

The EU's Nasty Bite

How the EU's new pesticide regulations will harm the fight against malaria



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The EU's Nasty Bite

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Executive Summary

Pesticides are widely used to control pests that pose risks to crops, livestock, human health and people's property. They are predominantly used in agriculture, where they are a highly cost-effective means of reducing crop losses resulting from insects, weeds, rodents and fungi. They have thereby contributed to the huge increases in agricultural productivity and falling food prices that have characterised the last half a century.

Pesticides have undoubtedly improved the lot of humanity, reducing the very real incidence of disease and death. However, as with all technologies, they also present certain hazards. Early pesticides, especially those based on arsenic for example, were highly toxic. More modern pesticides, including most of those developed and used in the past 60 years, are generally far less toxic, but are nevertheless not entirely without hazard.

In response to these hazards, the EU has since the 1970s sought to restrict the use of pesticides, requiring all plant protection products to go through a comprehensive 'risk-assessment'. As a result, many commonly-used agricultural pesticides have been effectively banned in the EU.

Certain activists have long argued that current EU directives on pesticides do not go far enough to protect human health and the environment, and that steps should be taken to reduce further levels of consumer and environmental exposure to pesticides. Partly in response to such demands, the European Commission has proposed a new 'Thematic Strategy on Pesticides'; this would further restrict which pesticides can be used in the EU. The legislation would result in an essentially arbitrary 'hazard-based' assessment of pesticides. The proposed legislation is due to go before the European Parliament in mid January 2009.

In addition to limiting the options farmers have to deal with pests - increasing their costs and reducing output - the legislation would likely have a major impact on programmes to control vector-borne diseases such as malaria and dengue fever. These programmes rely heavily on insecticides, production of which would be adversely affected. The legislation would also undermine the already fragile incentives to conduct research and development into new insecticides. Furthermore, there is a risk that the EU's strict Maximum Residue Levels for imported agricultural products would change in line with the legislation, forcing exporting countries to abandon the use of these insecticides for disease control. This would be a tragic loss of effective weapons for improved public health for the hundred of millions of people in poorer parts of the world at risk from these diseases.

The proposed legislation is arbitrary and capricious: it would prevent people in poor countries from using technologies that are unambiguously beneficial, with little or no benefit to humanity or the environment.

Background of the legislation

This paper concerns the EU's proposed Thematic Strategy on Pesticides. Although this strategy comprises several parts, our paper focuses on only one component, the "*Regulation concerning the placement of plant protection products on the market*".

The proposed Regulation would change the way in which pesticides and other agro-chemicals are judged safe for use. Currently, this is governed by Directive 91/414/EEC, which requires that all active ingredients in pesticides used in the EU undergo a risk-assessment before being approved for sale. By its nature, such a risk assessment takes into account the quantities of active ingredient to which humans or the environment are exposed. By contrast, the new Regulation would be based on 'hazard' alone - without due regard to exposure levels.

Risk-Benefit versus Hazard Evaluation

The use of pesticides entails both risks and benefits, which must be weighed carefully against one another. But the current revisions to pesticide legislation adopt a precautionary approach that seeks, however implausibly, simply to abolish risk.

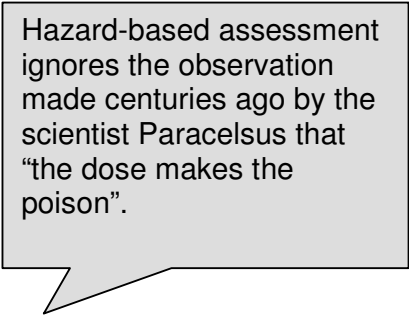
All products, from cars to cleaning fluid, entail 'risk'. Popular consumer products provide significant demonstrable benefits, so the few people who seek to ban them tend to be ignored - since politicians who followed such a course would be distinctly unpopular. Technologies that are used only by a small segment of the population, by contrast, tend to be more susceptible to arbitrary restrictions.

The existing pesticides Directive, from 1991, recognises the need to weigh risk and benefit. Chemicals are evaluated on the basis of their real-world applications and the risks they pose to humans and the environment. The new proposals, by contrast, jettison this principle, and examine exclusively *potential hazard* - as determined in a laboratory. Real world applications are ignored, as are the benefits of the chemical.

Assessing the safety of any chemical requires knowledge of how (and in what potential way) it might cause adverse effects. This is one form of hazard identification. The next step is to examine what exposure conditions would allow this to become a risk to humans, animals or the environment. This is known as 'risk assessment'. It is followed by 'risk evaluation', in which identified hazards and the estimated risks they present are evaluated. This is followed by 'risk estimation', which identifies outcomes and looks at the magnitude and associated consequences of these outcomes, as well as their probabilities. All of this work allows us to carry out a risk-benefit analysis of the effects of exposure, processes, contamination, persistence and so on (often in the form of an intervention study). This then determines what might be done.

Currently, hazard identification relies heavily on the use of animals in what are sometimes called "safety" tests. But these tests are carried out in a special way; doses are used at upper levels that are certain to produce an effect. Sometimes compounds that are not toxic to mammals are given in such large doses that they prevent the animal from obtaining adequate nutrition from its diet. The process of "titration" is then carried out, where doses are adjusted until a "No Observable Adverse Effect Level" (NOAEL) is discovered. As this testing paradigm requires the

demonstration of an effect and can thus be used to define a hazard, any substance - even water - will be hazardous (and there will be dispute about what is adverse).



Hazard-based assessment ignores the observation made centuries ago by the scientist Paracelsus that “the dose makes the poison”.

In fact, it is not sensible to test compounds at such high and improbable levels. These tests do not yield very useful information as the body’s metabolism is overloaded. There will seldom be a sensible scientific reason to exceed the average dose of human exposure by more than 10 times and certainly not more than 100 times. A system designed to identify hazard is not suitable for a hazard based intervention process.

Hazard-based assessment ignores the observation made centuries ago by the scientist Paracelsus that “the dose makes the poison”; after all, even coffee and wine contain levels of carcinogens and endocrine disruptors. Just because something can cause cancer in a rodent does not mean it will cause cancer in a person. Nor does it mean that person will be exposed for the rest of their life to doses that, in animals, could cause cancer.

Vector-borne diseases and the EU’s pesticides regulation

Because of its focus on hazard rather than risk, the proposed regulation would result in the banning of many pesticides. For example, if an active substance is genotoxic, carcinogenic or toxic to reproduction *in very high dose laboratory experiments*, it will be banned until it can be proven that their “effect would in practice be negligible.” Active substances that are similarly classified as neurotoxic, immunotoxic or “endocrine-disrupting” will be banned if they are deemed to pose a significant risk.¹ If a substance is crucial to protecting plant health, it may be approved for up to five years before it must be substituted by an alternative.

The final legislation will almost certainly result in fewer pesticides being approved as safe for use within the EU. Although the most immediate effects will be felt by EU farmers and consumers in the form of lower agricultural productivity and higher food prices, the legislation will have a number of unintended consequences that will hurt people in poorer countries. Of particular concern is its impact on the market for public health insecticides, which are vital for controlling vector-borne diseases such as malaria.

Vector-borne diseases collectively account for more than 1.5 million human deaths per annum globally, the most significant of which include malaria, filariasis, onchocerciasis, chagas and dengue (WHO 2004). The most prevalent vector-borne disease, malaria, kills over 1 million people every year, mostly children under five (*ibid.*). The burden of vector-borne diseases is shouldered mainly by LDCs, particularly those in Sub-Saharan Africa.

¹ European Parliament press release, December 18, available at http://www.europarl.europa.eu/news/expert/infopress_page/064-45244-350-12-51-911-20081218IPR45243-15-12-2008-2008-false/default_en.htm

In addition to its tragic human cost, malaria causes widespread economic damage, mainly through losses in productivity that occur through repeated and prolonged periods of illness. One study estimates that countries with high prevalence of malaria grow on average 1.3 per cent per annum less than they would have done otherwise (Gallup and Sachs 2000).²

The range of major vector-borne diseases and their disease burden are illustrated in tables 1 and 2.

Table 1: Major vector-borne diseases of humans, and associated aetiological agents and arthropod vectors

Disease	Pathogen/parasite	Arthropod disease vector
Protozoan diseases		
Malaria	<i>Plasmodium falciparum</i> , <i>Plasmodium vivax</i> , <i>Plasmodium oval</i> , <i>Plasmodium malariae</i>	<i>Anopheles</i> spp. Mosquitoes
Leishmaniasis	<i>Leishmania</i> spp.	<i>Lutzomyia</i> and <i>Phlebotomus</i> spp. sandflies
Trypanosomiasis	<i>Trypanosoma brucei</i> <i>gambiense</i> , <i>Trypanosoma</i> <i>brucei rhodensie</i>	<i>Glossina</i> spp. (tsetse fly)
Chagas disease	<i>Trypanosoma cruzi</i>	<i>Triatomine</i> spp.
Viral diseases		
Dengue haemorrhagic fever	DEN-1, DEN-2, DEN-3, DEN-4 flaviviruses	<i>Aedes aegypti</i> mosquito
Yellow fever	Yellow fever flavivirus	<i>Aedes aegypti</i> mosquito
Encephalitis*	Flavi-, alpha- and bunyaviruses	Various mosquito and ixodid tick species
Filarial nematodes		
Lymphatic filariasis	<i>Brugia malayi</i> , <i>Brugia timori</i> <i>Wuchereria bancrofti</i>	<i>Anopheles</i> , <i>Culex</i> , <i>Aedes</i> and <i>Ochlerotatus</i> mosquitoes
Onchocerciasis	<i>Onchocerca volvulus</i>	<i>Simulium</i> spp. blackflies

* Includes Japanese encephalitis, West Nile encephalitis, St Louis encephalitis, La Crosse encephalitis and tick-borne encephalitis.

Source: Hill et al. (2005)

² Allowing for other influences on economic growth, between years 1965 and 1990.

Table 2: The burden of vector-borne disease in disability-adjusted life years (DALYs) for major vector-borne diseases

Disease	Disease Burden (DALYs)* in Thousands	Mortality in Thousands
Malaria	42,280	1,124
Africa trypanosomiasis	1,598	50
Lymphatic filariasis	5,644	0
Dengue fever	653	21
Leishmaniasis	2,357	59
Chagas disease	649	13
Onchocerciasis	987	0

* DALYs – Disability Adjusted Life Years (the number of health years of life lost due to premature death and disability).

Source: World Health Organization (2002).

While there are treatments available for many of these diseases, including malaria, vector control is in many cases the most cost-effective means of reducing the disease burden - and is nearly always part of the solution. Many of the most successful malaria control projects involve the use of insecticides. Indoor residual spraying (IRS) with DDT, for instance, has been critical to the eradication of malaria in most of the northern hemisphere, and is currently endorsed by the World Health Organization for malaria control in Less Developed Countries. IRS involves spraying the inside walls of dwellings and other buildings with thin layers of insecticide, which deters mosquitoes from entering buildings and either repels or kills those which do manage to enter. This significantly reduces the chances of people being bitten, thereby reducing the incidence of the disease and interrupting the transmission cycle of the malaria parasite.

IRS with DDT has had a long and successful history: in the 1960s, for instance, a DDT-based IRS programme in India saw malaria cases falling from 75 million to less than 100,000 (Sharma 1987). In the post-World War II period, DDT use is estimated to have prevented between 50 and 100 million deaths from malaria (Roberts et al 1997).

The most prevalent vector-borne disease, malaria, kills around 1 million people every year, mostly children under five (WHO).

Other insecticides are also used to suppress the transmission of onchocerciasis. The twelve insecticides recommended by the World Health Organization against mosquito vectors are illustrated in Table 3. This table also demonstrates that only very small quantities of insecticides are needed for effective vector-control, certainly not the quantities required to pose a threat to health or the environment.

Table 3: WHO-recommended insecticides for indoor residual treatment against mosquito vectors

Insecticide	Chemical type	Duration of effective action (months)	Insecticide action	WHO hazard classification of ai*
Bendiocarb	Carbamate	2–6	Contact & airborne	II
Propoxur	Carbamate	3–6	Contact & airborne	II
DDT	Organochlorine	> 6	Contact	II
Fenitrothion	Organophosphate	3–6	Contact & airborne	II
Malathion	Organophosphate	2–3	Contact	III
Pirimiphos-methyl	Organophosphate	2–3	Contact & airborne	II
á-	Pyrethroid	4–6	Contact	II
Bifenthrin	Pyrethroid	3–6	Contact	II
Cyfluthrin	Pyrethroid	3–6	Contact	II
Deltamethrin	Pyrethroid	3–6	Contact	II
Etofenprox	Pyrethroid	3–6	Contact	U
λ-Cyhalothrin	Pyrethroid	3–6	Contact	II

ai: active ingredient

* Class II, moderately hazardous; class III, slightly hazardous; class U, unlikely to pose an acute hazard in normal use.

Source: World Health Organization (2006).

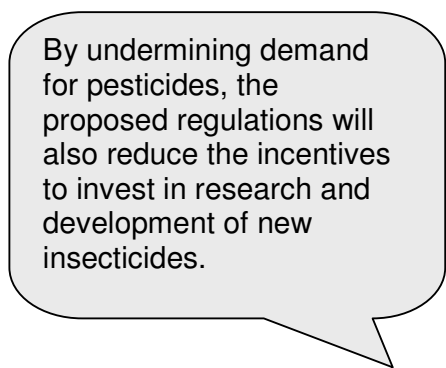
The continued use of these insecticides for disease control is directly threatened by the EU legislation. According to the UK Pesticide Safety Directorate, the “main impact of the developmental neurotoxicity criterion would fall to insecticides” (PSD 2008). This means that if products key to vector-control fail to pass one of the main cut-off criteria or are considered to pose a “significant risk” they could be banned.

Insecticide markets are based almost entirely on crop protection, with production for public health usually a discretionary, mostly philanthropic, extra. Without the agricultural market, production for public health will almost certainly become unsustainable. A review of public health pesticide products by the Boston Consulting Group for the Bill and Melinda Gates Foundation estimated the total public health market was worth only \$750 million in 2006, or 1.3 per cent of the total pesticide market (Boston Consulting Group 2007).

If a product is banned for agricultural use within the EU, it will remove a large element of its bulk demand. It is unlikely that companies would continue to manufacture the product only for public health use in poor countries, since to do so would result in potentially substantial losses. Even if chemical production does not cease entirely, supply and competition would certainly decline, resulting in higher prices and lower quality (as occurred with DDT). What happens within the EU pesticides market has a large global influence, as Europe produces a quarter of all the world’s pesticides (European Commission 2007).

By undermining demand for pesticides, the proposed regulations will also reduce the incentives to invest in research and development of new insecticides. The already high regulatory bar means that it currently takes up to 10 years and \$300-400 million to bring a new class of insecticides to market (Boston Consulting Group 2007). As a result, the EU pesticides industry launches only a handful of new active ingredients a year - which is about “ten times less than the rate at which they have been removed from the market”, according to Professor John Lucas, from Rothamsted Research.³

As a result of these high costs, there are already few incentives for commercial organisations to invest in R&D for public health insecticides, and there have been essentially no new chemicals introduced for such purposes in the past two decades. According to the WHO’s Insecticide Resistance Action Committee, “the most recent ‘new’ compound made available for vector control is etofenprox which was commercialized in 1986.”⁴



By undermining demand for pesticides, the proposed regulations will also reduce the incentives to invest in research and development of new insecticides.

There is an urgent need for new insecticides for public health, not least because agricultural and public health insecticides require substantially different properties and modes of chemical action. Agricultural insecticides are designed to be short acting and have a narrow activity spectrum, for instance, while PHIs often need long-lasting residual action and a broader spectrum of chemical activity, particularly if they are to be used for treatment of surfaces.

Agricultural insecticides will tend to act on the insect’s stomach after it has ingested a crop, while PHIs used for IRS will act as a contact poison after the insect has landed on a wall or other material. There is also increasing vector resistance to existing insecticides such as pyrethroids, which is likely to increase as the use of ITNs is ‘scaled-up’ under the auspices of the Roll Back Malaria Partnership. (Tren et al 2008). Yet, the RBM’s Global Malaria Action Plan (GMAP) estimates that a new active ingredient would require an investment of more than \$175 million over 12 years.⁵ Who is going to invest this money when there is so little prospect of a return?

The EU proposals actively undermine the R&D process for new insecticides by removing the prospect of a manufacturer recovering its development costs via the agricultural market. And although the proposed regulations cover plant protection

³ “Deputy backs calls for rethink of EU pesticide rules” The Parliament, 8 December 2008, accessed 05 January 2009, available at <http://www.theparliament.com/latestnews/news-article/newsarticle/deputy-backs-calls-for-rethink-of-eu-pesticide-rules/>.

⁴ Insecticide Resistance Action Committee: Prevention and management of insecticide resistance in vectors and pests of public health importance. Available at <http://www.iraonline.org/documents/vectormanual.pdf>

⁵ Roll Back Malaria Partnership: Global Malaria Action Plan: The Global Strategy: The Malaria Research Agenda: Research and Development for New and Improved Tools. Available: <http://www.rbm.who.int/gmap/2-4a.html>

products, they would make it virtually impossible to register new products for vector control which are drawn from the agricultural sector.

A number of chemicals used for vector control are directly under threat by the EU legislation. The developmental neurotoxicity criterion will affect the markets for organophosphates, carbamates, pyrethroids and ethylenebisdithiocarbamates, which form the basis of almost all of the 12 insecticides recommended by the World Health Organization in Table 3.

Aerosols of organophosphates, for example, are widely used for control of *Aedes aegypti*, the principal vector of dengue, chikungunya and yellow fever. Pyrethroids are used to control the vectors of a number of infectious diseases, including dengue and chagas. Cypermethrin, permethrin and lambda-cyhalothrin, all used in the treatment of bednets, are amongst the range of pyrethroids that could be banned. Deltamethrin, used in bednet treatment and IRS, could also be banned as a possible endocrine disruptor. It is worth noting that at-risk insecticides are also used against other disease-carrying pests, such as flies, fleas, lice, cockroaches, ticks and mites.

The legislation is an anti-development “non-tariff barrier” to trade

Small-scale farmers in LDCs will also be big losers from the new legislation. When exporting to the EU, these farmers already have to comply with numerous and increasingly stringent norms on food safety and standards, particularly with regard to the use of pesticides, Maximum Residue Level requirements (the maximum amount of pesticide residues that are allowed on imported produce) and traceability issues. Meeting such a large number of requirements is not only very costly, but also logistically difficult for many farmers. In Kenya alone there currently about 250,000 horticultural farmers, 200,000 of which are small-scale farmers with less than one hectare of land. Many of them struggle to find the funds to meet the requirements, and do not have the knowledge or literacy-levels to keep up to date with frequently changing regulations. Additionally, the high costs and difficulties associated with these regulations have prevented a lot of farmers and suppliers from exporting to the EU. The implementation of the newest EU food safety regulations (such as Traceability and Feed and Food Controls Regulations) could cost Kenya US\$400 million of export earnings per year (DFID 2004).

The new regulations will add further burdens. It is likely that the EU will revise its Maximum Residue Levels requirements and that farmers will have to adapt to these. Even if the EU does not change its MRL requirements, private industry standards will probably rise as a consequence of the legislation, placing similar constraints on farmers wishing to export to the EU.

There are parallels with this latest legislative reform, and DDT, which has had an enormous impact on malaria in the 20th century. Although it has never been officially banned for public health uses, the EU’s precautionary approach to MRLs on imported produce has discouraged its use for public health purposes in many malarious countries, unnecessarily increasing the burden of disease, and thereby contributing to millions of deaths.



The high costs and difficulties associated with these EU regulations have prevented a lot of farmers and suppliers from exporting to the EU.

However, environmentalists have long had concerns about the safety of the chemical, expressed most famously in Rachel Carson's 1962 book *Silent Spring*. These fears soon translated into bans. By 1972, the USA and Sweden (both, by that time, free of malaria thanks in part to DDT) had enacted bans. The bans saw the price of DDT increase as supply fell, and DDT IRS fell out of favour.

Over the last few decades the WHO has discouraged the use of DDT in member states - encouraged by pressure groups, who have often overstated the negative effects of DDT on human and animal health (Roberts et al. 2000). Until recently, most Western aid agencies discouraged the use of DDT and indoor residual spraying generally, and have provided little financial assistance to those governments that wish to go down this route (although WHO, USAID and other aid agencies have recently revised this policy).

The EU's stance on pesticides has directly undermined the use of DDT for IRS, through the imposition of trade restrictions on countries that adopt this disease control strategy. In spring 2005, EU representatives suggested to Ugandan ministers that if Uganda chose to use DDT for malaria control, exporters would face import restrictions against their agricultural products. Agricultural exports to the EU (mainly cut flowers, coffee and fish) account for 30 per cent of the Ugandan economy, so it is not surprising that representatives from these industries took out a High Court injunction to force the government to cease using DDT for malaria control. This was in spite of the fact that Uganda had over 12 million cases of malaria.⁶

Today, the proposed pesticide legislation presents similar threats. Less Developed Countries will no longer be able to use insecticides proscribed by the EU for disease control, because of the risk of breaching the EU's standards on MRLs on imported agricultural produce.

Over 160 senior scientists from around the world have signed a petition against the proposed EU amendments, expressing their concerns that the legislation will undermine public health in Less Developed Countries.

In addition to removing vital tools in the fight against disease, the legislation will act as a significant trade barrier, reducing the ability of millions of farmers to pull themselves out of poverty by exporting their produce to EU markets. This is directly at odds with the EU's commitments to end poverty in Africa, set out in its main policy statement on poverty-reduction, *The European Consensus on Development*, and its self-proclaimed status as "the world's largest donor of official development assistance" (European Union 2005).⁷

6 "Health abandons DDT in North" The New Vision, 5 August 2008, accessed December 2008, available at <http://newvision.co.ug/D/8/13/643070>.

7 European Commission. Development Policies. Accessed December 2008, available at http://ec.europa.eu/development/policiesgen_en.cfm.

Discussion

Farming associations and the chemical industry have highlighted the dangers posed by the legislation to agriculture and crop prices in the EU. As a result of their advocacy, the number of active substances that stand to be banned has been decreased significantly.

But very few people have considered the impact of these proposals on Less Developed Countries. The European Union prides itself on the fact that its member states collectively constitute over half of total global Overseas Development Assistance. In particular, the EU claims to have helped development by removing or reducing tariffs and quotas on most imports from poor countries. It seems perverse in the extreme that it will enforce a new regulatory package that will act as a significant non-tariff barrier for agricultural exporters to the EU. As agriculture is such a dominant part of many African economies, any unnecessary restrictions on trade with the EU will perpetuate poverty for millions.

The EU is also a supporter of the Millennium Development Goals, one of which is to halt and reverse the incidence of malaria by 2015. The EU pesticide regulation package would almost certainly make this goal impossible to achieve by effectively removing from the market some of the most potent weapons against the disease, as well as undermining the development of the vital next generation of public health insecticides.

Over 160 senior scientists from around the world have signed a petition against the proposed EU amendments, expressing their concerns that the legislation will undermine public health in Less Developed Countries. They also stated that the move from risk-based assessments to hazard-based assessments is 'unscientific' and puts in place 'new standards that are impossibly high.' Signatories include Professor Sir David King, former Chief Scientist to the UK Government; Professor Sir Richard Feachem, former Executive Director of the Global Fund to Fight HIV/AIDS, TB and Malaria; and Dr Nicholas White of Oxford University, one of the world's leading experts on malaria.⁸

The legislation will have direct and harmful impact on many hundreds of millions of people, mainly in Less Developed Countries. The costs of the legislation will be measured in lives lost, while the benefits will be marginal or hypothetical. When considering the most appropriate way forward for pesticide regulation, EU policymakers have a duty to consider those vulnerable people in LDCs who will be most affected by their decisions.

⁸ Petition available at http://fightingmalaria.org/pdfs/EU_pesticides_letter_of_petition.pdf.

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