods of exposure. The Forest Service has adopted a cancer risk level of one in one-million (1÷1,000,000) as a trigger that would require special steps to mitigate exposure or restrict and possibly eliminate specific uses.

Risk characterization involves a determination of cumulative risk, synergistic effects, and risk to sensitive individuals. During the conduct of risk characterization for all exposure scenarios the assessor should evaluate cumulative and synergistic effects:

1. Cumulative exposure situations should be considered since certain persons might be subject to repeated or cumulative exposures over time. For example, visitors who frequently use forest areas subject to treatment with pesticides might be at risk of greater exposure than other members of the public. Therefore, prepare realistic calculations of their potential to receive excessive doses based on additive doses from likely exposure scenarios, and:

    a. The number of visits to treated areas each year,

    b. The amount of vegetation they contact,

    c. The berries/mushrooms or other foraged items they consume, and

    d. The local water they drink while visiting.

2. Synergistic effects should also be addressed, especially if a pesticide proposed for use is known to exhibit this phenomenon. Share knowledge of these situations with the public and decisionmakers.

With non-human risk, compare the estimated doses with the lowest applicable acute or chronic NOAEL value (if available) to characterize the risk of acute or chronic effects. Calculate a hazard quotient (HQ) for each pesticide dose estimate by dividing the acute or chronic dose by the acute or chronic NOAEL. With TEPS species, an additional safety factor might be

applicable, depending upon available research, although EPA often applies safety factors of 5 or 10 when dealing with TEPS species. As with human risk, HQ values that are below one would generally represent acceptable levels of risk. Hazard quotient values that exceed one might represent unacceptable levels of risk. These doses should be evaluated to determine the likelihood of actual effects and the impacts of any effects.

22 - Documentation of Risk Assessment

When a risk assessment is prepared to support NEPA analysis, document the results (hazard, exposure, and risk). This documentation can take two forms:

1. Separate stand-alone publications prepared by agency internal or external writers; or

2. An appendix to a decision-making document prepared in compliance with the implementing regulations of the National Environmental Policy Act (NEPA). If a risk assessment is incorporated as an appendix or as a reference to an Environmental Impact Statement (EIS) or Environmental Assessment (EA), a summary of its content must be included in the body of the EIS or EA and the Record of Decision (ROD) or Decision Notice (DN). Prepare the summary in as non-technical terms as possible so that the public can reasonably understand the risks being considered in connection with a proposed action.

23 - Risk Management

Upon completion of a risk assessment, a number of techniques can be used to determine the best course of action for preventing identified problems. These range from taking appropriate risk management measures to reduce risk, to not taking the proposed action, thus avoiding potential risks. For example, it might be appropriate to use only certain formulations of a desired active ingredient, to use buffers near sensitive areas, to wear protective clothing or a respirator (requires appropriate training, refer to FSH 6709.11, ch. 20), to wash with soap and water, or to make applications when exposure is unlikely to occur.

Nearly all human activities involve some risk. The degree of risk ranges widely, both in fact and perception. Many activities, even though they involve risk, are both voluntary and acceptable to most people. Activities that are perceived to be very risky and perhaps unacceptable to the public require careful analysis and proper communication. Careful analysis involves judgments of science as previously described. Risk communication involves sharing this information with decisionmakers and the public as described in section 24.

The process of risk assessment is the most systematic means available for organizing, analyzing, and presenting information on environmental agents and events (such as pesticide use). Use risk assessment to support decisions concerning the need for and extent of controls of exposure necessary to protect public health and the environment. The most serious potential danger associated with the use of risk assessment results from failure to recognize their limitations. Writers of risk assessments shall clearly disclose all assumptions used and the reasons for selecting alternatives. Managers and decision makers shall also recognize the uncertainties

associated with risk assessments and incorporate those considerations into their decision-making. Absolute safety cannot be proven and the absence of risk can never be demonstrated. No chemical has been studied for all possible effects and the use of data from laboratory animals to estimate hazard or the lack of hazard to humans, wildlife or the environment is a process that contains uncertainty. Prudence dictates that reasonable care should be taken in the handling of pesticides. Avoidance of the unnecessary risk or accident is good risk management.

24 - Risk Communication

Risk communication is the act of conveying or transmitting information between interested parties about levels of health or environmental risk; the significance or meaning of such risk; or decisions, actions, or policies aimed at managing or controlling such risk. Risk communication takes a variety of forms, ranging from precautionary statements on pesticide labels to interactions among government officials, industry representatives, the media, Agency employees, and the public. Employees shall receive required OSHA Hazardous Communications (Right-to-Know) training (FSH 6709.11, ch. 60, sec. 61.21).

Care must be taken when communicating risk associated with pesticide to the public; especially when comparing exposure to pesticides with non-pesticide hazards (such as driving a car), or comparing exposure to other common food or drug items (such as cigarettes, alcoholic beverages, or salt). Be careful to avoid the appearance of 'trivializing' the real risks identified for the pesticides.

Consider the following for sensitive risk communication:

1. Accept and involve the public as a legitimate partner;
2. Plan and carefully evaluate risk communication efforts;
3. Listen to the public's specific concerns;
4. Be honest, frank, and open;
5. Coordinate and collaborate with other credible sources;
6. Meet the needs of the media; and
7. Speak clearly and with compassion.