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Mass Releases of Genetically Modified Insects in Area-Wide Pest Control Programs and Their Impact on Organic Farmers

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Abstract: The mass release of irradiated insects to reduce the size of agricultural pest populations of the same species has a more than 50-year record of success. Using these techniques, insect pests can be suppressed without necessarily dispersing chemical insecticides into the environment. Ongoing release programs include the suppression of medfly at numerous locations around the globe (e.g., California, Chile and Israel) and the pink bollworm eradication program across the southern USA and northern Mexico. These, and other successful area-wide programs, encompass a large number of diverse organic farms without incident. More recently, mass release techniques have been proposed that involve the release of genetically modified insects. Given that the intentional use of genetically modified organisms by farmers will in many jurisdictions preclude organic certification, this prohibits the deliberate use of this technology by organic farmers. However, mass releases of flying insects are not generally conducted by individual farmers but are done on a regional basis, often without the explicit consent of all situated farms (frequently under the auspices of government agencies or growers' collectives). Consequently, there exists the realistic prospect of organic farms becoming involved in genetically modified insect releases as part of area-wide programs or experiments. Herein, we describe genetically modified insects engineered for mass release and examine their potential impacts on organic farmers, both intended and unintended. This is done both generally and also focusing on a hypothetical organic farm located near an approved experimental release of genetically modified (GM) diamondback moths in New York State (USA).

Keywords: organic certification; sterile insect technique; genetically modified insects; diamondback moth; *Plutella xylostella*; law; regulation; coexistence; GM-SIT; biotechnology

1. Introduction

The intentional release of sterile or partially sterile insects as a means of reducing the size of reproductive populations of the same species acting as agricultural pests has been practiced for over 50 years (Chapter 1 in [1]). While large numbers of farmers throughout the globe continue to benefit from successful historical pest eradication programs or ongoing pest suppression programs, current awareness of this approach is often limited. We aim to briefly describe the principles and practices of the conventional sterile insect technique (SIT) and then discuss the implications for certified organic farmers of proposed elaborations of SIT that incorporate the mass release of genetically modified insects (GM-SIT). This includes discussion of not only intended biological outcomes [2], but also a holistic consideration of other likely impacts on farmers. In doing so it is important to emphasize that for many producers and consumers organic farming is much more than adherence to standards or certification regimes and encompasses principles of health, ecology, fairness and

stewardship [3]. This is in addition to emphasizing the importance of farmer autonomy and genuine choice for consumers, both of which remain at the core of a global industry estimated to be worth US$80 billion in 2015 [4]. While the above principles do not appear to have been breached and have not adversely impacted organic farmers operating in areas where conventional (non-GM) SIT releases have occurred (Figure 1), the proposed incorporation of GM technologies in future programs still warrants careful consideration. Failure to do so could expose farmers to unnecessary and potentially harmful economic uncertainty. From the perspective of organic farmers, the fact that insect pest control programs are generally conducted on an area-wide basis is of particular concern, as well as the fact that historically they have involved some degree of compulsory participation. It is this compulsion that appears to run counter to efforts towards coexistence [5], and the likely negative perception of the use of this technology by consumers warrants responsible discussion, ideally before releases of GM insects into the environment occur. Furthermore, most current measures aimed at fostering coexistence through limiting cross-contamination of crops in fields rely on promoting particular agricultural practices, often the use of buffer zones, to limit the flow of GM materials between fields. However, in SIT of all types, the movement of sterile (or partially sterile) insects between fields and farms is generally a necessary prerequisite for successfully suppressing pest populations below economically significant thresholds. This is because the infestation of crops from untreated areas is a more rapid process (occurring in as little time as it takes a mated female to fly into an area) than is suppression by SIT (which takes generations). The need to suppress insects on a suitably scaled area-wide basis also frequently dictates that control programs are undertaken not only on agricultural land but also in urban and suburban areas.

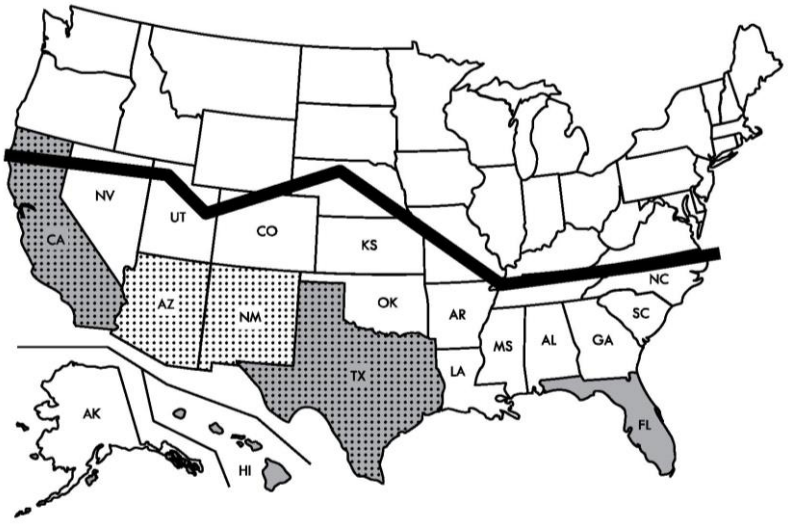

Figure 1. A wide variety of U.S. farmers have reduced their reliance on chemical pest control due to the success of past and ongoing area-wide pest control programs. Locations of some of the major conventional SIT control programs in the USA are shown. Gray states represent those with active medfly (an exotic pest of many fruit crops) suppression programs. Dotted states represent those involved in the pink bollworm (an exotic pest of cotton and okra) eradication program in Southern U.S. states and Northern Mexico. The thick black line represents the approximate maximum extent of screwworm before its eradication using SIT. None of these programs utilized GM-SIT.

1.1. What Is Conventional (Non-GM) Sterile Insect Technique and How Is It Used?

The release of sterile (or partially sterile) individuals as a means to reduce the reproductive size of a pest population dates back to the 1930s and was first formulated by the Russian scientist Alexander Serebrovsky (Chapter 1 in [1]). The basic principle of the approach is described in Figure 2a. To be successful in reducing target pest population sizes, it is generally essential that releases be conducted

on an area-wide basis without leaving any populations from which pests could readily re-establish themselves. Typically, sterilized insects are released from airplanes, with thousands being released per km^2 on a regular basis as suppression generally takes several generations. In eradication programs local releases can cease after eradication is confirmed, while in suppression programs (or preventative release programs) continuous releases can be sustained in the same locality indefinitely.

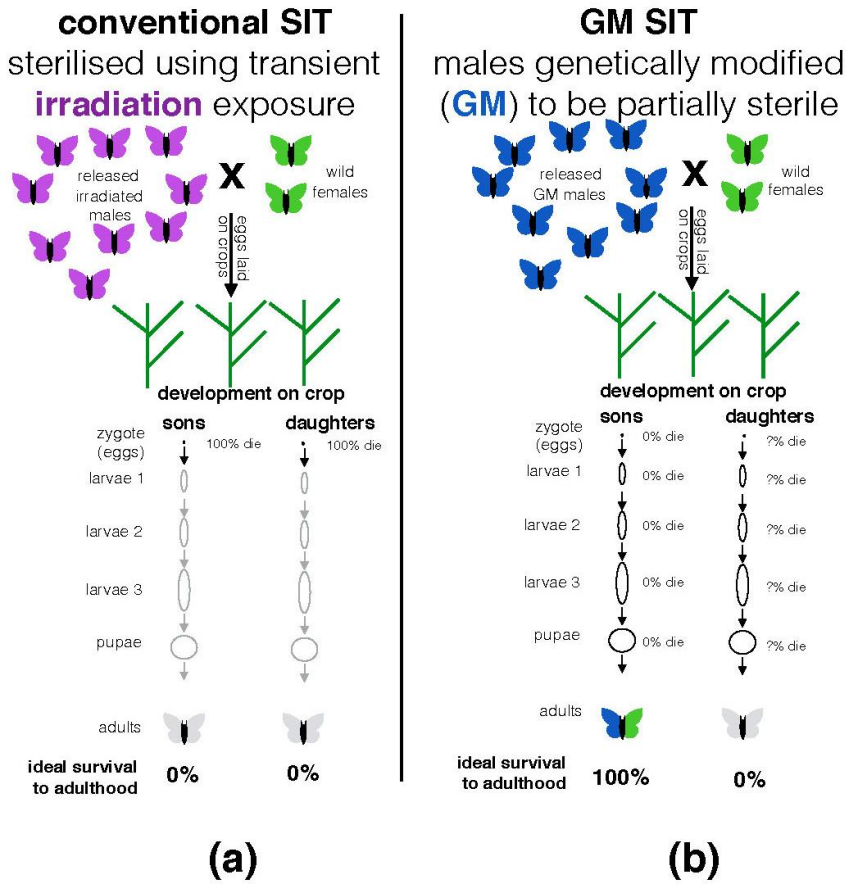

Figure 2. If fertile females are present near release sites any matings with the large number of released males will generate few if any adult daughters. Where mass releases are sustained over a number of generations this can result in a progressive reduction in the wild pest population (and ultimately its local elimination) or act to prevent the establishment of new pest populations. While all progeny of irradiated fathers die as early eggs (**a**), GM males are engineered so that sons complete their development into adults (**b**). The daughters of GM males mostly die at some point in their development; whether they die at a late stage (pupae or mature larvae) or as an egg is dependent on the specific properties of the release stock. All progeny of GM males inherit a recombinant DNA insert on their chromosomes; this is the case for both the sons surviving to adulthood and any individuals that die at earlier developmental stages. Note that if no wild females are present or are accidentally released with the males then no eggs can be laid (this may be the case for most of the time during preventative release programs aimed at stopping pest populations from becoming established in at-risk areas).

Perhaps the most successful program using conventional SIT involved the eradication of the new world screwworm (*Cochliomyia hominivorax*) that started in Florida in 1958 and eventually eradicated this wound-causing pest of domestic animals from the continental USA (Figure 1 and Chapter 1 in [1]; screwworm was often the cause of lethal myiasis in domestic animals). While the continent-wide program to eliminate screwworm is largely forgotten by modern farmers, the financial benefits to animal farmers of all types is on the order of a billion dollars annually [6]. Currently, the ongoing medfly (*Ceratitis capitata*) suppression program around the world, requiring the weekly

release of more than 3 billion sterile males, plays a significant role in the global trade in agricultural products [7]. As generally female insects are the more pestiferous, through egg-laying on plants, most programs focus on the release of only sterile males (though this is not always the case; see pink bollworm (*Pectinophora gossypiella*) or screwworm eradication programs, where both sexes are released). Conventionally, sterilization is achieved through transient exposure of developing insects to an ionizing radiation source prior to their release. This does not require their physical contact with any radiation source and does not render them in any way radioactive. Figure 1 provides some examples of SIT control programs in the USA; however, many successful programs with a wider range of species have also occurred (chapter 1 [1,8]). It cannot be ruled out that some species, due to features of their biology, are not amenable to radiation-based approaches (e.g., boll weevil (*Anthonomus grandis*), [9]) but are to GM ones and vice versa.

Broadly speaking, if certain biological conditions are met and enough sterile individuals are released, insect pest species can be suppressed in this manner (the notable exception being insects that can reproduce asexually), though the use of chemical pesticides may initially be helpful to lower insect densities. However this is different from stating that all SIT efforts will be successful as practical control programs. For example, if the resources required to generate and release sterile individuals are greater than the alternative available interventions or the benefits of pest control, then success is far from assured. Beyond biological, economic and program management considerations, the collective experience from a large number of ongoing and historical programs highlights the importance of good public relations. The principal textbook on SIT, *Sterile Insect Technique—Principles and Practice in Area-Wide Integrated Pest Management* (2005, [1]) devotes a full chapter to this topic, stating that "The overall communication of program goals, objectives, and activities is often not given as much attention as are the more technical aspects of a programme, and inadequate public support can be a cause of failure. [. . .] Public relations are important as these programs affect whole communities" (page 548). Furthermore it is also stated that for successful control programs "Legal authority is required to execute all aspects of the program, e.g., conduct operation on private properties, and operate quarantines" (page 59).

1.2. What Is the GM Sterile Insect Technique (GM-SIT) and Why Is It Being Proposed?

Most or all of the arguments made in favor of using genetically modified techniques (applying recombinant DNA methods) focus on increasing the efficiency and flexibility of SIT programs. We are aware of few proposals where GM techniques would work and conventional radiation-based techniques would not. However, this was not the conclusion of the United States Department of Agriculture Animal Plant Health and Inspection Service (USDA-APHIS), which in 2008 stated in a lengthy series of documents that:

> *There is an impending need for the development of more efficient, lower cost, and more effective control and eradication methods for the pink bollworm and invasive fruit fly species because of the continuing and increasing frequency of detection of fruit flies and other invasive and crop destructive insects. In order to achieve these objectives, the use of genetically engineered insects provides biological traits that are of value for use in sterile insect technique control methodologies. These novel biological traits are not available to present programs and could not be readily developed or adopted for program use by APHIS using other methods.* [10] (Page 20)

While exposure to ionizing radiation is very effective in sterilizing released individuals, it often offers no obvious way to separate males wanted for release. This is one way in which GM approaches could add value. It is generally considered highly desirable to only release males as even small numbers of released females have the potential to cause damage to crops through egg-laying. GM techniques have been developed that can kill females before release (though these may not in all instances be 100% effective). Figure 2b describes the principle behind a female-killing GM-SIT approach (using details of the diamondback moth trial (*Plutella xylostella*), see below). Note that Figure 2b illustrates that while

descriptions of some GM techniques use the word "sterile" it connotes something markedly different from its common language usage, indicating individuals not able to or rarely producing offspring. Conversely, in the GM approach illustrated in Figure 2b, all released males mating with wild females are intended to have all their male progeny survive.

Over the last 15 years more than US$50 million has been invested in GM insect control research and development, mainly by government agencies and charitable foundations (most is directed towards mosquito control [11]). Most recently, in 2016, the Intrexon Corporation (USA) established a subsidiary called *Intrexon Crop Protection* that is "dedicated to the biological control of agricultural pests and diseases", which incorporates GM-SIT approaches [12]. In 2015 Intrexon Corp. purchased Oxitec Ltd. (UK), which had developed GM-SIT approaches for a number of species.

GM methods aim to enhance the efficiency of SIT and the ease with which it can be adapted to emerging pest species. If successful, this could significantly enhance the use of SIT approaches and reduce agricultural losses and reliance on chemical pesticides. However, there are currently no field data that establish circumstances where GM-SIT approaches are superior to conventional SIT approaches. This is despite publicly funded agricultural field trials of GM pink bollworm occurring in isolated locations in the Arizona desert between 2005 and 2010 [13], a three-year open field trial approved for New York (NY) State in 2014 using diamondback moths (see below), and in Morocco a reported "pilot commercial field trial" for medfly [14,15].

1.3. The Experience of GM-SIT in the USA

In the USA, GM insects that are plant pest species are "regulated articles" under the purview of the United States Department of Agriculture (USDA, [16,17] and Section 2.2 in [18]). The USDA regulates releases of GM insects by considering their likely impact on the environment and human health (Section 3.6 in [18]). However, it is the Food and Drug Administration (FDA) that regulates the presence of most novel food additives that may directly or indirectly contaminate human food, it is conceivable that GM insects expressing novel proteins may be considered to fall under its remit [19,20]. Finally, as the Environmental Protection Agency (EPA) has jurisdiction over some novel proteins in food that possess biopesticidal properties, it is also conceivable that GM insects expressing novel biopesticidal proteins may be considered to fall under its remit [21]. Of the three government agencies it is only the USDA that has so far made clear efforts to prospectively regulate GM insects, evidenced by their having considered permit applications for open field releases since 2005 (Supplementary file 2 in [13]). Given the complexity of the regulatory framework in the USA (explained in Section 2.5 in [18]) and the absence of clear regulatory statements relating to the use of GM insects in agriculture by the EPA or FDA, it is beyond the scope of this article to consider all the many potential future outcomes. It is, however, possible to speculate that GM insects could become involved in food production without either of the two agencies (FDA or EPA) that generally most directly oversee food safety being involved. Indeed, in the case of GM diamondback moths, this appears likely, as with respect to the FDA it is stated in the permit proposal that "The permit applicant did not undergo this voluntary consultation because the GE diamondback moth is not anticipated to yield food or feed" (Section 2.5.2 in [18]; the terms GE and GM are equivalent). With respect to the EPA it is stated that "EPA did not review these GE diamondback moth strains because it neither contains PIPs [plant incorporated protectants] nor does it require use of any new pesticides that otherwise would not be used on other non-GE diamondback moths" (Section 2.5.3 in [18]). It is noteworthy that U.S. government agencies are "mandated to exercise oversight of GE organisms only when there is evidence of 'unreasonable' risk" (Section 2.5 in [18]). Some may consider this situation an appropriate and efficient regulatory process and for others it may be viewed as a deficiency.

It is perhaps noteworthy that the FDA regulates the use of GM mosquitoes in the USA [22]. Furthermore, the FDA also sets tolerances for "natural or unavoidable defects in food for human use that present no health hazard"; this is done for explicitly aesthetic reasons and includes the presence of insect parts [23].

It is unclear which, if any, of the three agencies has any responsibility to consider likely negative impacts of regulatory decisions on the international trade of food crops. In the past the EPA has imposed restrictions on certain GM crop varieties (and crops grown near them) from entering international commerce as part of their domestic approval procedure (e.g., page 4, [24]).

In 2008 the USDA Animal Plant Health and Inspection Service (USDA-APHIS) produced a 334-page environmental impact statement (EIS) entitled "Use of Genetically Engineered Fruit Fly and Pink Bollworm in APHIS Plant Pest Control Programs" (2008-EIS, [10]) that formed the basis of an announcement that "APHIS has decided to integrate the use of genetically engineered insects into the sterile insect technique used in agency plant pest control programs" [25]. The legal authority to undertake the mass release of GM insects was cited as the Plant Protection Act and the document contained no discussion of the need for new laws (state or federal) to provide a legal basis for the intentional dispersal of GM insects into the environment including over private property [10,25]. If, in the opinion of USDA-APHIS, conventionally sterilized insects are legally equivalent to their GM counterparts, this would appear to have potentially more widespread consequences than the USDA's assumption of "substantial equivalence" between GM and non-GM crops (though only six public comments were received on this topic during consultation [26]). While organic farmers are mentioned in the lengthy 2008-EIS [10], it only discusses the intended positive benefits and gives no consideration to unintended consequences. The following quotes are illustrative in that regard:

> *There are organic growers found at certain locations within the [existing control] program area[s], and their needs are important program considerations.* (Page 78)

> *Although there are risks to organic farmers from the drift of pesticides in chemical control applications, the increased use of SIT in preventive releases reduces the need for future pesticide applications. The potential mortality to predators and parasites of plant pests and to pollinators, due to pesticide use, as well as the potential loss of "pesticide-free" status, is critically important to organic farmers. The mitigation measures for pesticide applications are designed to minimize exposure to bees, through advanced notification to beekeepers, which allows them to move their hives away from exposure to pesticides. The use of nonchemical control methods, including SIT, precludes concerns of organic farmers and beekeepers.* (Page 110)

> *Successful eradication can dramatically reduce the need to use pesticides for crop protection. Although there are risks to organic farmers from the drift of pesticides in chemical control applications, the increased use of SIT in preventive releases reduces the need for future pesticide applications.* (Page 109)

Despite this landmark announcement to integrate GM insects into USDA-APHIS pest control programs, no such program has commenced in the intervening eight years, although substantial discussion surrounding a GM pink bollworm moth program occurred in 2009–2010 [27–29]). Furthermore, all 11 permits for releases of GM insects issued between 2001 and 2010 have been granted only to USDA agencies and occurred at isolated experimental facilities in the Arizona desert (see Supplementary Materials file 2 in reference [13]).

In 2014 the USDA-APHIS Biotechnology Regulatory Service approved an application for an experimental open release permit for a GM diamondback moth [30], and for the first time the applicant was not an agency of the USDA but Cornell University and the New York State Agricultural Experiment Station (NYSAES). Local organic farmers have been noticeably critical about the lack of information regarding the proposed release [31,32]:

> *Andy Fellenz grows vegetables and small fruits on five acres of Lester Road property in the town of Phelps [Upstate New York]. His farm has had organic certification from the New York Organic Farming Association since 2005. "I'm aware of the moth trials, but I'm not well informed on the topic and whether having genetically modified moths on my plants could harm my organic*

> *certification," Fellenz said. "I do think Cornell has not been open on how they would do the trials. They did not give much public notice on the nature of their plans and did not give an opportunity for discussion."* [33]

While the extent of the legal consequences of the release of GM insects in agricultural pest control programs is yet to be completely identified, some potentially relevant precedents have already been established. Drawing on both litigation and regulations in various jurisdictions (principally Australia, Canada, China, the EU, and the USA) we attempt to provide some insight into two issues relating to the release of GM insects to control agricultural pests: (1) the potential for negative consequences resulting from the loss of organic certification and (2) the fact that international trade in organic products could be impacted directly through the infringement of regulations in importing countries, or indirectly through adverse consumer perceptions.

Throughout this article the word "contamination" will be used to denote the presence of GM insect adults, larvae, or body parts in agricultural products offered for sale. This is to reflect the strong philosophical divide between proponents and opponents of GM technologies in agriculture, but we do not use this word in any pejorative sense. While organic producers may favor the term "genetic contamination", proponents of GM technology will refer to "adventitious presence". It should also be noted the USDA Organic Standards use the term "contamination" to refer to the infiltration of organic crops with prohibited substances including genetically modified organisms. For reasons of article length, we will not speculate on questions of health or safety relating to the contamination of food for human consumption with GM insect body parts (either alive or dead).

1.4. The Hypothetical Example of an Organic Certified Spinach Farm Located near a Release Site of GM Moths

To narrow the scope of this article to a manageable degree, while still providing useful insight, we will focus on the hypothetical case of a spinach farmer in the vicinity of the diamondback moth trial approved in November 2014 for upstate New York (NY). The hypothetical farm is certified organic and exports spinach directly or indirectly to other markets such as Canada, China, Japan, and the EU, either as fresh frozen or canned product intended for human consumption labeled as "100% organic". The crop spinach, which is only an occasional host for diamondback moths (Table 1), was chosen over more commonly parasitized Brassica crops as there are published guidelines for the acceptable presence of caterpillars in spinach sold for human consumption in the USA (Table 2). Were the corresponding food sanitation tolerances publicly available for broccoli or cabbage all the same, the considerations raised here could likely be applied to these crops. The choice of spinach does, however, serve to highlight that farmers growing crops that are not the primary targets of GM insect control programs can still potentially be impacted by them. Where possible, we use the available reported properties of the GM approach approved for release ([30], Figure 2b) and current knowledge of the biology of the wild diamondback moth. As our understanding of the biology of the moth could change in the future, and the details of the trial are unclear in some respects, we intend this case to serve as a hypothetical discussion as opposed to an analysis of the actual trial approved by federal and state regulators. However, we will draw on reported elements of the NY trial where available.

Some pertinent biological details of the diamondback moth are listed in Table 1. Of particular interest is the potential impact of the moth on a wide range of farms and crops, due to its ability to develop on a broad range of plants. The very different cropping periods for these plants could inhibit the ability to reduce crop contamination by eliminating releases in the periods prior to harvesting. Equally striking is the very high potential dispersion capacity of this species as a migrant, which renders the ultimate geographic range of potentially impacted farms difficult to predict (note that diamondback moths have two modes of dispersal, long-range migrants and locally; see Table 1).

Table 1. Features of the diamondback moth.

Diamondback moth	Features
Host range	Very broad, most Brassicas—including broccoli, Brussels sprouts, cabbage, Chinese cabbage, canola, cauliflower, collard, kale, kohlrabi, mustard, radish, turnip, and watercress. Also occasionally found on other plants, including spinach [34].
Physical characteristics of life stages	Larvae (caterpillars) 1.7, 3.5, 7.0, and 11.2 mm, respectively, for each instars, pupa is 7 to 9 mm. Both caterpillars and pupa are generally found on leaves.
Number of eggs laid by mated female	100–300 Generation time of approximately 1 month (but can be shorter).
Dispersion capacity	Not considered a particularly strong flier and the only two published studies using release-and-recapture experiments with this species indicate that within growing crops 99.5% of released individuals probably disperse much less than an average of 300 m [35,36]. However, in one of the studies 8% of all recaptured individuals in their summer release dispersed at least 800 m (7/86, [35]). While in the second study the longest reported dispersion was restricted up to 300 m [36]. Dispersion from harvested areas remains to be explored as noted by these studies authors. Diamondback moths are considered a migratory species and can cover hundreds of kilometers per day [37] in suitable winds, though it remains unclear what triggers migratory behavior.
Diamondback moth control methods	Diamondback moths exhibit increasing resistance to some chemical insecticides. Organic control methods do exist [38].
New York State	Diamondback moths are not native to the USA. It is unlikely that this species represents a significant pollinator in NY. Any wild populations are likely initially established each year by long-range migrants after harsh winter conditions in NY. Not known what the frequency of accidentally released GM females will be (1% reported in [39] page 11). Not clear at what developmental stage (zygote, larval instars, or as pupae) female progeny of the OX4319L-Pxy stock described in the NY permit die due to the action of the genetic construct integrated in to their chromosomes (see Figure 2b). Organic farms growing cabbage, cauliflower and broccoli are located within 10 km of probable release sites [40].

A release permit (13-297-102r) was granted to Cornell University and NYSAE in November 2014 by USDA-APHIS Biotechnology Regulatory Services for open releases of diamondback moths for three years of seasonal releases (April to October, [30]). NY state regulators would also need to have given approval. A proposed start date of 1 April 2014 through 31 March 2017 is given in the application [18]. Permission was given for experimental open releases of both a wild-type stock (Vero Beach, both males and females) and a GM stock (OX4319L-Pxy, males only, property of Oxitec Ltd. a subsidiary of Intrexon Corp.) with up to 72 releases a year; up to 20,000 males per release to a maximum of 100,000 moths per week; in fields of up to 10 acres planted with brassicas (e.g., cabbage or broccoli). The precise location of the trial is not public but is within the 870 acres of the NYSAE land in Geneva, NY. While the permit is stipulated as being a "release" permit it is made clear in the supplemental conditions that "This authorization is valid for the release of this genetically engineered insect only in the areas described in the application" (see File S1 point 9). The presence of released moths outside of the permit area must be reported to the USDA within 24 h and the permit holder must deploy traps to monitor moth movement up to 1 km away from their release sites. The basis for the assumption that all moths will stay on NYSAE land is not discussed in detail in the permit application or the accompanying statutory Environmental Assessment (EA) document ([18], though see page 11), but presumably both the regulators and the applicant are satisfied that this is the case (neither of the two published mark-recapture studies of diamondback moths [35,36] are cited in this 149-page document). It is also stipulated that "This is a crop destruction trial", meaning that no plant products involved in the experiment shall be used for food or animal feed (see File S1 points

10 & 12). Cornell University withdrew the permit in March 2016 and it was recently announced that no open releases were actually conducted [41]; however, we will consider the hypothetical situation that open releases of the type approved in the 2014 permit were undertaken. In summary, the permit issued by biosafety regulators gives no permission for any released moths to be on private property outside the 10 acres explicitly defined in the permit (see File S1 points 9 & 12). Equally, the permit does not grant permission for insect body parts to be found in any agricultural products intended for human consumption.

However, as pointed out by a peer reviewer of an earlier draft of this article, in the USA the USDA may see it as beyond their remit to regulate outside the defined release area or 100 m quarantine area (though see File S1 points 9, 10 & 12). In this case, and in the absence of FDA or EPA statements to the contrary, some may assert that GM moths found on food crops outside the permitted release area contravene no written regulations. Consequently, while these experimental escapee moths would have no permission to be on food crops, their presence may not be explicitly prohibited by any of the three regulatory agencies. We do not offer any opinion as to the legal or strategic merits of this speculation, but outline it here for reasons of completeness. As far as we are aware, this is the first time this scenario has been presented in a public document.

2. Results

2.1. Could an Organic Farmer Lose Organic Certification?

The benefits of controlling or eliminating pest insects without resorting to chemical pesticides are clear to all farmers, particularly those who farm organically. However, the possibility exists that organic farmers growing crops that could act as a host for locally released GM insects could lose their organic certification (see discussion below and speculation [32,42,43], USDA regulations [44] §205.105 and §205.2, also [45]), with a concomitant loss of revenue and markets. Given the higher costs of organic production, loss of certification (and thus the loss of the price premium attached to organic products) would have a significant effect on producers. However, GM insects present a challenge not only to producers but also to third-party organic certification bodies and could have significant legal consequences for both. These concerns center on two issues: (1) could decertification occur if contamination of organic products with GM insect body parts is detected by an organic certifying body? and (2) even in the absence of any detectable contamination, could actions or omissions by an organic farmer towards GM insect releases result in decertification? We shall deal with these in turn.

2.1.1. Detected Contamination of GM Insects Approved for Presence in Food

If the organic spinach produced by the hypothetical farmer is intended for human consumption and food hygiene standards similar to those stipulated by the USA Food and Drug Administration (FDA) are applied, then it is possible to make an estimate of the maximum presence of insect material that would result in it being rejected as unfit for human consumption (Table 2). These food hygiene standards for "Natural or unavoidable defects in food for human use that present no health hazard" [23] are applied to all marketed human food and do not consider whether the insect material is GM; they are not applied for safety reasons but are purely for consumer aesthetic reasons. For spinach the presence of caterpillars whose aggregate length exceeds 12 mm in 24 pounds (10.9 kg) of spinach is the maximum permissible. If it is assumed that all caterpillars were GM diamondback moths and that their combined weight was conservatively less than 100 mg then it is possible to calculate a maximal level of contamination of food fit for human consumption of less than 0.000009% for spinach in the USA. While this represents a very small percentage of contamination, it is probably still technically detectable and this is what is significant from a regulatory perspective. This is because organic certifiers and importing countries may in certain circumstances apply a "zero tolerance" policy towards GM insect parts in food regardless of the level of percentage contamination (see discussion below).

Unlike insects sterilized by ionizing radiation, GM insects (even the male progeny of released individuals, Figure 2b) can be distinguished from purely wild individuals at any developmental stage or for a substantial period after death using genetic techniques or by detecting the fluorescent proteins most expressed. While detecting this level of contamination would be challenging using the current genetic techniques applied to routinely monitor for contamination in crops sold as food and feed, newer methods based on the enrichment of transgenes and targeted next-generation sequencing are rapidly increasing sensitivity [46]. The sensitivity and reliability of all genetic techniques could be greatly enhanced by physically eliminating as much plant material as possible prior to DNA extraction (e.g., by washing off insects or through their manual collection). Furthermore, inclusion of the complete nucleotide sequences of transgenic constructs within publicly available permit approval documents could also facilitate routine detection.

Table 2. U.S. food sanitation tolerances for spinach stipulate levels of insect parts permissible in food considered fit for human consumption. This sanitation standard is applied without reference to whether insect parts are GM or not; in theory all spinach destined for human consumption in the USA is subject to it. The FDA has the power to set tolerances for "natural or unavoidable defects in food for human use that present no health hazard" for aesthetic reasons [23,47].

Product	Action Level
Spinach, Canned or Frozen	Average of 50 or more aphids, thrips and/or mites per 100 g OR 2 or more 3 mm or longer larvae and/or larval fragments or spinach worms (caterpillars) whose aggregate length exceeds 12 mm are present in 24 pounds OR Leaf miners of any size average 8 or more per 100 grams or leaf miners 3 mm or longer average 4 or more per 100 g
	Defect Source: *Pre-harvest infestation* Significance: *Aesthetic*

This estimate of the maximal level of contamination of 0.000009% is of a degree well below even the most stringent statutory thresholds above which contamination by GM material that is approved for presence in food dictates labeling action (either as a food constituent or as an ingredient). However, with respect to organic certification it is the manner in which any level of detected contamination is perceived/addressed by the certifying body that is critical. For example, the contract with farmers used by the National Association of Sustainable Agriculture Australia (NASAA) contains the following clause [48]:

> *Organic certification shall be withdrawn where NASAA considers there is an unacceptable risk of contamination from GMOs or their derivatives.* (Clause 3.2.9)

> *Contamination of organic product by GMOs that results from circumstances beyond the control of the operator may alter the organic status of the operation.* (Clause 3.2.11)

In the event that our spinach farmer had signed a contract or a GM-free affidavit [49] containing similar language, it would appear that the certifying body would be entitled to withdraw organic certification from impacted farms (regardless of whether or not the farmer intentionally facilitated the use of GM insects). The implications of this type of contractual language were considered in recent litigation in Western Australia. In *Marsh v. Baxter* a certified organic farmer sued a neighbor for GM contamination after his organic certifier withdrew certification on over 70% of his farm due to the presence of volunteer GM canola [50]. No tort claims were found, with the finding that the plaintiff having suffered only pure economic loss being a major factor. A tort is a civil wrong, or wrongful act, whether intentional or accidental, from which injury occurs to another. So, more generally, tort law refers to the body of law that allows an injured person to obtain compensation from the person who

caused the injury. The legal doctrine of pure economic loss is one of the most controversial aspects of the law of torts, and the law of negligence in particular. Pure economic loss refers to economic loss that does not flow from personal injury or physical property damage. The courts in Canada, the USA, and most common law jurisdictions have had a historical reluctance to award damages in such circumstances:

> *Liability for pure economic loss presents considerable difficulties. Most obviously, it raises the risk of indeterminate liability. Such difficulties were generally resolved on the basis of a broad rule that excluded liability for such losses.* [51,52]

On appeal to the Western Australia Court of Appeal (WACA) all tort claims were again rejected, but the WACA was more explicit stating, that by having his land certified organic by NASAA the organic farmer made his land "abnormally sensitive". They also were severely critical of NASAA's zero tolerance threshold for GM, which is in part based on the above clause 3.2.11. In February 2016 the plaintiff was refused leave to appeal to the High Court of Australia. While organic certification bodies would prefer not to deny farmers, they cannot ignore the reputational damage that inaction on their part might cause to them or their clients. Similarly, an organic certification body that adopted anything other than a "zero tolerance" policy with regard to GM contamination might lose its membership in umbrella organizations such as the International Federation of Organic Agricultural Movements (IFOAM).

In the event of GM larvae, adults or pupae being detected in certified organic crops, it is unlikely that the organic producer would be able to gain legal redress for any negative impact on their reputation and the value of their organic products. In the Starlink Litigation in 2002, corn that was not approved for human consumption entered the human food supply chain. In its judgement the court was explicit in its ruling over the nature of the losses suffered by growers:

> *The economic loss doctrine has grown beyond its original freedom of contract based policy justifications. Farmers' expectations of what they will receive for their crops are just that, expectations. Absent a physical injury, plaintiffs cannot recover for drops in market prices. Nor can they recover for any additional costs, such as testing procedures imposed by the marketplace.* [53]

The key issue with all of the litigation mentioned is that the courts have consistently refused to find any "physical injury" associated with the "contamination" of an organic crop by GM material. The "injury" sustained may be to certification, the ability to export, or the price that could be achieved through sale, but again these are not categories of harm that the common law recognizes; they lie in the realm of purely economic loss. It should also be noted that even in litigation where damages have been paid, for example the Starlink litigation, these are usually cases where *unapproved* GM material has "contaminated" a particular supply.

2.1.2. No Contamination Is Reported but the Risk of Contamination Is Perceived to Be Significant by the Certification Body

The NASAA contract contains further relevant clauses that are commonplace in the organic industry [48,50]:

Clause 3.2 states as a general principle:

> *Even where evidence of GMOs is not detected in finished organic product, the deliberate or negligent exposure of organic production systems or finished products to GMOs is outside organic production principles.*

Clause 3.2.5:

> *Operators must not knowingly permit exposure or fail to take action against the application of or exposure to GMOs.*

Both these clauses speak to the intentions, actions, and omissions of farmers, indicating that these can be pertinent to the withdrawal of certification. However, it is apparent that the USDA Organic standards may treat these or similar cases differently and form the probable basis of an assertion that only where organic farmers intentionally used GM insects would they endanger their USA Organic certification (see [44] §205.105 and [45]).

> *Even if strays are found, legal experts say that national organic standards penalize only the deliberate use of a genetically modified organism. "If these moths came across into an organic field inadvertently, that would not be a problem for the farmer," attributed to Susan Schneider, a legal expert who specializes in agriculture and food law at the University of Arkansas School of Law.* [54]

Despite this assertion, it is unclear if these statements consider the peculiarities specific to area-wide pest control programs, such as the manner in which such programs are financed and managed. For example, the ongoing suppression of the pink bollworm (Figure 1a) is funded by all cotton farmers in control areas via the imposition of a compulsory levy on every bushel of cotton sold. Interestingly, this fee may be waived for conventional farmers who plant GM cotton but not for organic farmers. If a pink bollworm control program elected to incorporate GM insects into their programs, as was repeatedly discussed in the period between 2009 and 2010 [27–29], it is far from obvious how organic certification bodies would justify maintaining their organic certification if farmers were paying for the program (in this case direct payment under compulsion). The consequences of a failure to comply with control and quarantine measures within areas of releases can be severe and are not always confined to cotton farmers. For example, okra (which is also a host to pink bollworm) farmers have recently been taken to court over compliance issues relating to cotton pest control (page 48 [55]). Where control programs are directly or indirectly funded by organic farmers it remains unresolved whether they will be able to successfully claim that their involvement is "unintentional" ([32,42,43], USDA regulations [44] §205.105 and [45]). Likewise, if GM insects are released on or over an organic farm (many control programs release from airplanes) could their failure to take action to prevent exposure of their crop be grounds for concern? Would an organic farmer who agreed to releases be at greater risk of decertification? Would an organic farmer who sat on a program management board utilizing GM insects also be at greater risk? Clearly the lack of autonomy of organic farmers placed in these situations is not entirely without precedent. For example, the drift of sprayed chemicals or GM pollen from adjacent farms is often outside the direct control of organic farmers, but all parties have access to mitigation measures, e.g., planting of buffer zones, employing particular spraying or harvesting practices and notifying and cooperating with neighbors. However, in the case of pest control programs it is generally critical that no areas remain untreated, including organic farmland, so it is hard to envisage how analogous practices would be implemented. In a small number of cases where mitigation measures have failed, redress to the courts has sometimes been sought, with the relevant cases being related to pollen drift and the growth of volunteer GM plants in organic crops. Two such cases are discussed below.

2.1.3. *Hoffman v. Monsanto* (Saskatchewan, Canada)

Hoffman was an organic canola grower in the Canadian Province of Saskatchewan [56]. Since it entered the Canadian market in 1995, Monsanto's GM Roundup Ready Canola has proved exceedingly popular. One of the major concerns for organic growers is the promiscuity of GM Canola and the consequent widespread emergence of 'volunteer' GM Canola as canola pollen can travel significant distances. Hoffman sued Monsanto and Bayer Crop Science for damages relating to the widespread contamination of his organic fields by their GM Canola varieties. As stated above, if an organic farmer's produce is contaminated with GM material, loss of certification is likely. Loss of certification results in the loss of the significant price premium associated with organic production.

Hoffman's lawsuit was unsuccessful. The Province of Saskatchewan (along with most other Canadian jurisdictions) has legislation that facilitates the filing of class-actions by multiple parties

against the same defendants [57]. This legislation usually speeds up the litigation process and reduces costs. Hoffman and many other organic canola growers attempted to achieve certification for a class action against Monsanto & Bayer.

In 2005, Justice Smith of the Court of Saskatchewan Queen's Bench denied Hoffman's application for certification in the Class Action suit. Her judgment (for the most part) rejected Hoffman's application on the basis that he had no legal cause of action. In his claim, Hoffman relied in part on the traditional common law causes of action such as nuisance, negligence, and strict liability, the so-called property torts. In her judgment Justice Smith systematically rejected all these claims and could see no valid cause of action. In 2006, the Saskatchewan Court of Appeal unanimously upheld her decision and the farmers were denied leave to appeal by the Supreme Court of Canada in December 2007 [58]. In April 2008 they stated that they could not afford to "go it alone" in individual legal actions against Monsanto & Bayer.

To state it plainly, in her decision Madam Justice Smith failed to find any cause of action for the farmers ruling out any tort claims and statutory claims. This decision likely represents the death knell of anti-GM class actions in Canada. As an aside, 95% of Canola grown in Canada is now GM, Canola is one of the most lucrative of all Canadian agricultural exports, and the organic market has evaporated. This is due, in large part, to the aforementioned proliferation of GM Canola that renders it virtually impossible to certify any organically grown canola as GM-free [59].

2.1.4. *Marsh v. Baxter* (Western Australia)

This case involves a very similar fact pattern to Hoffman [50]. A certified organic farmer sued a neighbor after his organic certifier removed certification of over 70% of his farm due to the presence of significant amounts of volunteer GM canola. As with Hoffman, no tort claims were found, with the finding that the plaintiff having suffered only pure economic loss being a major factor. On appeal to the Western Australia Court of Appeal (WACA) all tort claims were again rejected, but the WACA was more explicit than the Trial Division. They stated that by having his land certified organic by NASAA (the National Association of Sustainable Agriculture Australia) the organic farmer made his land "abnormally sensitive." They also were severely critical of NASAA's zero tolerance threshold for GM. In February 2016 the plaintiff was refused leave to appeal to the High Court of Australia.

In summary, based on current law (and given the low levels of contamination anticipated for GM insect releases) the courts would be unlikely to grant relief to farmers losing their certification, even if they demonstrated economic losses as a result of decertification or contamination. Both Hoffman and Marsh indicate that there is little likelihood of redress via the courts even in the event of detected contamination leading to significant economic losses (though there may be differences between jurisdictions [60]).

2.2. Eroding Confidence in Organic Certification Bodies and or the Loss of International Export Markets

Were a part of a GM diamondback moth detected in spinach exported to Japan, China, or the EU and its presence was unapproved this would likely trigger the rejection of the shipment and attract a high degree of global media attention (see discussion of Starlink and Viptera cases above and numerous examples in Table 25 [61]). This is based on the fact that many countries maintain a zero tolerance policy towards unauthorized GMOs [61–63]. This attention may be more pronounced if the spinach were certified as "100% organic" under international certification schemes. Whether or not the U.S. regulator approved of the contamination would be immaterial, as the GM moth currently could not have been approved for human consumption by the importing countries. In a situation where unapproved GM material is detected in human food, it is probable that the importing country would adopt a "zero tolerance" policy ([62,63], Figure 3). Based on similar situations that have arisen with unapproved GM crops (such as Starlink) it can reasonably be anticipated that the rejection of imports is likely to be viewed negatively by consumers domestically (see figure on page 45 in [64]) and internationally. It is also reasonable to assume that the suspension of future imports on all

potentially impacted products will incur a cost to the exporters. Both the Starlink and Syngenta Viptera (see below) litigation are strong authorities for this hypothesis. While the Starlink litigation related to contamination via unapproved GM material, the Syngenta Viptera litigation relates to damage to export markets caused by GM material that is fully approved by U.S. regulators for both unconfined release and export.

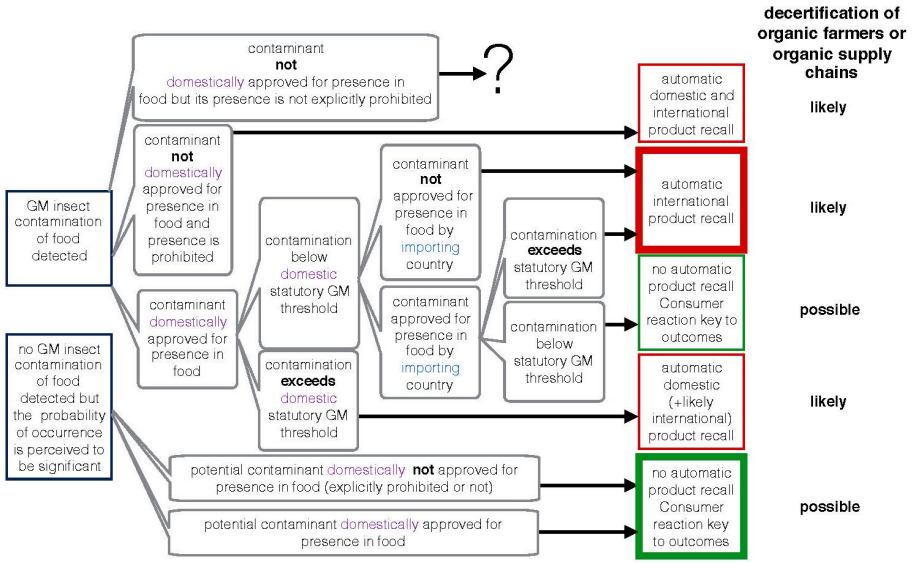

Figure 3. Potential regulatory outcomes of actual or potential contamination of food by GM insect parts. As far as we are aware, no country has approved the presence of GM insect parts in human food; however, some of the above scenarios consider the outcomes should this occur (colored boxes apply to both organic and non-organic produce). The probable consequences for organic farmers and organic supply chains are given on the right. Not all the possible scenarios shown are discussed in the text, the focus being on the two outcome boxes with thick boarders. The box leading to a '?' represents a hypothetical situation where we are unable to provide any insight into the many possible outcomes. Note that the "statutory GM threshold" indicating a permitted level of GM insect material approved in food (which no country has currently established) is unrelated to the "food sanitation standards" discussed in the text (Table 2).

Syngenta Viptera Litigation (USA)

U.S. regulators approved a GM corn called 'Agrisure Viptera' [65] for sale in 2010 and the product was commercially launched in August 2010 in advance of the 2011 planting season. In addition to domestic U.S. approval, Syngenta also received import approval from Canada, Japan, Australia, Brazil, Mexico, New Zealand, South Korea, Russia, and Taiwan. Significantly, import approval was also sought from China but had not been achieved by the time of product launch. In October 2014, four specialist class action law firms began an action against Syngenta for damage caused to U.S. corn farmers by China's rejection of shipments containing traces of Viptera corn. The suit seeks damages approaching US$1 billion and has so far enlisted over 300 farmers. Potentially affected corn farmers are encouraged to join the litigation at a website established by the law firms that clearly outlines the arguments that will be pursued:

> *If you've arrived here, you are probably a corn farmer feeling the financial impact of Syngenta's bioengineered corn. A recently filed class action lawsuit alleges that Switzerland-based Syngenta knowingly marketed two genetically modified strains of corn—Agrisure Viptera and Agrisure Duracade—that are illegal in China. When China detected a genetic trait found in Viptera (MIR162), they stopped accepting shipments. That caused the price of corn to plummet. That affects you, your farm and your family.* [66]

Syngenta has stated that it will vigorously defend its actions:

> We developed a superior product that helps farmers; we applied for and received government approvals from the U.S. and major export markets at the time; and we submitted an import application to the Chinese government that was timely, accurate and complete. Syngenta believes the lawsuits are without merit and strongly upholds the right of growers to have access to approved new technologies that can increase both their productivity and crop yields. The issues involved in these cases are extremely important and affect every American farmer's right to benefit from new technologies that help grow better crops. When a U.S.-approved product like Agrisure Viptera (event MIR162) is kept out of a market for political and economic reasons, farmers—and consumers—lose. [67]

In addition to these class action lawsuits, Syngenta's Viptera product line, and its effect on corn exports to China, was the subject of litigation between Syngenta and Bunge Ltd., and Syngenta and Cargill. Whether this litigation is settled in the courtroom or in the boardroom, it highlights the consequences that can arise from inadvertently importing unapproved material into certain jurisdictions (note that unapproved contamination is generally considered on a zero tolerance basis). Furthermore, both this litigation and the Starlink litigation provide clear evidence of the tremendous economic damage that can be caused. The Starlink recall is estimated to have depressed all U.S. corn prices by 6.8% in the year following the recall and the litigation was eventually settled out of court for US$750 million [68]. Similarly, the plaintiffs in the Syngenta Viptera litigation are seeking hundreds of millions of dollars in damages.

3. Discussion

In the context of the hypothetical spinach farmer it is noteworthy that while a permit to experimentally release GM diamondback moths was issued, it cannot authorize GM insects to be present outside of the release locations. Furthermore, the permit cannot authorize releases of GM insects onto private property (outside that specified in the permit). Furthermore, the permit states that no material containing GM insects should be used as food or animal feed. Consequently, while the absence of any reported notification or consideration of neighboring organic farmers (some of which are within 10 km of the probable release site) might arguably be sufficient for an experimental release where no GM insects actually move into any crops destined for market, the approval process should not serve to establish any precedents for future area-wide programs (either by the USDA or their delegates). With regards to future control programs, it is remarkable that in more than 500 pages of text by USDA experts or their consultants only the benefits of proposed GM-SIT releases are discussed [10,18,25,30]. This is all the more remarkable given the persistent and well-publicized requests for clarity surrounding possible negative impacts on organic farmers, some of which are outlined above [30,32,33,39,42,43,54]. One possible explanation for this exclusion is that the USDA-APHIS currently views its role as requiring an examination of a very narrow range of potential socioeconomic effects. For example, the only issues addressed in the 2014 GM diamondback moth release were listed as follows:

> *Environmental considerations: soil resources; water resources; air quality; climate change; plant communities; wildlife and biological diversity.*
>
> *Human Population Considerations: Farm worker health and health of general public.* [30]

All other potential socioeconomic effects (including those explicitly raised in the 287 public comments relating to this permit application [69]) were ignored, leading to a situation where many legitimate concerns are not considered as relevant factors in the approval process. This omission raises a crucial question: whose responsibility is it to address such concerns and when should consideration of them occur? Is it within state or federal jurisdiction, should it be litigated in the courts, or should it be within the competence of the USDA? Alternatively, if the USDA's jurisdiction ends after

a consideration of environmental protection, are concerns relating to all the other issues discussed above the responsibility of the permit applicant? If so, who is responsible for considering the impact of releases on organic farmers, and the potential damage to lucrative export markets?

In our hypothetical example the level of contamination of food still fit for human consumption is probably quite low (0.000009%) and the likelihood of GM insect contamination occurring is proportional and dependent on the proximity of the organic farm to the experimental release. While this degree of contamination is much lower than courts have been willing to consider as significant in the context of GM plant material or seeds that have been approved for human consumption, we have shown above that it may still have practical importance in a number of instances (this is in addition to being philosophically objectionable to some farmers and consumers). Of course if the GM insect material was unapproved for presence in food in an importing country, even low levels are likely to be subject to a "zero tolerance" policy by regulators or politicians (e.g., see Viptera example above).

We have focused on two potentially significant consequences of a mass-release GM-SIT program, one relating to the impact on organic farmers and the second relating to damage to lucrative export markets. Given that no applied GM-SIT program has yet been conducted, do opportunities exist to plan any future uses in such a way as to eliminate, or at least ameliorate, these potentially significant consequences?

3.1. Taking into Account Organic Producers

If the experience of the 2014 NY trial is anything to go by, much work needs to be done in this area. At present there is no requirement to notify neighbors of an impending release and the provision of any information is solely at the discretion of those conducting the release. Furthermore, the conditions for permit approval are not publicly available and can only be accessed by lengthy Freedom of Information requests. In addition, public consultations held prior to the 2014 permit approval resulted in the submission of 287 overwhelmingly negative comments, some raising specific questions about the impact on organic farmers, yet the permit was still granted with minimal clarification [30,69]. It is clear that the current process leaves farmers who may be affected by an impending release with few options (and little information) to protect their crops. However, we suggest that several options, both legislative and non-legislative, are available to address at least some of these shortcomings.

3.2. Mandate Consultation and the Consideration of Impacts in Approval Regimes

With regards to commercial releases and area wide programs, we assert that they would be unlawful in the absence of specific state or federal legislative/regulatory approval. If this is the case, these legislative or regulatory processes provide an opportunity to consider the concerns of organic farmers who may be impacted by the release of GM material. In this regard, positive precedents already exist in some state legislation pertaining to area-wide SIT releases. For example, the New Mexico Pink Bollworm Control Act states:

> *When prescribing control measures, the committee shall make every effort to adhere to integrated pest management practices, to allow organic cotton producers to choose organic pest management practices that will allow them to maintain their organic certification and to adhere to the management goals of individual cotton producers consistent with the goal of complete eradication of the pink bollworm;*
>
> *The pink bollworm control committee shall confer with an organic cotton producer to determine measures that might be taken to attempt to keep all or a portion of the organic cotton producer's cotton acreage below trigger levels for required treatment. If the organic cotton producer chooses to use a nonconventional method, the committee shall pay the costs of the nonconventional method used by the organic cotton producer, provided the costs do not exceed the equivalent costs of conventional control methods. If pink bollworm trigger levels are reached on the organic cotton producer's acres and pink bollworm migration from outside these acres has been eliminated as a cause of these levels,*

> *the organic cotton producer shall be allowed to harvest these acres but shall not be allowed to grow cotton on the acreage for one year*. [70]

3.3. Ensure that the Scope of Existing Approvals Regimes Encompasses GM Material

Legislators and regulators should explicitly clarify whether the existing legal basis of SIT programs includes the authority to release GM insects. In 2011 the U.S. Office of the Inspector General indicated that existing regulations for the release of GM organisms only applied to GM insects by "inference". They concluded that this was an undesirable state of affairs both in practice and with regard to public perception (page 9–12 in [71]). The audit states:

> *In November 2009, Biotechnology Regulatory Services officials told us that they were working on drafting the Decision Memorandum to the Secretary setting forth three possible options for clarifying the regulations that apply to GE animals and insects: (1) arguing that these regulations in their current form give APHIS sufficient authority to regulate GE animals and insects; (2) modifying these regulations to make it clearer how they relate to GE animals and insects; or (3) formulating completely new regulations.* [71]

As far as can be publicly determined, USDA-APHIS has made no progress in publicly clarifying, or even consulting on, this key issue. We can only agree with the reasoning and recommendations of the USDA's own auditors. These amendments should be subject to the normal scrutiny afforded to legislative change. This would provide an opportunity for organic farmers to be heard, and for amendments to be tailored to at least acknowledge their concerns. It is not clear, for example, whether GM techniques would fit within the definitional requirements of the New Mexico legislation mentioned above. Again, the process by which clarifying amendments become law would afford opportunities for consultation with organic farmers and other stakeholders. We would observe that the regulator APHIS discreetly deciding that conventional SIT regulations in their current form provide them with sufficient authority to regulate the release of GM insects affords no such opportunities for public consultation.

3.4. Mandate Consultation and Engagement between the Producers of GM Insects and Potentially Affected Farmers

While the release of any GM insect will have consequences for organic farmers, not all insects are equal. The diamondback moth is a rather "courageous" choice for this technology given its migratory behavior and broad host range; there are other targets such as cotton pests where compromise and coexistence are more promising. It would be relatively straightforward to include requirements for consultation on proposed GM insect choices and to ask producers to identify those species that would represent the least potential risk to organic farmers.

While none of the above suggestions will necessarily eliminate the impact on organic farmers in their entirety, it is imperative that "don't ask don't tell" scenarios be avoided (i.e., do not ask local farmers for their opinion on releases and do not tell them anything about the nature and timing of releases). As previous experience has illustrated, neither the courts nor international markets provide acceptable and long-term solutions to these issues. Only through developing legislative and approval regimes that consider the full range of impacts on producers, allow for meaningful public consultation, and mandate the consideration of less harmful options can we begin to address these pressing issues.

3.5. Clarify Where the Responsibility Lies to Consider Probable Export Market Impacts

If USDA-APHIS or other regulatory authorities are justified in not considering any likely impacts of approved permits outside of a narrow interpretation of the biological environment, then it should be made clear to stakeholders what are the appropriate fora that will address their concerns (ideally prior to releases commencing, [72,73]).

As far as we are aware, the only authoritative statements on this matter are in a 2014 letter to an NGO from the European Commission Health and Consumers Directorate-General (page 13, [42]).

This letter identifies the importing EU member state as being responsible for ensuring that "imports conform to EU Regulations". The same letter also implies that in the opinion of the commission countries exporting into the EU also have responsibilities with respect to unauthorized GM insect contamination, based on the respondent for the commissioner writing that "I have however taken the action of requesting information from the relevant Brazilian authorities as how they intend to ensure that this unauthorized GM insect [medfly] is not exported to the EU via Brazilian fruit". It is perhaps noteworthy that the proposed experimental release of medfly in Brazil that was the topic of the letter was subsequently abandoned, though this may have been entirely unrelated to the letter.

3.6. Opportunities as the USDA Prepares a New Environmental Assessment (EA) Document for Experimental GM Diamondback Moth Release

On 7 November 2016 the USDA announced that two key documents (EA and FONSI) underlying the approval of the 2014 NY permit (13-297-102r) had been withdrawn due to technical issues relating to public notifications. It was also announced that the USDA has received a new release application and is "currently preparing an EA for this new application and will publish notices associated with the EA and FONSI (if one is reached)" [41]. The generation of a new EA document provides an ideal opportunity to prominently and clearly resolve some of the issues raised above. Specifically:

1. Will the USDA describe what if any remedial actions are likely if GM insects are reported outside release or quarantine areas authorized in approved permits?
2. Will the USDA publicly clarify, prominently and in plain language, whether any agricultural products upon which unapproved GM insect parts were detected would be allowed to enter the food chain? This should include reference to all relevant regulations from the USDA, EPA, or FDA. If there are no regulations prohibiting the presence of experimental GM insects on food crops outside of authorized release zones, this should be plainly stated.
3. A more comprehensive public consideration of all the available evidence (e.g., [35,36]) on the dispersal characteristics of diamondback moths would further enhance the credibility of the EA and any FONSI (if one is reached).
4. All permits issued should proactively be made public at the earliest possible stage, including all supplementary conditions. This information is unambiguously covered under Freedom of Information Act requests but can take months or years to process through this route.

We would observe that writing a new EA is an excellent opportunity for the USDA to incorporate many of the suggestions above (and respond to the questions in [31]) to provide a positive early precedent in the application of this developing technology. In this light we believe it is valuable to point out that any concerns about the application of GM techniques in the organic farming community may not be absolute. As discussed by Wickson et al. [74] in this issue, the draft text of the International Federation of Organic Agricultural Movements public consultation on genetic engineering and genetically modified organisms [75] currently includes the following text:

> *Technologies such as GMOs should only be introduced—and then under controllable circumstances only—based on democratic, transparent assessment of the technology through processes that include decision-makers from every area of society and every group of people who will be impacted by the technology.*

This implies that for this highly influential organization there is no absolute principled prohibition on the use of GM techniques, but the manner in which they may be introduced is important. It is also significant that this discussion document explicitly includes in its scope GM arthropods (a taxonomic phylum that includes all insects).

4. Conclusions

One of the most fundamental questions that remains to be resolved is: if the only effective coexistence measure for GM-SIT is isolation by distance from releases, would this impact the outcome of

future court rulings or permit approvals? Assumptions about the practical effectiveness of coexistence measures have almost always been a factor in court rulings in favor of GM technologies obtaining regulatory approval (e.g., in the arguments relating to the deregulation of Roundup Ready Alfalfa in the USA [76,77]). The scale of isolation required for GM-SIT is likely to be an important consideration and will be highly species-specific, which makes it difficult to arrive at general conclusions about sufficient coexistence measures. Regarding diamondback moths specifically, one of the only two release-and-recapture studies on this species reports an explicit estimate of a minimum of 3 km isolation required between treated and untreated populations. If treated sites are less than 3 km from untreated populations, suppression may be ineffective due to immigrants from untreated areas (this study is based on data from a single experiment in Australia [36]).

The goal of controlling insect pests while reducing the use of chemical insecticides (without impacting predators or parasitoids that can naturally suppress them) is a very worthwhile endeavor. If successful, such methods would benefit all farmers, particularly those who pursue organic methods. While many millions of dollars have already been spent in the development of agricultural GM-SIT approaches, fundamental questions about their application remain unanswered. This article seeks to address a very limited number of recurring questions and while our consideration is motivated by an examination of the potential impact on organic farmers, most of the issues actually apply to farmers more generally.

Where possible we have tried to integrate relevant information on legal precedents and available biological knowledge, providing readers (including policy makers) with a starting point for generating answers to these questions. In addition, we have provided insight into existing precedents regarding GM-SIT regulation (mostly in the USA). In particular, we have highlighted the fact that legislation that does not explicitly mention GM bio-control agents is being interpreted as providing legal authority for their release. This interpretation warrants careful re-examination, a point already noted in 2011 by the USDA's own internal auditor [71].

Furthermore, we suggest careful scrutiny of arguments linking the permitted use of GM vaccines in organic certified livestock [74,75] as somehow precedent setting with respect to organic produce and the mass release of flying GM insects (e.g., [78]). This is because any developments are unlikely to enhance coexistence efforts if they do not reflect the primary regulatory frameworks that have developed over the last 20 years governing the relationship between certified organic products and their conventional counterparts (particularly as GM insects can likely be detected as even trace contaminants in consumer products).

It should be noted that while answers to these questions are developed, farmers would not be left without any capacity to use area-wide SIT. Indeed, the number of conventional SIT projects appears to be rapidly expanding, both in geographical terms and in relation to the number of target species involved [79]. Furthermore, existing conventional SIT programs will continue to provide all types of farmers with protection. In this respect it is critical that the focus that conventional SIT programs have developed over the last 50 years on public engagement and consent is not undermined by any GM programs that may unwisely choose to bypass these steps (chapter 5.4 [1]).

It is possible that GM-SIT approaches may indeed be effective in meeting the challenges of dealing with emerging pest species [2,10,78]. It is also possible that proponents or regulators of GM-SIT may consider an explicit or implicit "contaminate and wait" approach appropriate. This would leave either the courts or export market forces to determine the most satisfactory approach to help farmers manage their pest risks. We would, however, argue that this is likely to knowingly impose an avoidable burden of uncertainty on individual farmers and the agricultural industry as a whole.

Supplementary Materials: The following are available online at www.mdpi.com/2071-1050/9/1/59/s1, Figure S1: Supplemental permit conditions for 2014 NY permit 13-297-102r.

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