Pesticide Emergency Use Authorization: An Underutilized Tool for Controlling Invasive Pests in Africa

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New Invasive Pest Emergencies

Prompted by the inadvertent introduction of the invasive insect pest, the Fall Armyworm (FAW; Spodoptera frugiperda), into Africa in 2016, this brief examines the regulatory emergency pesticide response capabilities in select African countries. The scope of this brief includes conventional pesticides and biopesticides, and reports findings from a pesticide regulatory survey of ten African countries The brief addresses current (Suguiyama, 2019). regulatory requirements and potential challenges in the timely approval of Pesticide Emergency Use Authorization (PEUA) as a regulatory tool, using the FAW invasion as context. It also recommends policy and pest regulatory actions for combatting any other future invasive pest or massive pest outbreaks.

PEUA is a regulatory tool that allows for expedited pesticide review and approval, with an approval period of one year or less. The PEUA is an underutilized regulatory tool in the surveyed countries, which is unfortunate for FAW control efforts, because highly effective, low toxicity insecticides are registered and available for use elsewhere (Prasana et al., 2018). In many jurisdictions globally, crop plants genetically engineered (GE) to produce insecticidal molecules are regulated as biopesticides. Importantly, these GE crops provide the main control option for FAW in the Americas.

The transboundary movement of invasive agricultural pests is occurring with increasing frequency and can cause high levels of crop losses, as the 2016 FAW invasion and the recent 2019-2020 desert locust outbreak in East Africa have made abundantly clear. A welter of interacting forces – including increased aircraft movement, globalization, international expansion human habitat, agricultural intensification, environmental degradation and

Key Findings

- Invasive pests pose special problems for farmers and regulators, particularly in cases like Africa's current Fall Armyworm outbreak, for which no approved control agents were initially available.
- In such emergencies, farmers respond with the only tools they have available -- off-label application of older and often toxic chemical pesticides.
- The timely authorization of pesticide emergency use offers a regulatory tool that can help farmers respond effectively to new pests.
- In order to quickly identify a new invasive pest species and approve effective control tools, affected countries require an early detection system and established protocols for declaring pest emergencies.
- In issuing pesticide emergency use authorizations, regulators should give preference to known registered products and safer pest control alternatives, such as biopesticides.

changing climate – contribute to the increased frequency of transboundary pest outbreaks.

Invasive agricultural pests pose special problems for farmers and regulators because they typically arrive without locally registered pesticides suitable for their control in their new habitat. Without pesticides registered for use against the invasive pest and the crops on which it feeds farmers are left with few control options until the necessary registration process (in many countries two years or longer) is completed.

This brief summarizes recent experience with PEUAs in 10 African countries. It explores reasons







for the limited current use of PEUA to control FAW and recommends specific actions to increase utilization of this important regulatory tool in response to FAW and other future pest emergencies.

Fall Armyworm Invades Africa

In 2016, the FAW, a voracious crop-eating insect pest, was first identified in coastal West Africa. The best evidence suggests it was introduced from the Caribbean region of the Americas. Because FAW moths can travel as far as 1,500 kilometers, this new invasive pest spread rapidly across all tropical regions of Africa and Asia. Primarily a pest in maize and sorghum fields, FAW caterpillars (Figure 1) feed on the foliage, tassels and seeds of the host plant (Figure 2). Although crop losses may vary significantly across locations, aggregate yield losses in affected crops are substantial. In 2018, estimates suggest that FAW destroyed 17.7 million tons of maize on the African continent, causing roughly \$4.6 billion in damage (FAO, 2019). Though it feeds primarily on maize and sorghum, the FAW strain introduced into Africa and Asia can also be found in smaller numbers on millet. sugarcane, tomatoes, and other crops. These affected crops are significant for food security as well as the economic welfare of farmers, especially smallholders throughout the continent.

In the absence of effective control measures, affected African farmers initially responded with off-label application of older and in many cases more toxic chemical insecticides. Recent field assessments in Malawi, for example, found farmers directly applying organophosphates (profenofos) and pyrethroids (cypermethrin) onto affected plant leaves, without any protective equipment (Murray et al., 2019). As the scale of the now endemic FAW infestation is understood, agricultural researchers and plant protection agencies have increasingly recognized the danger to human health and the environment in the wake of widespread, reflexive recourse to older and more toxic insecticides (Jepson et al., 2020). Yet alternative safer use insecticides exist in the Americas, the home range of the FAW, where researchers have developed insecticides that are highly effective on FAW and have low mammalian toxicity. However, these alternative products are not widely registered in Africa.

Figure 1. Fall Armyworm caterpillar and damage.



Photo Credit: International Maize and Wheat Improvement Center (CIMMYT)

Figure 2. Damage from Fall Armyworm larvae.



Photo Credit: The Observer News, Kamyowka, Uganda

Regulatory Provisions for Pesticide Emergencies

When a new transboundary or invasive pest is detected early, national pest control authorities are sometimes able to quarantine affected areas with a goal of eradicating the pest. As a second line of defense, national pest control authorities typically attempt to contain pest outbreaks using available pest control measures, before the outbreak becomes critical. However, early containment and timely implementation of mitigation remedies may not be possible for all pest emergency situations.

For new, exotic transboundary pest infestations, just like for established pests, agricultural researchers

encourage the use of an integrated pest management (IPM) strategy. This strategy is based on conservation biological control, host plant resistance, good agricultural practices and the judicious use of (safer use) pesticides when warranted. For invasive pests this creates a challenge because in some instances a pesticide may already be registered for use in the crop, but for other pests, and in other instances the pesticide may not be registered at all.

In most African countries, any new commercial pest control product, whether chemical or biological, requires extensive data and efficacy testing in the specific African country prior to regulatory approval. Based on a pesticide registration survey conducted in 2019, the regulatory approval of pesticide products in Africa typically requires between 1.5 to 3 years under normal circumstances (Table 1). In cases where a new invasive pest introduction or an extreme pest crisis require immediate action, the normal pesticide registration review process may prove unnecessarily time consuming, particularly for pesticide products that have already been tested and registered for pest control in other countries with similar agronomic conditions.

Table 1. Pesticide regulations in 10 African	countries
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	Conventional Pesticides*			Biopesticides		
Country	Full registration review time	Provisional sales authorization	Pesticide emergency use authorization (PEAU)	Covered under existing regulations?	Reduced registration requirements?	FAW emergency declared
Ethiopia	2-3 years	yes	yes	no	no	no
Ghana	1.5 years	yes	yes	yes	yes	no
Kenya	2.5 years	yes	yes	yes	yes	yes
Mali	2 years	yes	yes	yes	yes	no
Niger	2 years	yes	yes	yes	yes	no
Nigeria	90 days	no	yes	no	no	no
Senegal	2 years	yes	yes	yes	yes	no
Uganda	1.5 years	yes	yes	yes	in process	no
Tanzania	1.5 years	no	yes	yes	in process	no
Zimbabwe	3 years	yes	yes	yes	yes	yes

^{*} Notes on these different forms of pesticide regulatory approval:

Source: Suguiyama (2019).

Full registration is valid for 3-5 years in most countries and requires that a pesticide complete full regulatory testing and environmental reviews.

Provisional sales authorization is typically valid for 1-3 years, following a partial regulatory review and leads to full registration contingent on submission of any outstanding testing or other documentation.

Pesticide emergency use authorizations (PEUA) are valid for much shorter time periods, usually one cropping season, and require regulatory declaration of emergency based on documentation of likely losses and absence of alternative control tools. Emergency use authorization does NOT necessarily lead directly to full registration.

Pesticide Emergency Use Authorization, in Principle, and in Practice

When confronted with a new invasive pest, national and regional pest control authorities can employ streamlined regulatory processes to facilitate pesticide approvals for safer and effective control measures. This provides a rapid policy response to address immediate food security needs, but also considering human health and environmental concerns associated with initial reliance upon broad spectrum pesticides. This policy response takes place often years in advance of the research and education that are required to develop and implement locally adapted IPM strategies.

According to our 2019 pesticide registration survey, most African countries have some combination of existing regulatory processes that, in principle, allow for expedited pesticide review and approval:

- 1. Pesticide Emergency Use Authorization. Regulators in all ten of the African countries surveyed have legislative authority to issue pesticide emergency use authorizations for specific products and specific pests (Table 1). These are normally approved for a period of one year or less and require a prior formal pesticide emergency declaration (see below).
- 2. Label expansion. A common way of authorizing emergency pesticide use involves extending authorization of already registered pesticide products for controlling new pests on newly affected crops. This "label expansion" requires supporting technical information showing efficacy for controlling the emergency pest in affected crops.

In order to invoke either of these pesticide emergency use authorization procedures, regulators must first declare a formal pest emergency. Such declarations have occurred many times in the past, for example, during emergencies created by the tomato leafminer, *Tuta absoluta*, fruit flies, and banana and cassava diseases. Table 2 identifies the relevant national or sub-regional regulatory bodies that are empowered to declare pest emergencies in the ten surveyed countries. Box 1 describes the general conditions that typically warrant pesticide emergency use of effective, properly evaluated pesticides.

African regulators require that prior industry research carried out on the specific pest, crop and climate combinations be made available for their review prior to granting PEUAs. In the case of the desert locust, there has been a long period of time where such research has not taken place, and industry is now being encouraged to test lower risk pesticides so that new and safer pesticide candidates may be available.

Table 2. Regulatory Authority to Declare an Emergency Pest Situation in Selected Countries

Country	Authority
Ethiopia	Ministry of Agriculture
Ghana	Ministry of Agriculture in
Gilalia	coordination with the
17	Environmental Protection Agency
Kenya	Pest Control Products Board,
	Ministry of Agriculture, Livestock
	and Fisheries
Mali	National Pesticide Authority that
	follows a harmonized regional
	protocol approved by the Sahelian
	Pesticide Committee
Niger	National Pesticide Authority that
	follows a harmonized regional
	protocol approved by the Sahelian
	Pesticide Committee
Nigeria	Pest Department, Federal
	Ministry of Agriculture and Rural
	Development
Senegal	National Pesticide Authority that
	follows a harmonized regional
	protocol approved by the Sahelian
	Pesticide Committee
South Africa	Department of Agriculture,
	Forestry and Fisheries
Uganda	Agricultural Chemicals Board
Tanzania	Outbreak Pest Sub-Committee in
	consultation with the National
	Plant Protection Advisory
	Committee
Zimbabwe	Ministry of Agriculture in
	consultation with stakeholders

Source: Suguiyama, 2019.

In practice, recent applications of emergency use provisions have worked well in South Africa and in Kenya in providing access to pesticides for control of FAW. The Department of Agriculture, Forestry and Fisheries of South Africa developed, in coordination with key stakeholders, an emergency registration protocol for agricultural remedies (Box 2). This protocol approved timely pesticide products, including conventional pesticides and biopesticides for FAW control. Kenya similarly instituted a multiinstitutional technical team, provided capacity building to country extension staff, and fast-tracked, on an emergency basis, the registration of individual products that proved effective in controlling FAW. Most African countries have legal authority to allow temporary registrations, usually for one year, to address pest emergencies along with the registrant's commitment to pursue full registration afterwards.

Apart from these two examples, only a handful of African countries have invoked emergency provisions to confront FAW. Several possible reasons may explain the frequent failure to invoke emergency use provisions:

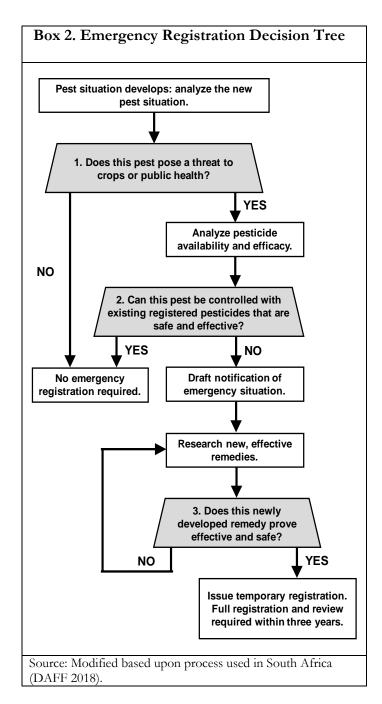
- Weakness in the pest monitoring infrastructure, whether regional or national, in relaying pest identity and damage severity information to regulatory and government officials.
- Delays in identifying the pest emergency situation.
- Inadequate coordination between agricultural researchers, pesticide regulatory offices, and industry partnerships for timely technical cooperation.
- Lack of registrants seeking to work in certain pesticide markets because of the limited commercial scale of the market, or because of weaknesses in regulating the market.

Box 1. Examples of Conditions that Could Warrant Emergency Use of Effective and Properly Evaluated Pesticides.

An invasive pest that threatens agricultural crops or public health causing 'significant' economic damage (yield losses) and where no effective, registered pesticides or agronomic practices are available to farmers.

- An existing or cyclical pest that creates a crisis situation threatening agricultural crops or public health whose increased incidence causes 'significant' economic damage (yield losses) and where no effective pest control tools or feasible agronomic practices are available to farmers. Desert locust is a good example.
- Once the pest species has been identified, the economic damage on affected crop or crops has been documented, and the pest threat has been documented as meeting the statutory definition of a 'pest emergency condition,' an official declaration of a pest emergency is required and the need for pesticidal control.
- The identification of safe and effective pesticides will require engagement with key stakeholders and the pesticide industry.
- The emergency use of a pesticide may be authorized for regional, national or specific geographical areas.
 Emergency uses may also be issued for pest quarantine or crisis situations.
- Requests for emergency uses may only be sponsored by Provincial, State or County agricultural agencies.
- Pesticides with unacceptable human health (especially high mammalian toxicity) and/or environmental risks cannot be considered for emergency uses.
- Existing information on pesticides (i.e. technical information, risk assessments, established maximum residue levels for affected crops, and efficacy information) will be required for the issuance of emergency uses.
- Preference for emergency use should be given to pesticides (conventional chemicals or biopesticides) that are currently registered and thoroughly evaluated in Africa or in similar agroecological environments elsewhere in the world.

Sources: FAO (1992), Health Canada (2017), South Africa (2018), and U.S. Environmental Protection Agency (2017).



Recommended Actions

Based on surveys with pesticide regulators and plant protection specialists in ten African countries, the following policy or pest management actions would help to expand the use of emergency use provisions in combatting FAW or any other future invasive pest or massive pest outbreaks:

- Strengthening regional and national programs for early detection and identification of invasive pests and emergency pest outbreaks.
- Timely official declaration (by the regulatory authority listed in Box 2) of a pest emergency, which is necessary before emergency use can be authorized and implemented.
- Development of national protocols and processes for implementing emergency use provisions.
- Increased cooperation between regulators, agricultural researchers and private industry to identify, test and register effective, safer pesticides for pest emergencies.
- Regional harmonization efforts currently under way in West, East and Southern Africa offer significant potential cost reduction to private industry seeking regulatory approval for pest control products in Africa.
- Mutual sharing and acceptance of pest control information among countries can help to accelerate introduction of effective and safer pest control technologies.
- Placing an emphasis on pesticides that do not require extensive use of and specialized Personal Protective Equipment (PPE), recognizing that acquiring PPE is expensive, rarely available or used in many African countries.
- Consideration of GE maize seeds (Bt maize)
 which can control FAW and other stem and
 leaf-feeding Lepidoptera without recourse to
 toxic insecticides. Therefore, continued
 engagement on this topic offers significant
 potential gains in pest control, food
 production and environmental safety.
- Consideration of IPM compatibility with all PEUA options in addition to human health, environmental and efficacy impacts (Farrar et al., 2018)

 Expediting efforts to explore newer and safer approaches that promote IPM will be necessary to avoid serious health and environmental risks while at the same time ensuring African food security in the face of the FAW introduction and any other pest management crisis.

Conclusion

All ten countries surveyed for this brief have PEUA policies in place. During the Fall Armyworm crisis, only Kenya chose to use their PEUA procedure. Kenya was successful in providing farmers with emergency access to modern, safe and effective insecticides for Fall Armyworm management. In the other nine countries, farmers had no other choice but to use widely available and highly toxic, and in many cases, unregistered insecticides. There are several possible explanations for the unintended consequence of not implementing existing PEUA policy. In this brief paper we have articulated actions that may expand the use of the emergency use provisions for combating invasive species. Further studies are needed to determine which actions will help overcome barriers to expanded use of the PEUA regulatory tool.

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This policy research brief reports findings from a pesticide regulatory survey of ten African countries (Suguiyama, 2019).

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