

Pesticide Risk Indicators: Unidentified Inert Ingredients Compromise Their Integrity and Utility

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Abstract Pesticide Risk Indicators (PRIs) are widely used to evaluate and compare the potential health and environmental risks of pesticide use and to guide pest control policies and practices. They are applied to agricultural, landscape and structural pest management by governmental agencies, private institutions and individuals. PRIs typically assess only the potential risks associated with the active ingredients because, with few exceptions, pesticide manufacturers disclose only the identity of the active ingredients which generally comprise only a minor portion of pesticide products. We show that when inert ingredients are identified and assessed by the same process as the active ingredient, the product specific risk can be much greater than that calculated for the active ingredient alone. To maintain transparency in risk assessment, all those who develop and apply PRIs or make decisions based on their output, should clearly disclose and discuss the limitations of the method.

Keywords Pesticide Risk Indicators · Inert ingredients · IEQ · GUS

Introduction

In recent years there has been increasing awareness of the potential adverse health and environmental effects of pesticides. Efforts to reduce or eliminate pesticide use have

become common and, when pesticides are used, there is often a desire to choose the least toxic alternatives. A wide variety of tools have been developed to analyze the hazard and exposure characteristics of pesticides for various potential human health and environmental impacts. As a group, these tools are generally known as “Pesticide Risk Indicators” (PRI). PRIs vary in scope and format, and may consider impacts such as toxicity to humans, birds, fish or beneficial insects and pollution of surface waters, groundwater and air. In some instances, multiple impacts may be considered and an overall rating developed.

PRIs have been used to guide pesticide selection by multinational, national, state and local governmental agencies, farmers, property managers, golf course managers, integrated pest managers, community groups and individuals. They have been applied to prospective assessments of pesticide impacts, as in the design of pest management programs and the preparation of Environmental Impact Statements, to monitoring the impacts of agriculture and pesticide policies, and in the evaluation of ongoing pest management programs (WHO 2005; Mancini 2006; Eklo 2004; USDA Forest Service 2007; City of San Francisco 2007; Scherm 2003; Environmental Asset Management 2007; TDA 2001; OECD 1997a). Pesticide Risk Indicators vary in the range and type of pesticide attributes they include in their analysis—some focus purely on toxicological risk, while others consider the transport and fate of the applied chemicals. Most PRIs aim to produce a simplified metric or ranking system to facilitate comparison of risks associated with pesticide use and to better inform product selection. More than 100 PRIs have been developed worldwide and at least several are in widespread use. Greitens and Day (2007), Watts (2004), Van Bol and others (2003), OECD (1997a), and Levitan (1997) have reviewed, evaluated and compared many PRIs. The Groundwater Ubiquity Score (GUS) estimates the potential

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for groundwater contamination based solely on a pesticide's persistence in soil (DT_{50}) and mobility in soil (K_{OC}) (Gustafson 1989). More complicated tools, such as the Pesticide Root Zone Model (PRZM), predict pesticide transport and transformation through the crop root and unsaturated soil zone (Suárez 2005). Both the Pesticide Leaching Model (PELMO) and Pesticide Emission Assessment at Regional and Local scales (PEARL) also incorporate consideration of transformation or metabolism by-products of the active ingredient (FOCUS 2009a, b). The Pesticide Environmental Risk Indicator (PERI) estimates the risk associated with pesticide impacts in each of three environmental compartments: groundwater, surface water and air (Reus and others 2002). Similar approaches are employed by the Multi-Attribute Toxicity Factor Model (MATF), the Environmental Yardstick for Pesticides (EYP), and the Environmental Impact Quotient (EIQ) (Benbrook and others 2002; Reus and others 2002; Kovach and others 1992). The Ipest decision tool takes the analysis one step further by considering the site specific conditions where the pesticide is applied (van der Werf and Zimmer 1998). The inclusion of variables such as runoff risk based on slope gradient and soil type as well as weather conditions make this a more complicated analysis that must be performed each growing season.

Pesticide Products Contain a Mixture of Ingredients

If pesticide products were composed only of pesticidal ingredients, then PRIs might accurately and reliably be employed to predict or assess pesticide impacts. But, in fact, pesticide products are generally comprised of the pesticidal ingredient(s) formulated with a variety of solvents, synergists, surfactants, and other ingredients formulated to improve the stability, delivery and effectiveness of the pesticidal ingredient. In the terms of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) pesticidal ingredients are described as “active” ingredients, while all those ingredients formulated for purposes other than a pesticidal effect are inert (sometimes called “other”) ingredients.

When the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was first passed (FIFRA 1947), pesticides were known as “economic poisons” and they were regulated by the United States Department of Agriculture. As then defined, the ingredient statement on the label could contain either the name and percentage of each active ingredient and the total percentage of the inert ingredients or the name of the active ingredient, together with the name of each and total percentage of the inert ingredients.

FIFRA was substantially revised by the Federal Environmental Pesticide Control Act (FEPCA 1972), following

the 1970 transfer of pesticide regulatory responsibility to the newly created Environmental Protection Agency. As amended in 1976, FIFRA required only that the identity of all active ingredients and the total percentage of all inert ingredients be disclosed in the ingredient statement on pesticide labels. The 1976 amendment also prohibited EPA from disclosing the identity or percentage quantity of any deliberately added inert ingredient of a pesticide absent a determination by the EPA Administrator that disclosure was necessary to protect against an unreasonable risk of injury to health or the environment.

In Europe, OECD member nations use slightly different terminology but make the same distinctions between active and inert ingredients. Inert ingredients may be known as “adjuvants” and “formulants” and formulations may be called “preparations” (OECD 1994).

While many pesticide products may contain the same active ingredient, the inert ingredients with which they are formulated may differ, even in pesticide products intended to control the same pest. For example, the National Pesticide Information Retrieval System (NPIRS) lists 50 different glyphosate-containing products currently registered with the EPA to more than 20 different registrants (NPIRS 2008). Insofar as these products are designed for a variety of applications (e.g. aquatic, terrestrial, food crop, home and garden) and application methods (e.g. machine or hand sprayed, dry broadcast), as well as being produced in various forms (e.g. concentrated liquid, ready-to-use spray, foam, dry powder or pellet) by different manufacturers, the inert ingredients must necessarily differ from one product to the next.

Pursuant to FIFRA, the U.S. Environmental Protection Agency (EPA) requires pesticide manufacturers to provide the agency with the results of a suite of toxicological, ecological, and environmental fate tests before a pesticide can be sold. Most of the tests (about 2/3 of the toxicology tests, 3/4 of the ecological effects tests, and 1/2 of the environmental fate tests) use only the active ingredient(s) (US EPA 2005a). Thus, only limited information about the effects of the complete product formulation, as marketed and applied, is available.

Generally, individual inert ingredients are only minimally tested. For example, in 2006 EPA revoked the tolerances of dozens of inert ingredients because the agency found that there were insufficient data to make the safety assessment required by the Food Quality Protection Act. EPA suggested to inert ingredient suppliers that “for the majority of the inert ingredients a study such as OPPTS' Harmonized Test Guideline 870.3650 ... would fulfill the data gaps” (US EPA 2006). However, Guideline 870.3650 is described as a “screening test” that only “provides limited information” (US EPA 2000).

Despite this lack of information, a growing body of research suggests that inert ingredients can play a significant

role in determining the impacts of a pesticide on human and environmental health. Cox and Surgan (2006) reviewed research showing that inert ingredients can increase the ability of a pesticide to cause developmental neurotoxicity, genotoxicity, and disruption of hormone function. Inert ingredients can also increase dermal absorption of a pesticide, decrease the efficacy of protective clothing, and increase mobility and persistence in the environment.

Further research continues to show that these pesticide mixtures (active plus inert ingredients) have effects that cannot be accurately predicted by using data about active ingredients alone. For example:

- A dicamba-containing herbicide caused three times more damage to ovary cells than did dicamba alone (Gonzalez and others 2007).
- Absorption through the skin of a permethrin-containing insecticide was 4–10 times greater than for permethrin alone (Reifenrath 2007).
- A glyphosate-containing herbicide was more toxic to a non-target aquatic plant (*Lemna gibba*) than was glyphosate alone (Sobrero and others 2007).
- A permethrin-containing insecticide caused complete mortality of developing tadpoles at a concentration of 9 parts per billion; a similar concentration of permethrin alone did not cause mortality (Boone 2008).
- Mortality of zebra finches following exposure to a fipronil-containing insecticide was caused by a solvent (diacetone alcohol) in the product rather than the active ingredient (Kitulagodage and others 2008).
- An imidacloprid-containing insecticide caused twice as much mortality of *Daphnia magna* as did equivalent concentrations of imidacloprid alone (Jemec and others 2007).

Furthermore, inert ingredients are generally not minor constituents of formulated pesticide products. To the contrary, inert ingredients constitute a significant proportion of typical pesticide formulations. A survey of over 200 common household products in retail stores in Oregon found that inert ingredients accounted for an average of 86% of the total product (NCAP 2006a). Surveys of home and garden pesticide products sold in New York in 1990, 1997, and 1999 yielded similar results (Surgan and Gershon 2000). Agricultural products also contain a significant proportion of inert ingredients. In a review of over 100 agricultural pesticide products, inerts accounted for an average of >50% the total product (NCAP 2006b).

PRIs Fail to Consider the Impacts of Inert Ingredients

PRIs cannot account for the presence of inert ingredients without their chemical identity and information about their

properties and potential health and environmental impacts. With few exceptions, such information is not publicly available and, as a result, those who develop PRIs are unable to include them in their analyses. Therein lies a substantial limitation to their utility, especially when those who may rely upon the analyses are unaware of the limitations. In some instances, like the EIQ, scores are derived and published for specific active ingredients, while in other instances, like GUS, an equation is derived to be applied by the risk evaluator to active ingredients of concern. In either case, the assessment is conducted on the active ingredient alone.

Although the inert ingredients of pesticide products are rarely identified on product labels, the identities of the inert ingredients of a very few pesticide products can be determined from sources such as Material Safety Data Sheets and registrant responses to inquiries. In addition, a court ruling in 1986 required the government to make some of the information available under the Freedom of Information Act. (NCAP v. Browner, Freedom of Information Act 1966). Although specific pesticide product formulations may have changed over time, the information available from such sources can provide valuable insights into the inability of PRIs to accurately and reliably reflect the risks associated with the use of formulated pesticide products.

Inert Ingredients can Change the Estimate of Risk Substantially

The Groundwater Ubiquity Score (GUS) is an indicator of the potential for groundwater contamination based on the carbon adsorptivity (K_{OC}) and soil half-life (DT_{50}) of chemicals assessed (Gustafson 1989). Insofar as data for those properties are generally available for many chemicals, it is a straightforward analysis to compare the GUS for several pesticide active ingredients and the inerts with which they have been formulated. Glyphosate, Imazapyr, 2,4-D and Alachlor are all herbicidal active ingredients. They are listed in Table 1 along with several compounds which have been formulated with them as inerts in some pesticide products.

In each instance, the inert ingredients have a higher Groundwater Ubiquity Score than the active ingredients with which they are formulated, indicating a somewhat greater tendency for the inerts to contaminate groundwater. Gustafson proposed three GUS benchmark categories, each indicating an increasing propensity to travel to groundwater: “non-leacher,” “transitional,” and “leacher.” 1,2-benzisothiazolin-3-one is a “leacher” as compared to glyphosate, its co-formulated active ingredient which is classified as a “non-leacher”. Similarly, chlorobenzene is a “leacher” as compared to the “non-leacher” Alachlor, its

Table 1 Comparison of groundwater ubiquity scores for four active ingredients and their co-formulated inerts

Name	Koc	Soil half-life (days)	GUS score	GUS designation
Glyphosate	24,000 (NPIC 1994)	30 (European Commission 2002)	−0.56	Nonleacher
1,2-benzisothiazolin-3-one	104 (Dow 2007)	30 (US EPA 2005b)	2.93	Leacher
POEA	2500–9600 (Wang and others 2005)	42 (Giesy and others 1998)	0.98	Nonleacher
Imazapyr	100 (Wauchope and others 1992)	90 (Wauchope and others 1992)	3.91	Leacher
Isopropylamine	33 (Howard 1997)	20–200 (Vincoli 1997)	4.96	Leacher
2,4-D	53 (Gustafson 1989)	7 (Gustafson 1989)	2.18	Transitional
Butoxyethanol	67 (OECD 1997b)	7–28 (USDHHS 1998)	2.49	Transitional
Alachlor	161 (Gustafson 1989)	14 (Gustafson 1989)	2.06	Transitional
Chlorobenzene	126 (US EPA 1995)	35 (US EPA 1995)	2.93	Leacher

Active ingredients designated in bold type

“Leacher” (GUS > 2.8), “Transitional” (GUS 1.8–2.8), and “Nonleacher” (GUS < 1.8) are used as defined by Gustafson (1989)

1,2-Benzisothiazolin-3-one is an inert ingredient in Ortho Fence & Grass Edger Formula II, EPA Registration No. 239-2516 (A. Layne, U.S. EPA, personal communication to C. Cox—November 17, 2004)

POEA (Polyethoxylated tallowamine) is an inert ingredient in Roundup ProDry Herbicide EPA Registration No. 524-501, EPA (2004) (A. Layne, personal communication to C. Cox—November 17, 2004)

Isopropylamine is an inert ingredient in Stalker/Chopper, EPA Registration # 241-3945 (BASF 2008)

Butoxyethanol is an inert ingredient in Weed-Rhap A-4D, EPA Registration No. 5905-501 (C. Furlow, U.S. EPA, personal communication to C. Cox—February 2, 2004)

Chlorobenzene is an inert ingredient in Alachlor, EPA Registration # 524-5103 (Micro Flo Company 2000)

co-formulated active ingredient. Table 1 also illustrates the problems that arise when one generalizes about all products containing a specific active ingredient. As shown for glyphosate, the potential environmental risks depend upon the inert ingredient formulated in the product, information not provided on the label or otherwise readily available to end-users. Reliance on GUS to protect groundwater resources can provide false comfort to those who might use this tool to assess the potential impacts of pesticide applications.

Kovach and others (1992) factored the physical, chemical and toxicological properties (human, avian, fish and beneficial arthropod species) of pesticide active ingredients in the calculation of the Environmental Impact Quotient. The score is derived for the active ingredient alone, regardless of the inerts with which it may be formulated. The calculation yields separate Farmworker, Consumer and Ecology scores as well as a Total EIQ score. This total score can then be multiplied by the pesticide’s application rate to determine an EIQ Field Use Rating. The EIQ is designed to require minimal calculation by the end user; scores are calculated and published for individual active ingredients. The user simply consults a table to obtain the score for an active ingredient of interest. The published EIQ scores are updated and new active ingredients added, as data becomes available (NYSIPMP 2007).

In calculating EIQs for inert ingredients we relied upon the calculations presented by Kovach and others (1992) and consulted with current NYSIPMP personnel where clarification was needed (D. Marvin, personal communication February 5, 2008). Given the broad range of data

required to calculate the EIQ, data availability is a substantial limiting factor. Even when the identity of an inert ingredient could be determined, it was difficult to find sufficient physical, chemical and toxicological data to support the calculation.

Table 2 compares the derived EIQ scores for three active ingredients (glyphosate, imazapyr and 2,4-D), which are used in a wide variety of herbicidal products, to inerts formulated with them in at least one such product. Each of the inerts has a higher “Farm Worker Score” than their co-formulated active ingredients, indicating that the inerts have a greater potential to cause adverse health impacts to farm workers than their co-formulated active ingredients. POEA also has a higher “Ecology Score” than glyphosate, the active ingredient with which it is formulated. While the “Consumer Score” for the inerts was the same or lower than the “Consumer Score” for their co-formulated active ingredients, the “Total Score” for the inerts is consistently greater than that of their co-formulated active ingredients. Used as intended, the published EIQ scores may not fairly represent the potential adverse health and environmental impacts of formulated products.

There are currently 130 different herbicidal active ingredients with listed EIQ scores. After identifying active ingredients appropriate for their needs, end-users of the EIQ score can select the active ingredient with the lowest score to find the herbicide with the lowest potential for adverse health and environmental impacts. It is instructive, then, to see where the various inert ingredients would fall in the rank order of active ingredients.

Table 2 Comparison of EIQ rating metrics and scores for various active ingredients and their co-formulated inerts

Ingredient	Dermal toxicity factor	Fish toxicity factor	Leaching potential factor	Surface loss potential factor	Soil half life factor	Beneficial arthropod toxicity factor	Farm worker score	Consumer score	Ecology score	Total score
Glyphosate	1	1	5	1	1	1	8	7	31	15.3
POEA	3	5	3	3	1	1	24	5	45	24.7
	Dermal LD ₅₀ 1260 mg/kg, Aquatic LC ₅₀ 3 mg/L, (Williams and others 2000)	Aquatic LC ₅₀ 3 mg/L, (Doliner 1991)	Koc 2500 to 9600 (Wang and others 2005)	Koc 2500 to 9600 (Wang and others 2005)	(Soil half-life 42 days (Sax and Lewis 1989))					
Imazapyr	1	1	5	1	5	1	8	5	41	18.0
Isopropyl-amine	3	1	1	5	3	1	24	4	38	22.0
	Dermal LD ₅₀ 380 mg/kg (Sax and Lewis 1989)	Aquatic LC ₅₀ 40–80 ppm (US Coast Guard 2001)	Koc = 33 (Howard 1997)	Koc = 33 (Howard 1997)	Soil half-life 20–200 days (Vincoli 1997)					
2,4-D	1	1	1	5	1	1.7	8	3	45.5	18.8
Butoxyethanol	3	1	1	5	1	1	24	3	35	20.67
	Dermal LD ₅₀ 100–610 mg/kg (OECD 1997b)	Aquatic LC ₅₀ 2137 mg/l (OECD 1997b)	Koc = 67 (OECD 1997b)	Koc = 67 (OECD 1997b)	Soil half-life 7–28 days (DHHS 1998)					

Active ingredients in bold

The EIQ metrics for chronic, systemic, bird and bee toxicity omitted from Table 2 as they were the same for the active ingredients and their respective inerts. The EIQ system bases both surface loss potential and leaching potential solely on Koc

Table 3 Total EIQ rank for three active ingredients and their co-formulated inerts

Ingredient	EIQ rank (of 130 herbicides)
Glyphosate	28
POEA	~84
Imazapyr	41
Isopropylamine	~77
2,4-D	53
Butoxyethanol	~68

Active ingredients designated in bold type

EIQ rank increases with the likelihood of adverse impacts (Kovach and others 1992)

It is clear, as shown in Table 3, that reliance on the assessment of the active ingredient alone can result in a substantial underestimation of the potential adverse impacts of a formulated product. Glyphosate scores in the 78th percentile of herbicidal ingredients while morpholine and POEA would be in the 38th and 35th percentile respectively. The inert ingredients can substantially affect the potential impact ranking of the product selected. Unfortunately, the end-user of the EIQ score cannot determine where a specific glyphosate-containing herbicide formulation might rank. Indeed, even in the unusual circumstance when the identity of the inert can be determined, it is very difficult to gather sufficient information about the inert to make the calculation independently.

The EIQ can be further refined for specific applications by deriving a Field Use Rating, the EIQ score multiplied by the actual application rate. With this step, the disparity between the risk evaluation of active and inert ingredients using the EIQ can become much greater. Since active ingredients typically comprise only a small fraction of formulated pesticide products, the multiplier for the inert ingredient(s) in a product can be substantially higher than that of the active ingredient. Under these conditions, even an inert ingredient with a lower EIQ score than its co-formulated active ingredient can prove to be the greater concern. Were it possible, of course, the EIQ scores for all of the ingredients in a formulated product should be summed.

Conclusions and Recommendations

Health and environmental risk assessments should be comprehensive and transparent, assessing all associated risks and clearly disclosing the data used, assumptions made and limitations of the methodology applied. Pesticide Risk Indicators, as they are currently available and used, offer the advantage of a relatively inexpensive and quick

estimate of risk. However, they are neither comprehensive nor transparent because of the limited knowledge of the identity and properties of the inert ingredients and properties of formulated products (pesticides as they are sold and used). Because inert ingredients and formulated products may have physical, chemical and toxicological properties entirely different from those of the active ingredients alone, their impacts may be quite different. Because inert ingredients often comprise a substantial portion of the formulated product, their impacts can be quantitatively more significant. As we have demonstrated, although PRI methodologies are complex and broad in scope, without sufficient information about all chemical constituents their estimate of the risks associated with the use of an active ingredient may differ significantly from the actual risks of use of pesticide products in which that active ingredient is formulated.

In the absence of information about the identity and properties of inert ingredients and formulated products it is difficult for PRIs to estimate relative risks (for example, trends in pesticide risk over time or replacing use of one pesticide product with another) because the inert ingredients may vary over time or between products.

Given the current secrecy surrounding the identity of inert ingredients it is especially important to conduct pesticide risk assessments and related risk communications in a transparent manner. We suggest that PRI methodologies be accompanied by clear statements of the limitations of the analyses in light of the unavailability of full ingredient lists for pesticide products. Risk assessors who use PRIs to evaluate pest control alternatives should include in their assessment a discussion of the limits of the method for their clients and for the public.

We also invite the risk assessors and research scientists who develop and use PRIs, as well as those who rely upon the results of PRIs, to join the efforts of state governments, health professionals, and environmental organizations to promote full disclosure of pesticide ingredients.

The laws and regulations which currently enable pesticide registrants to maintain secrecy in regard to the inert ingredients in pesticide products are, in large part, beyond the control of the research community which has developed the PRIs, and beyond the control of the non-scientific communities which may depend on PRI evaluations to determine pest management policies and practices. Litigation and/or legislation may be required to force full disclosure of inert ingredients in pesticide products. Additional research will certainly be required to adequately characterize their physical, chemical and toxicological properties, and the properties of formulated products because most of this data is currently not required by the pesticide registration process. If such information were available it would be a relatively simple matter to modify

PRIs. Until such time as that information is available, we recommend that PRIs be used with caution and with full disclosure of their limitations.

The development of tools to accurately estimate the health and environmental hazards associated with the use of pesticide products is a laudable goal. In light of the inability of existing PRIs to achieve that goal in the absence of sufficient information about inert ingredients, we recommend that governmental agencies, other organizations, communities and individuals seek first to reduce pesticide use before they rely upon the selection of pesticides with apparently favorable PRI rankings. The large number of non-chemical alternative techniques that are widely used suggests that this approach will often be successful.

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