CENTER FOR
FOOD SAFETY

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OPP Docket
Environmental Protection Agency Docket Center (EPA/DC) (28221T)
1200 Pennsylvania Avenue, NW
Washington, CD 20460

RE: Docket No. EPA-HQ-OPP-2016-0226

Comments on "Pesticides; Draft Guidance for Pesticide Registrants on Herbicide Resistance Management Labeling, Education, Training, and Stewardship"

Center for Food Safety appreciates the opportunity to comment on EPA's draft guidance for herbicide-resistant weed management, entitled "Draft Pesticide Registration (PR) Notice 2016-XX – Guidance for Herbicide-Resistance Management, Labeling, Education, Training, and Stewardship" (henceforth referred to as "EPA Herbicide Guidance"); and "Draft Pesticide Registration (PR) Notice 2016-X – Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling" (henceforth, "EPA Pesticide Guidance"). Documents cited in these comments and listed in the references section at the end are also being submitted to the docket as supplementary materials to these comments.

First, it should be said that two guidance documents that rely almost completely on label information are an entirely inadequate response to the rapidly increasing threat posed by herbicide-resistant weeds. The scale and gravity of the threat demand that EPA act with the full force of law. There is no substitute for binding federal regulations, and anything short of a federal regulation is merely a suggestion that does not mandate compliance. EPA has found that herbicide-resistant weeds constitute an adverse effect under FIFRA (EPA Pesticide Guidance, pp. 2, 5; EPA Herbicide Guidance, pp. 6-7). EPA cannot effectively carry out its mandates under FIFRA to address the adverse effects of herbicide resistance through guidance; the Agency must do so through notice-and-comment rulemaking pursuant to the Administrative Procedure Act.

With this draft guidance and the similar guidance on pesticide resistance management labeling, EPA purports to take a "holistic, proactive approach to slow the development and spread of herbicide-resistant weeds, and prolong the useful lifespan of herbicides and related technology" (EPA Herbicide Guidance, p. 2). The guidance as proposed, however, is narrow, reactive, and anything but holistic; and thus will almost certainly be ineffective.

NATIONAL HEADQUARTERS
660 Pennsylvania Avenue, SE, Suite 302
Washington, D.C. 20003
T: 202-547-9359 F: 202-547-9429

CALIFORNIA OFFICE
303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
T: 415-826-2770 F: 415-826-0507

PACIFIC NORTHWEST OFFICE
917 SW Oak Street, Suite 300
Portland, OR 97205
T: 971-271-7372 F: 971-271-7374

HAWAI'I OFFICE
1132 Bishop Street, Suite 2107
Honolulu, Hawaii 96813
T: 808-681-7688

office@centerforfoodsafety.org centerforfoodsafety.org

A truly holistic approach must acknowledge the intersecting and mutually supportive goals of herbicide-resistant (HR) weed management and protection of human health and the environment (see e.g. Appendix 1; and CFS 2,4-D Soy 2012, pp. 17-21). This is consistent with the principles of integrated pest management (IPM), of which integrated weed management is a part. An approach that encompasses all three goals naturally makes as its top priority reduced dependence on and use of herbicides. This is not only the most effective means of inhibiting weed resistance, but would also lead to less herbicide-induced human disease and reduced environmental harm. In contrast, the narrow focus on HR weed management that characterizes EPA's approach here will lead to a misguided ***intensification*** of herbicide use, to the detriment of human health and the environment as well as farmers' long-term welfare.

A holistic approach could also aim higher because it would be more effective. With reduced dependence on herbicides and a concomitant increase in the use of non-chemical weed management techniques, farmers could in most cases reduce selection pressure sufficiently to ***prevent*** the evolution and spread of herbicide-resistant weeds rather than merely ***slow down*** the process, the aim of EPA's herbicide-centric approach. Weed scientists agree that prevention of resistance is not an unreasonable goal (e.g. Neve 2008).

A holistic approach would also entail a more holistic analysis of the problem. EPA would consider, for example:

1) The aspects of herbicide-resistant crop systems that make them especially strong promoters of weed resistance;
2) The economic and time-management factors that influence farmers' use or non-use of recommended practices for herbicide-resistant weed management;
3) The relative efficacy of herbicide label instructions versus other approaches;
4) The need for measures to prevent resistance versus only monitoring; and
5) The economic incentives and marketing practices of pesticide companies and how they impact resistance management.

EPA's failure to analyze these and other important factors has resulted in an herbicide resistance management guidance that will be ineffective and unworkable.

Why herbicide-resistant crop systems promote rapid evolution of weed resistance

EPA sets out three categories of concern – low, moderate and high – for evolution of herbicide-resistant weeds. EPA places herbicides in one of these three categories based on whether or to what extent populations of weed species have evolved resistance to them in the U.S. Low concern = herbicide classes to which there is no record of resistance in the U.S.; moderate and high concern categories encompass herbicide classes with limited and more prevalent weed resistance, respectively. The high concern category, however, also includes ***any*** herbicide (regardless of its history re: weed resistance) that is a "partner for conventionally bred or GM herbicide-resistant crops" (EPA Herbicide Guidance, p. 11). While this additional classification criterion is correct, EPA provides no analysis to support the "high concern" for resistance in the context of herbicide-resistant crops. This analytical failure is presumably related to the U.S. government-wide fear of saying anything even remotely critical of agricultural biotechnology. We summarize the missing analysis below.

In brief, herbicide-resistant (HR) crops are marketed and used by farmers as crop ***systems*** comprised of the HR crop and post-emergence application of the herbicide(s) to which the crop is resistant. HR crop systems promote excessive reliance on and frequent use of the herbicide(s) to which the HR crop is resistant, and they promote application of that herbicide later in the growing season to larger weeds. When an HR crop system is widely adopted, as the Roundup Ready system is, these resistance-promoting features act across a huge expanse of cropland. These four factors – frequency, exclusivity, and extensiveness of the companion herbicide's use, and application later in the growing season – make HR crop systems especially strong and problematic promoters of weed resistance. For a more detailed and documented treatment of this subject, see CFS 2,4-D Soy (2012), pp. 21-24.

<u>Why doubling down on herbicide use is the wrong response</u>

The major recommendations in EPA's herbicide resistance management guidance relate to use of multiple herbicides in the form of tank mixes (EPA Pesticide Guidance, p. 8; EPA Herbicide Guidance, pp. 19-20). In the case of HR crops, the chief recommendation is to make pre-emergence applications of soil-applied non-system herbicides together with post-emergence use of the system herbicide(s) (e.g. EPA Dicamba Benefits 2016, p. 3; see also CFS Dicamba 2016, pp. 23-24). The rationale for this approach is that by attacking the weed with herbicides that kill via different modes of action, resistance to any individual herbicide is supposed to be forestalled. However, this "multiple modes of action" approach has been the primary recommendation for resistance management for decades, and yet herbicide-resistant weed populations are emerging as rapidly as ever (Figure 1). This is the mark of a failed approach.

One reason for its failure is the rapid emergence of resistance to multiple herbicides: 44% of weed populations with multiple herbicide resistance have emerged since 2005 (Mortensen et al. 2012; see also Figure 2). Multiple herbicide-resistant weed populations most frequently emerge via accumulation of resistance traits over time. For instance, many weeds evolved resistance to atrazine and other triazine herbicides in the 1970s and 1980s. ALS inhibitor resistance emerged rapidly in the 1980s and 1990s. Glyphosate resistance (from use of glyphosate with Monsanto's Roundup Ready crops) has emerged since the late 1990s, and often evolves in weeds with pre-existing resistance to ALS inhibitors, triazines, and/or other classes of herbicide.[1] As resistance to different modes of action accumulates in weed populations, doubling down with use of multiple herbicides becomes an ever less effective approach. For a discussion of this with respect to dicamba and dicamba-resistant crops, see CFS Dicamba Cotton-Soy DEIS (2014), pp. 21-30. Weeds can also evolve resistance to multiple

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[1] See http://www.weedscience.com/Summary/MOA.aspx?MOAID=12; note the large number of glyphosate-resistant weed populations that have resistance to multiple SOA's, or "sites of action" (denoted in red).

herbicides at once via detoxification mechanisms that are part of plants' natural defense mechanisms. However they develop, the rise of multiple herbicide-resistant weeds demands that weed resistance management take a new approach – one that prioritizes less reliance on herbicides, which lessens selection pressure for resistance, and increased use of non-chemical modes of weed control.

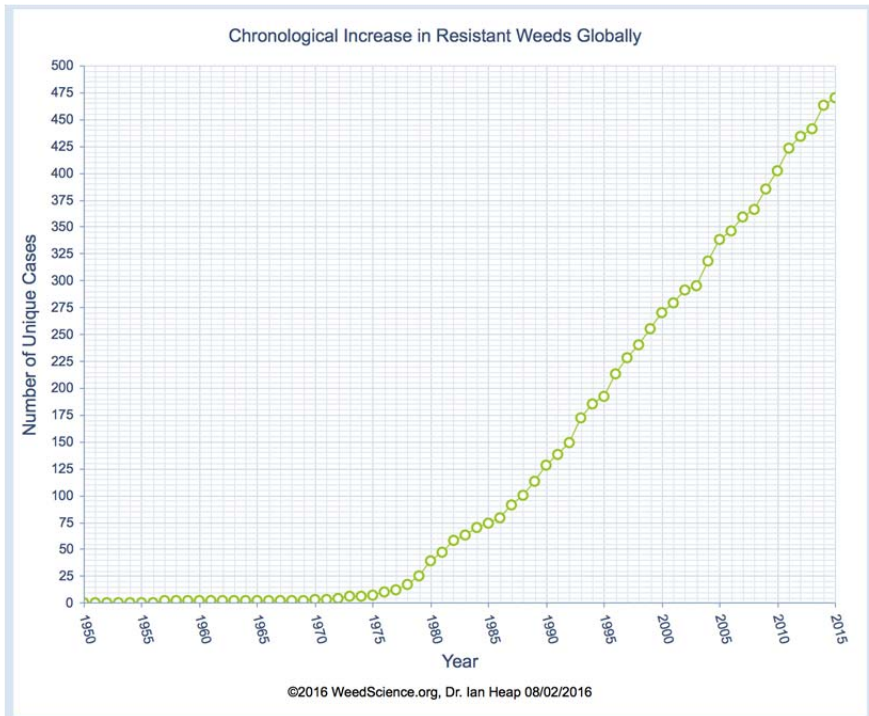

Figure 1: Chronological Increase in Resistant Weeds Globally.
Source: www.weedscience.com, accessed 8/2/16.

Economic and time-management factors as they relate to HR weed management

Even to the limited extent that using multiple herbicides does provide short-term resistance management benefits (at the cost of greater resistance in the longer-term), this approach is often not used for economic and time-management reasons. Farmers are strongly incentivized to rely exclusively on the HR crop herbicide partner(s) to recoup the substantial price premium for the HR trait(s), which can comprise half or more the price of the seed (Orloff et al. 2009). For the same economic reasons, farmers are understandably disincentived to pay still more (beyond the HR trait premium and the HR crop companion herbicide(s)) for ***additional*** non-system herbicides that are not part of the expensive HR crop system.

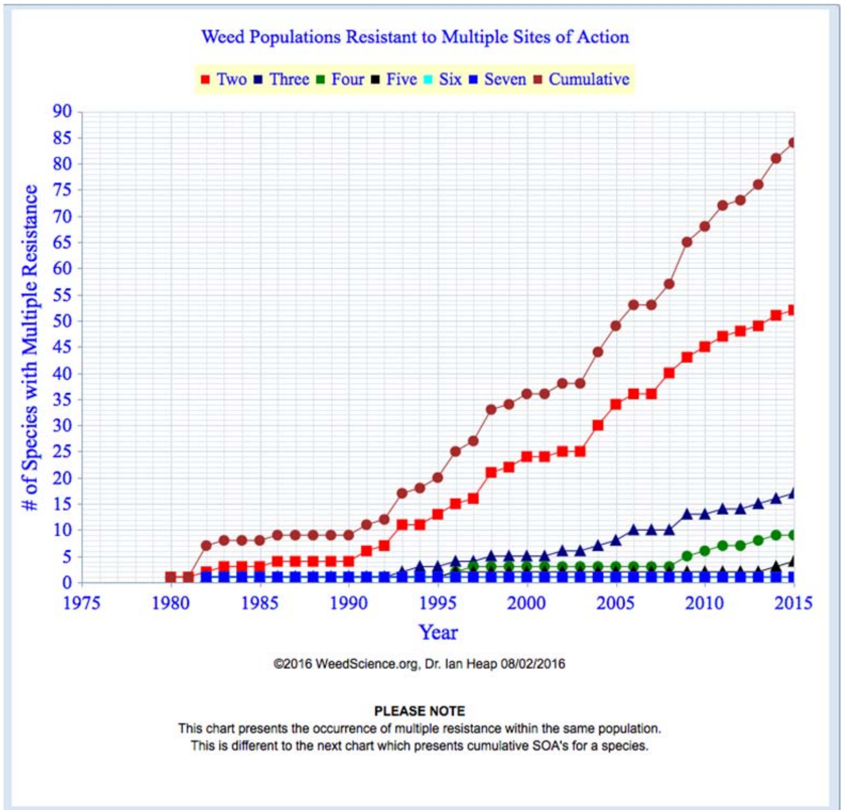

Figure 2: Weed Populations Resistant to Multiple Sites of Action.
Source: www.weedscience.com, accessed 8/2/16.

Convenience and labor-saving are among the most attractive features of HR crop systems to farmers (Duffy 2001, MacDonald et al 2013), at least until resistance emerges, when these benefits are eroded or lost. But convenience and labor-saving are premised on the simplicity of total reliance on post-emergence use of the HR crop system herbicide(s), which fosters rapid evolution of resistance. Use of one or more soil-applied, pre-emergence herbicides entails at least one additional herbicide application at or near planting time, one of the busiest times of year for most farmers. This is a huge time commitment, especially for growers who farm thousands of acres. Farmers ask why they should pay the price premium for HR seed if they are to employ a “conventional” weed control regime involving the extra time, expense and complexity of making multiple applications of different herbicides. As discussed further below, EPA’s recommendation that farmers scout their fields to detect potentially resistant weeds takes no account of the time this would require, especially for larger farms.

For many farmers, following this standard herbicide resistance management recommendation is tantamount to sacrificing the very benefits – convenience, reduced labor and reduced expenditures on herbicide – they paid for in the form of the HR trait premium. Academic weed scientists seldom appreciate these important economic and time-resource drivers of farmer decision-making with respect to HR weed management.

Label information must not be confused with herbicide resistance management

EPA's resistance management guidance relies heavily on adding various items of information and directions to the herbicide label. However, weed resistance management statements similar to though less extensive than those recommended now by EPA have been included on herbicide product labels since at least 2004 (NGSF 2004, p. 36), and have obviously been ineffective, especially with respect to inhibiting glyphosate-resistant weed development. Participants at the second National Glyphosate Stewardship Forum, which included weed scientists, farmers, representative of commodity groups, industry and regulatory agencies (including EPA), found that resistance management statements on labels have "low impact" at inhibiting resistance to glyphosate (NGSF 2007, pp. 39, 42).[2] This testimony should be taken seriously, as it represents the consensus view of all the important stakeholders at a forum explicitly convened to tackle the very problem EPA purports to address with this guidance. EPA provides no empirical evidence that in any way supports the efficacy of label statements concerning resistance management, while experts, including EPA officers, have judged labels to have "low impact" (see last footnote). There is also no empirical assessment of the factors (e.g. economic, time constraints) that influence farmers' real-world herbicide choices and the degree to which they do or do not implement herbicide resistance management directions, as discussed above.

Monitoring must not be confused with herbicide resistance management

EPA maintains correctly that "[T]he prevention of the development of herbicide-resistant weeds should be the first priority of a weed resistance plan" (EPA Herbicide Guidance, pp. 10-11). Yet this is mere empty verbiage. EPA's guidance fails to mandate any effective measures to ***prevent*** evolution of resistance in weeds, but rather proposed only ***monitoring*** to detect resistance after it has already emerged. An approach based solely on monitoring is doomed to failure, because the emergence of a resistant weed population is a slow, incremental process. In most cases it will begin with a ***single plant*** with the rare mutation that confers resistance to the herbicide, which then over the course of years of exposure to the herbicide gradually multiplies until it becomes an at all noticeable ***population*** of resistant weeds. Busy farmers may well fail to notice a few weeds that survive treatment with an herbicide; or if noticed, assume that they are simple "escapes" that were missed during a spraying operation. Crespo (2011) notes that resistance often escapes detection until at least 25% of the individual weeds in a particular population carry the resistance mutation. By that time, it may well be too late to effectively control the resistant weeds, especially in the case of outcrossing weeds able to disperse the resistance trait long distances via cross-pollination, or weeds with the ability (like horseweed) to disperse their resistant seeds even greater distances to infest neighboring or distant fields.

[2] Two breakout groups at the second National Glyphosate Stewardship Forum (2007) that made this same finding that label information has "low impact" each had an EPA participant: Bill Chism and Rick Keigwin. Bill Chism, with EPA's Biological and Economic Analysis Division, is the point person for the EPA Herbicide Guidance, which relies almost entirely on "low impact" label information.

Experience shows that weed resistance can evolve very rapidly when an herbicide is used as part of an herbicide-resistant crop system. For instance, glyphosate-resistant horseweed emerged within just three years in Delaware fields planted continuously to glyphosate-resistant soybeans treated with glyphosate (VanGessel 2001). Similarly, glyphosate-resistant (GR) horseweed was first reported in Tennessee cotton and soybean fields in 2001, and by 2004, just three years later, it had infested an estimated 1.5 million acres of Tennessee cropland (NGSF 2004, p. 60). Stahlman et al. (2013) found that "[g]lyphosate-resistant kochia spread rapidly throughout the central U.S. Great Plains within 4 years of discovery" (emphasis added). These examples illustrate how foolhardy it is to rely so heavily on scouting, while completely eschewing any preventive measures that could prevent or greatly slow resistance evolution such that monitoring would have a reasonable chance of detecting resistance before it had gotten out of hand.

While scouting fields for potentially resistant weeds is a worthwhile activity, it is not at all clear that EPA understands the limits of this approach. Many farms today are thousands of acres. Thorough scouting of huge fields on this scale would require a substantial commitment of farm labor that many growers will simply not make. To the extent that "scouting" is done at all, it is often a superficial affair that involves looking out the window of an automobile or truck while driving by. This once again underscores the need for effective measures to prevent evolution of herbicide-resistant weeds in the first place.

<u>EPA's plan must incorporate resistance prevention components to have any chance of success</u>

EPA fails to require any effective measures to prevent or substantially delay emergence of weed resistance. The most effective measures would have to involve reducing selection pressure by limiting the frequency with which an herbicide is applied, in a single season and/or over years, in line with the recommendations of many weed scientists. This is particularly true in the case of herbicides applied in the context of HR crop systems. In the case of inhibiting evolution of glyphosate resistance, for instance, scientists recommend annual rotation between a Roundup Ready and non-Roundup Ready crop, with glyphosate applied every other year instead of every year (Heap 1997). Syngenta's Chuck Foresman similarly recommended limiting glyphosate use to two applications in a two-year period (NGSF 2004, p. 26). EPA does not discuss or even mention the possibility of placing limits on the frequency of herbicide use as an herbicide resistance management tool.

It is also perverse that the EPA would fail to prescribe any resistance prevention components in light of the Agency's long experience with managing insect resistance to the Bt toxins in GE, insect-resistant corn and cotton, so-called Bt crops. EPA has had great success in ***preventing*** resistance to the first generation of Bt crops, which carry toxins that kill above-ground pests like the European corn borer and cotton bollworms. But this success was only realized because EPA established strict, mandatory "refuge" requirements under which growers had to plant (in most cases) 20% of their field to a non-Bt variety to prevent resistant pests from evolving in the first place. This "spatial refuge" approach is appropriate for mobile insects, while for sessile weeds a "temporal refuge" would accomplish the same purpose. This would involve imposing restrictions on the frequency with which an herbicide could be applied to a particular field during a single season and over years. This is precisely the approach that many weed scientists have proposed. Frustrated by the rapid increase in glyphosate- and multiple-resistant weed populations, six weed scientists recently stated that: "The time has come to consider herbicide-frequency reduction targets in our major field crops" (Harker et al. 2012). Shaner and Beckie (2014) likewise recognize the need for "reasonable [herbicide-]frequency use intervals" to forestall evolution of weed resistance.

Pesticide company marketing practices conflict with resistance management

Pesticide companies have not been good faith partners in herbicide resistance management, and can never be expected to be, because effective herbicide resistance management requires major reductions in the frequency of herbicide use, which entails less sales and profits. For a detailed, documented discussion, see CFS Dicamba Cotton-Soy DEIS, pp. 18-19, 32-35). The fact that pesticide companies' financial interests militate against meaningful herbicide resistance management is still another reason for EPA to pursue mandatory regulation rather than voluntary guidance.

Conclusion

EPA recognizes that herbicide resistance is an adverse effect under FIFRA, yet has proposed only weak guidance in response. The guidance consists largely of loading additional information about herbicide resistance onto herbicide labels, an approach that stakeholders, including EPA officers, have judged to be ineffective. EPA has failed to provide a holistic analysis of herbicide resistance, prescribe any measures to prevent weeds from evolving resistance in the first place, and relies excessively on a monitoring approach that will almost certainly fail. EPA is urged to pursue mandatory federal regulations to effectively confront the increasing threats to farmer welfare, the environment and human health posed by herbicide resistance.

Appendix 1

Why Reduce Reliance on Pesticides?

Concern about the side effects of synthetic pesticides began emerging in scientific and agricultural communities in the late 1940's, after problems with insect resistance to DDT. The public became concerned about the unintentional effects of pesticide use after Rachel Carson's book on bioaccumulation and other potential hazards was published in the 1960's. Many unintentional effects of pesticide exposure on nontarget species have been reported since then, including acute pesticide poisonings of humans (especially during occupational exposure), damage to fish and wildlife, and damage to species that are beneficial in agricultural ecosystems. Since the 1960's, some pesticides have been banned, others restricted in use, and others' formulations changed to lessen undesirable effects.

Human Health Impacts. The American Association of Poison Control Centers estimates that approximately 67,000 nonfatal acute pesticide poisonings occur annually in the United States (Litovitz and others, 1990). However, the extent of chronic health illness resulting from pesticide exposure is much less documented. Epidemiological studies of cancer suggest that farmers in many countries, including the United States, have higher rates than the general population for Hodgkin's disease, leukemia, multiple myeloma, non-Hodgkin's lymphoma, and cancers of the lip, stomach, prostate, skin, brain, and connective tissue (Alavanja and others, 1996). Emerging case reports and experimental studies suggest that noncancer illnesses of the nervous, renal, respiratory, reproductive, and endocrine systems may be influenced by pesticide exposure. Case studies, for example, indicate that pesticide exposure is a risk factor for several neurodegenerative diseases, including Parkinson's disease and amyotrophic lateral sclerosis, also known as Lou Gehrig's disease (Alavanja and others, 1993). A comprehensive Federal research project on the impacts of occupational pesticide exposure on rates of cancer, neurodegenerative disease, and other illnesses was begun about 5 years ago in North Carolina and Iowa; about 49,000 farmers who apply pesticides and 20,000 of their spouses, along with 7,000 commercial pesticide applicators, are expected to participate in the study (Alavanja and others, 1996).
Direct exposure to pesticides by those who handle and work around these materials is believed to pose the greatest risk of human harm, but indirect exposure through trace residues in food and water is also a source of concern (EPA, 1987). The effects of these pesticide residues on infants and children and other vulnerable groups have recently been addressed with a new legislative mandate in the Food Quality Protection Act of 1996.

Environmental Quality. Documented environmental impacts of pesticides include poisonings of commercial honeybees and wild pollinators of fruits and vegetables; destruction of natural enemies of pests in natural and agricultural ecosystems; ground- and surface-water contamination by pesticide residues with destruction of fish and other aquatic organisms, birds, mammals, invertebrates, and microorganisms; and population shifts among plants and animals within ecosystems toward more tolerant species. Most insecticides used in agriculture are toxic to honeybees and wild bees, and costs related to pesticide damages include honeybee colony losses, honey and wax losses, loss of potential honey production, honeybee rental fees to substitute for pollination previously performed by wild pollinators, and crop failure because of lack of pollination. Approximately one-third of annual agricultural production in the United States is derived from insect-pollinated plants (Buchman and Nabhan, 1996), and flowering plants in natural ecosystems may not thrive because of fewer pollinators. The destruction of the natural enemies of crop pests has led to outbreak levels of primary and secondary crop pests for some commodities, and pest management costs have increased when additional pesticide applications have been needed for these larger or additional pest populations. Measurable costs related to pesticide residues in surface- and groundwater include residue monitoring and contamination cleanup costs and costs of damage to fish in commercial fisheries. Bird watching, fishing, hunting and other recreational activities have been affected by aquatic and terrestrial wildlife losses due to pesticide poisonings. The destruction of invertebrates and microorganisms that have an essential role to healthy ecosystems is an emerging issue.

Pesticide Resistance. After repeated exposure to pesticides, insect, disease, weed, and other pest populations may develop resistance to pesticides through a variety of mechanisms. The newer safety requirements for pesticide registration along with the increasing pace of pest resistance have raised doubts about the ability of chemical companies to keep up with the need for replacement pesticides. In the United States, over 183 insect and arachnid pests are resistant to 1 or more insecticides, and 18 weed species are resistant to herbicides (U.S. Congress, 1995). Cross-resistance to multiple families of pesticides, along with the need for higher doses and new pesticide formulations, is a growing concern among entomologists, weed ecologists, and other pest management specialists.

Emerging Issues. Important new issues are the impact of endocrine-system disrupting pesticides on human health and wildlife -- including potential reproductive effects and effects on child growth and development (EPA, 1997), and the potential for synergistic impacts from exposure to pesticides (Arnold and others, 1996).

Source: USDA AREI (2000), Chapter 4.3, p. 5.

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