HAZARD VS. RISK-BASED APPROACHES TO PROTECTING HEALTH AND ENVIRONMENT FROM PESTICIDES

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Executive summary

Pesticides are designed to kill living organisms. By their very nature they have the potential to harm the environment and, in some cases, human health. Pesticide regulation aims to strike a balance between allowing the use of these chemicals to control pests and protect crops while preventing, or minimising, their negative effects on the environment and human health.

A variety of regulatory models exist to manage pesticide risks, each placing different emphasis on the competing goals of environmental and health protection versus access to pesticides. This paper discusses two of the dominant models in use by governments today: the so-called "Hazard-based" and "Risk-based" approaches.

The UK – along with the EU – currently follows a version of the hazard-based approach to pesticide regulation. This follows the principle that if an active substance possesses intrinsically hazardous characteristics – for instance by being able to cause cancer or persistent pollution – then it is simply considered too dangerous to be used safely and should not be authorised. This approach is in line with the precautionary principle which states that "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically".[1] It is highly effective at controlling risks and relatively simple to operate, but an inevitable consequence is that it reduces the range of pesticides available to use.

Almost all other countries, including the US and Australia, follow a risk-based approach. This model places greater emphasis on assessing and managing the risks of the chemical *in use* and relies on the deployment of checks and measures to keep these risks below acceptable levels. **It is important to realise that managing risks in this way will never be as effective as removing the hazard at source and will add complexity and cost**.

It is a well-accepted principle that the most effective, reliable and economically efficient way of controlling risks is to eliminate the hazard at source. This is the fundamental principle that guides risk management in all hazardous industries.

The UK's decision to leave the EU has opened the door to a reform of the UK's regulatory system for pesticides and the Government has already introduced "…its own autonomous sanitary and phytosanitary (SPS) regime to protect human, animal and plant life and health and the environment".[2] At present, this closely mirrors the EU system, but some groups are now actively lobbying for a move away from the hazard-based approach to pesticide regulation with the aim of increasing the range of pesticides available for use in the UK.[3]

Such a switch could not only permit UK farmers to use pesticides that are currently banned, but could also allow higher levels of pesticide residues in imported food. This is because Maximum Residue Levels (MRLs) are less stringent for pesticides that are authorised for use in the UK so, as current pesticide bans are overturned, MRLs would inevitably rise. As a result, the UK's pesticide regime is a key target in trade negotiations with large agricultural exporters like the US and Australia which use weaker, risk-based approaches to regulate pesticides. In fact, successive US Governments have long made it clear that they consider the EU's hazard-based approach as an unnecessary trade barrier which should be overturned.[4] This has been the case

under both the Obama and Trump administrations and it remains to be seen whether President Biden will take a different approach.

While advocates for such a switch deploy benign-sounding phrases, such as "science-based" to describe the alternative model, there is little doubt that moving to a risk-based approach, similar to the US model of pesticide regulation, would result in an increase in the number – and toxicity – of pesticides approved for use in the UK. As such, a shift would directly conflict with the UK government's oft-repeated promise that leaving the EU will not result in a weakening of environmental protections. It would also undermine the Government's commitment to "…not compromise on our high environmental protection, animal welfare and food standards".[5]

What is more, moving to a risk-based approach would have profound implications for the regulatory authorities and increase the burden on farmers and other pesticide users as greater emphasis is placed on the management of risks in use. The current system heads off a range of hazards at the authorisation stage and, as a result, the UK's existing measures designed to control risks associated to pesticide use will be inadequate in a risk-based system. In order to maintain a similar level of environmental and health protection, many more control measures would be needed and more checks and balances developed and deployed.

Yet, even with comprehensive checks and procedures, a risk-based approach is unlikely to be as effective as the UK's existing model. The chance of failure exists even with the most complex of risk management systems, let alone those that rely on end users to behave in a particular way – for example wearing personal protective equipment, or following safety instructions. In the case of hazardous pesticides, if any of these systems break down, the potential consequences for human health and the environment are severe and sometimes irreversible.

In the US, for example, an overly complex and bureaucratic approvals process has become riddled with loopholes and shortcuts to make the system more manageable. These include waivers on toxicology data, conditional and indefinite authorisations based on incomplete scientific evidence and a risk-benefit analysis mechanism, which weighs up perceived economic 'benefits' against the environmental and health risks of using a given pesticide. The costs to human health, the environment and the economy are telling. There are a reported 10,000-20,000 acute pesticide poisonings every year in the US and this is widely acknowledged to be a serious underestimate of the true level.[6] Meanwhile, the external costs of pesticide use are an estimated $9.6 billion annually. One study which modelled the effect of adopting the US model in the EU, estimated that the external costs would amount to an additional €4.3 billion across the bloc.[7]

The critical questions for pesticide regulators – and society – are what is an acceptable level of protection from pesticide-related harms? How much are we willing to pay for the system to keep this level of protection? And who should foot the bill?

The argument around hazard-based vs risk-based approaches is therefore, in effect, a debate about the level of risk that a society is willing to tolerate. Those countries which have adopted hazard-based regulatory models have come to the conclusion that some pesticides are so dangerous that the level of risk that they will tolerate can only be achieved by preventing exposure to the hazard – i.e. banning them. Those that have chosen to follow a risk-based approach, have concluded that another measure – or combination of measures – can achieve the desired level of protection. Experience from countries which have adopted risk-based approaches to pesticide regulation clearly shows that this model is not as effective as a hazard-based system so, in practice, it means they have accepted a higher level of risk.

It is firmly in the UK interest to maintain a hazard-based approach to pesticide management to protect environmental and human health and to minimise regulatory complexity and cost.

Hazard vs. Risk – a fundamental choice

The UK system for regulating pesticides is the subject of heated debate. Agribusiness and the agrochemical industry have long complained that the EU system unnecessarily limits the range of pesticides available to farmers and other users and reduces their options for managing pests.

Major agricultural exporters like the US have also complained that the tight limits on pesticide residues in food unfairly locks some of their goods out of the EU market. The EU places strict pesticide Maximum Residue Limits (MRLs) on agricultural goods entering the bloc, especially for pesticides that are not permitted for use in the EU. The EU, along with consumer and environmental groups on the other hand, argues that the restrictions are in line with the precautionary principle and are needed to protect human health and the environment from the most dangerous chemicals.

Setting pesticide standards at the EU level has also created a level playing field for farmers across the bloc, and has allowed UK farmers to trade without restriction.

With its departure from the EU, the UK now has the freedom to set its own standards for pesticides and move away from the EU model. This has prompted a debate over whether the UK should take this opportunity to fundamentally change its approach to pesticide regulation by abandoning the current generic risk-based model and switch to a specific risk-based system. This debate is more colloquially known as the 'hazard-based' approach vs. the 'risk-based' approach.

Risk vs hazard based approaches – misleading terminology creates a false choice

While regulators and other stakeholders often refer to the choice between hazard vs risk-based approaches, this actually presents an overly black and white picture which misrepresents the debate. The reality is that risk management is in fact a spectrum with all regulatory systems for pesticides sitting somewhere on the scale between hazard-based and risk-based approaches. For example, much of the EU regime – which is often touted as the only hazard-based system in the world – is itself based on an assessment of risk. Once active substances have passed the EU's hazard criteria, they are then assessed for risks associated to their use and mitigation measures to control risks in use are designed accordingly. Only the most hazardous pesticides are knocked out by the EU's hazard criteria and so never make it into the risk assessment process. In contrast, risk-based systems like that used in the US – while not screening out products based on their inherent hazards – do ban some active substances because the risk assessment process has concluded that all other control measures would be inadequate to effectively manage risks.

For this reason, some have moved away from using the term 'hazard vs risk' and instead adopted the more nuanced descriptions of 'Generic Risk Based' vs 'Specific Risk Based'. Generic Risk Based refers to screening an active substance based on a set of criteria such as acute toxicity or environmental damage. In other words, it prioritises measures that reduce or eliminate the hazard. Meanwhile, 'Specific Risk Based' refers to a system under which the particular risks associated to each active substances are identified and mitigation measures put in place to address them and reduce the probability of potential harms occurring – it therefore places more emphasis on measures that control risks associated to use.

For the purposes of this briefing, we have used the terms 'hazard-based' and 'risk-based' because this is how the debate is currently framed by regulators. However, it is crucial to remember that every pesticide regime is a combination of the two approaches. Where a regulator chooses to sit on the spectrum between hazard and risk depends on what level of protection they are trying to achieve for human health and the environment, coupled with the level of risk they are willing to accept to continue using pesticides.

What's the difference between a hazard and risk-based approach?

These two approaches are often presented as opposing. However this is a misrepresentation of risk management. 'Hazard' is the potential for a chemical (in this case a pesticide) to cause harm to human health or the environment; Risk, on the other hand, is the *probability* that the harmful outcome happens. Hazard cannot be separated from risk; it is an integral part of it. Pesticide risk management focuses on reducing the probability (and hence frequency), that people or the environment will be exposed to pesticides.

The difference between the two regulatory models actually lies in the types of measures that are prioritised to achieve the desired levels of protection and risk.

The hazard-based approach to pesticide regulation is founded on the principle that if an active substance possesses certain hazardous characteristics – for instance by being able to cause cancer or persistent pollution – then it is simply too dangerous to be used safely. As a result, any chemical which possesses any of these characteristics is automatically refused authorisation and no further assessment of risk, or possible management measures, is conducted. This approach is highly effective at preventing harm – removing the hazard automatically cuts the chance of human or environmental exposure to it to zero. It is also relatively simple to operate because it does not need any additional measures to control risks in use. But this model inevitably results in more pesticides being banned than under a risk-based model.[8]

In contrast, the risk-based approach, does not automatically ban hazardous chemicals. Instead, it places greater emphasis on assessing and managing the risks of the chemical. In practice, a substance can still be banned, but only if all measures and steps to prevent exposure have been considered and evaluated, and shown to be inadequate at keeping risks below *acceptable* levels. This approach not only requires the in-depth assessment of the potential impacts of exposure under real life scenarios, but also requires an evaluation of the effectiveness of the measures available to prevent exposure. This introduces a level of uncertainty into the process because these assessments inevitably incorporate assumptions and estimations which are not always reliable. In reality, risk-based systems tends to ban far fewer active substances than their hazard-based equivalents.

What would the UK need to do to maintain current levels of protection under a risk-based system?

Crucially, the risk-based model's effectiveness relies on the deployment of a raft of measures, checks and procedures to control the risk of the chemicals in use. In the UK, many of the protective measures related to pesticide use are found in voluntary guidelines and codes of conduct, the implementation of which are poorly monitored let alone policed. If a risk-based system were to have any chance at providing a similar level of environmental and health protection then these voluntary requirements would need to be replaced with mandatory measures. Brand new measures would also need to be introduced to maintain protections under a risk-based system. These might include, no spray zones around water bodies or residential areas; increased reporting and prior notification of pesticide applications; increased monitoring of environmental parameters and the introduction of a comprehensive human biomonitoring programme. Rigorous and comprehensive monitoring and enforcement systems would be needed under a risk-based system to ensure that measures are followed and work as planned. The UK's post-authorisation monitoring system has already been criticised as inadequate even under the current hazard-based system.[9]

It is important to realise that managing risks in this way will never be as effective as removing the hazard and will add complexity and cost. This is particularly true in the case of countries such as the UK which do not have a comprehensive or effective farm inspection system in place and so would need to invest significantly in strengthening existing systems. In addition, measures which rely on human intervention – such as the use of personal protective equipment or modifying behaviour – are particularly unreliable and have a very high failure rate. Similarly, many control measures are expensive and will need effective detection and policing combined with high penalties to deter non-compliance.

If any of these control measures fail, then the consequences for human health and the environment can be severe and irreversible.

How do hazard and risk interact with each other under the current UK system?

Current UK regulation of pesticides is based on EU Regulation 1107/2009 concerning the 'placing of plant protection products on the market (PPPR) – the key piece of legislation governing the authorisation of pesticides across the EU.[10] This includes elements of the hazard-based approach because the hazardous properties of a pesticide are considered before authorisation and those chemicals with certain hazardous properties – known as 'cut off criteria' – are not authorised (see case study on page 7 for a fuller description of the EU approach).

Bjorn Gaarn Hansen, Executive Director of the European Chemicals Agency (ECHA), explained the difference between the two systems:

> *"The EU's generic risk-based approach is not exclusive to it. Both the test methods and the classification system we use are international standards, the former based on OECD test guidelines and the latter on the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS). So internationally, the concept of needing an upper limit in order to be relevant to possible risks is well established.*
>
> *The GHS[11] itself is, in fact, a hazard-based approach: if a substance itself or in a mixture has a specific hazard, it should be communicated to the users so as to alert them to possible risks arising from the use. This helps them manage the risks, for example by wearing gloves for skin irritant substances…*
>
> *…In conclusion, the 'hazard-based' and the 'risk-based' approaches are both based on risk. When the exposure is certain, the 'hazard-based' approach stops at the classification – because the risk is likely. This is why we have started to use the term 'generic risk-based' approach."* [12]

This statement recognises that measures designed to manage risks associated to use will only ever be partially effective at preventing exposure – every system has a possibility of failure and, as a result, exposure at some point is "certain" to occur. This principle is well accepted in the UK's approach to managing risks in the workplace which emphasises that risks should be reduced to the lowest reasonably practicable level by taking preventative measures, in order of priority.

Chafer Sentry applying glyphosate to stubbles in North Yorkshire. Photo: Chafer Machinery, Flickr CC BY 2.0

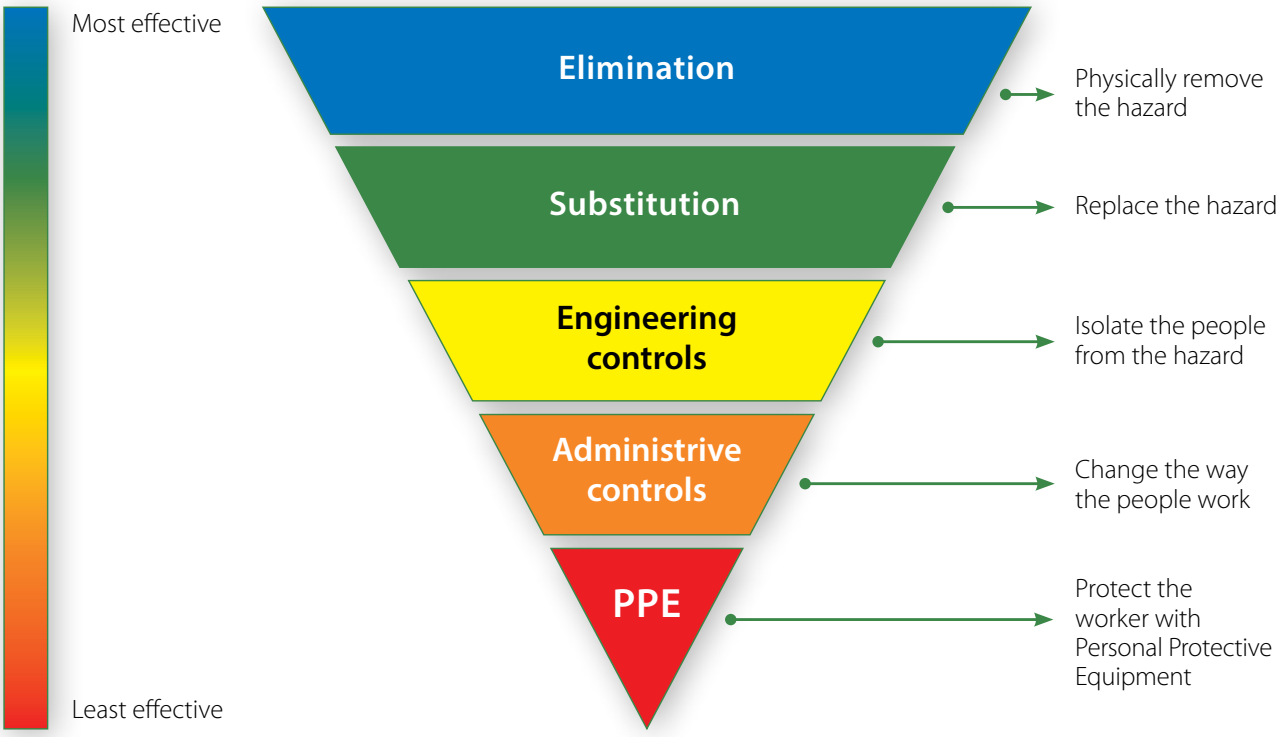
Is the hazard-based approach only applied to pesticides and where does the hierarchy of control fit in?

Controlling exposure to hazards is a core, basic approach to protecting workers and the environment which is applied far beyond pesticides. It is a guiding principle of occupational health and safety in all hazardous industries whether it be construction or a complex, high-hazard industrial plant like a nuclear power station. The fundamental principle underpinning risk management in all of these sectors is that the first step is to "eliminate the hazard". Only if this is impossible, should other means of controlling the risk be considered.[13]

The approach of limiting hazards and controlling risks "at source" as early as possible in the process is sometimes termed 'prevention through design' and this is perhaps best illustrated through the "Hierarchy of Control". The further one moves down the hierarchy of control, the less effective the control measure, and the more interventions are needed to maintain a high level of protection for human and environmental health. The most effective measures – in terms of both minimising cost and controlling risks – lie higher up the hierarchy of control.

Applying the hierarchy of control to the case of pesticides, an example of an elimination strategy could be using pest-resistant varieties or changing the way a crop is grown to prevent pest build up and reduce the need for a pesticide to be used; while substitution would involve replacing a hazardous pesticide with a less toxic alternative. Engineering controls could include no-spray zones or only allowing use in closed environments like greenhouses. Administrative controls could include training and guidance for users. It's important to recognise that "Administrative controls and PPE programs may be relatively inexpensive to establish but, over the long term, can be very costly to sustain. These methods for protecting workers have also proven to be less effective than other measures, requiring significant effort by the affected workers".[14]

HIERARCHY OF CONTROL



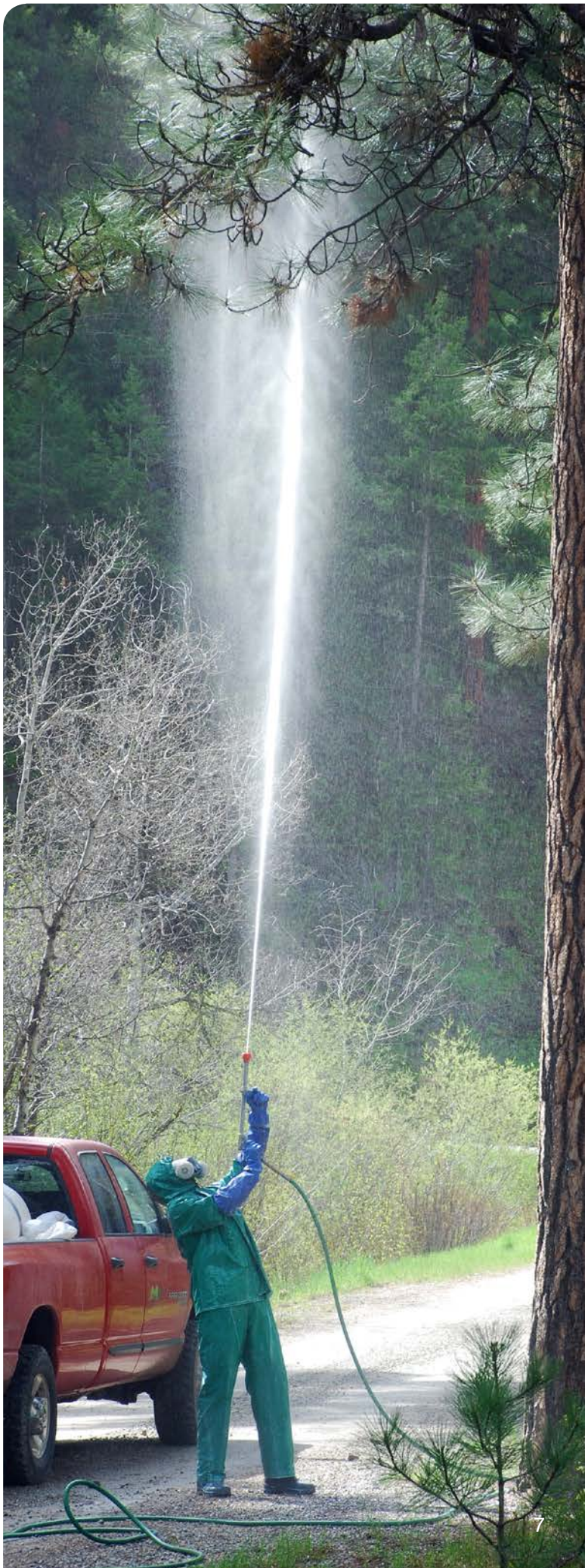
Infographic by the US National Institute for Occupational Safety and Health (NIOSH)

A regulatory system that supports the hierarchy of control would include bans and restrictions on pesticides which would stimulate the development of less hazardous approaches or substances and promote their uptake. The EU's system of "candidates for substitution" which identifies hazardous pesticides and seeks to find less hazardous alternatives is an example of this. Clearly in line with the hierarchy of control outlined above, this aims to identify the pesticides that pose the greatest risk to human health and the environment and provides the regulatory system with a clear method for prioritising them for phase out.

What level of risk should be tolerated in exchange for using pesticides?

The critical questions for pesticide regulators – and society – are what is an acceptable level of risk for pesticides? How much are we willing to pay for the system to keep the risks below this level? And who should foot the bill?

The argument around hazard-based vs risk-based approaches is therefore, in effect, a debate about the level of risk that a society is willing to tolerate. Those countries which have adopted regulatory models based on hazard-based have come to the conclusion that some pesticides are so dangerous that the level of risk that they will tolerate can only be achieved by preventing exposure to the hazard – i.e. banning them. Those that have chosen to follow a risk-based approach, have concluded that another measure – or combination of measures – can achieve the desired level of protection. Given that these measures are not as effective, in practice, it means they have accepted a higher level of risk.



Treatment of mountain pine beetle with the pesticide Carbaryl in Bitterroot National Forest Campgrounds. Photo: US Forest Service Northern Region, Flickr CC BY 2.0

Who does it better? The EU vs. the US

Hazard-based approach – EU case study

Regulation 1107/2009 concerning the 'placing of plant protection products on the market (PPPR)' is the Regulation that deals with the authorisation of all pesticides across the EU. The defining feature of PPPR is in Annex II, which states that a pesticide cannot be approved if it is: carcinogenic; mutagenic; toxic for reproduction; persistent, bio-accumulative and toxic for the environment (PBT); a persistent organic pollutant (POP); very persistent and very bio-accumulative (vPvB); or endocrine disruptive.[15] These 'cut-off criteria' (also referred to as 'hazard criteria') mean that any substance with these inherent hazardous properties should not be approved for use in the EU, although some derogations are permitted. For example, in instances where there is a significant threat to environment or human health from a particular pest, the PPPR allows emergency use, but these derogations are only temporary – lasting for no more than 120 days – and place strict limits on the use.[16]

The EU approval process is often described as the strictest in the world, due, in part, to these cut-off criteria. For this reason, there is fierce debate around the effectiveness of the EU system. Proponents argue that strict cut-off criteria saves the EU costs due to the reduced volume of risk-assessments needed to approve a substance. The EU's use of cut-off criteria eliminates many risks from the outset which therefore do not need to be managed in use.

For the remaining pesticides which do not meet the cut-off criteria, risks are managed through a range of different measures, many of which are devolved to Member States. Each Member State has its own National Action Plan on pesticides, which sets out a framework for managing the risks associated to the use of approved pesticides. It is worth noting that many of these plans have received criticism for failing to effectively manage risks surrounding the use of pesticides that are not screened out by the cut off criteria.[17]

The EU is estimated to have saved a vast amount on healthcare costs for people who would otherwise have been exposed to pesticides.[18] Whilst no estimates exist on costs saved through the EU cut-off criteria under PPPR, a study from 2003 estimated that the annual damage caused by the 133 most used pesticides in the then EU24 was €78 million. Another study estimated that if the US approvals system applied in the EU, the additional costs would amount to €4.3billion.

The EU list of cut-off criteria is not comprehensive and only covers certain hazards. As a result, it is more accurate to say that the EU has only partially adopted a hazard-based approach. All pesticides have the potential to cause harm to living organisms, and so can be considered inherently hazardous. If the EU adopted a pure hazard-based approval process that eliminated all hazards, very few, if any, synthetic pesticide would be authorised for use in the EU. Yet, at time of writing, 467 pesticides are authorised for use in EU countries[19], meaning that not one of these pesticides meets the cut off criteria.[20]

While far from perfect, the EU regulatory system eliminates some of the most extreme hazards whilst allowing for the control of other hazards through additional risk management tools. An ambitious new UK system could build on the current approach by expanding the range of cut-off criteria and strengthening their definitions, as well as tightening a derogation process to minimise unnecessary emergency authorisations. On the other hand, if the UK Government chooses to lower or eliminate hazard-based cut-off criteria it would lead to increased risks or higher costs and complexity to maintain the current level of protection.

Risk-Based approach – US case study

The US approvals process for pesticides is riddled with loopholes and deficiencies. Far from being 'science-based', the approvals process allows for broad margins of scientific uncertainty which are inherent in a risk-based approach. These loopholes include waivers on data, open-ended conditional authorisations and inclusion of an economic risk-benefit analysis in the approvals process. This often results in litigation cases against the US Environmental Protection Agency (EPA) and agrochemical companies, such as the recent case concerning the approval of dicamba, which found that the "EPA substantially understated the risks" posed by the pesticide.[21]

It has been reported that 72 pesticides approved for outdoor agricultural use in the US are banned for use in the EU, and in turn the UK. Together they account for over 25% of all agricultural pesticide use in the US – almost half a million kilograms.[22] The EPA rarely uses

its powers to withdraw pesticides from the market, and the majority of withdrawals are actually amendments to permitted "tolerances" such as residues or pollution limits which make continued use of a particular pesticide impractical. However these amendments are easier to reverse than formal bans which means authorisations could be reinstated. What is more, most of the withdrawals (97 out of 134) in the US have been voluntary, industry-led to pre-empt regulatory action and not initiated by the EPA due to health or environmental concerns.[23]

As in the EU, the EPA relies on data provided by the manufacturers themselves when assessing a pesticide. In order to be authorised, the EPA only requires that a pesticide[24] "will not generally cause unreasonable adverse effects on the environment" which it clarifies as "any unreasonable risk to man or the environment…". What is more, evaluations must take "…the economic, social, and environmental costs and benefits of the use of any pesticide" into account.

The question is then, what is the threshold for "unreasonable risk" when there are no clearly defined cut-off criteria? And how should the potential health and environmental impacts on broader society be weighed up against the possible economic benefits for farmers and agrochemical companies?

The emphasis on risk assessment and the ability to establish effective ways to manage the risk from extreme hazards (such as carcinogens or Persistent Organic Pollutants) is built on shaky ground. Risk assessments rely heavily on a number of assumptions due to a lack of data. A 'typical' risk assessment conducted by the EPA consists of around fifty assumptions[25], making the scientific basis of outcomes highly questionable.

Another loophole is the system's relaxed approach to derogations. The EPA allows "emergency" temporary authorisations for pesticides. However, in contrast to emergency derogations in the EU system, which limits the use of emergency authorisations to 120 days, the US system permits emergency authorisations which can last from one to three years.

What is more, the EPA also allows for the "conditional" registration of a "pesticide containing an active ingredient not contained in any currently registered pesticide" for an unspecified amount of time to allow the company to gather more data, if this is deemed to be in the "public interest". [26] While Congress intended for this to be used rarely, between 2012 and 2015, roughly 65% of pesticides authorised in the US were under these conditional authorisations.[27,28,29] This means that a large number of pesticides in use in the US have not been fully evaluated.[30]

Access to legal redress for victims of pesticide poisoning

While the US approach to pesticide regulation is far more lax than the UK's, its legal system does at least give victims of pesticide poisoning a better chance of seeking justice through the courts. American cancer sufferers have pursued lawsuits over their exposure to the weedkiller glyphosate, arguing that their illness was caused by exposure to the chemical. And more than 50,000 people are reportedly now close to agreeing upon a multi-billion dollar settlement.

However, in the UK, where glyphosate is also the most commonly used weedkiller, those who suspect they have become ill as a result of exposure have been unable to bring a single case to court, let alone win. This echoes the experience of hundreds of British sheep farmers who were poisoned by organophosphates in the 1980s who, due to the UK law's high bar of proof, were unsuccessful in a number of court challenges.

It is a sad reality that if the UK moved away from a hazard-based system towards a weaker risk-based system, then it could face a perfect storm of greater human and environmental harm without appropriate access to legal redress for those suffering as a result.

Even full evaluations, can result in approvals being based on incomplete data, as industry can apply for a 'waiver' on toxicity studies when there is deemed to be 'sufficient evidence'.[31] Relying on partial or incomplete datasets undermines the scientific integrity and reliability of the US system. Yet even with these shortcomings and inadequacies, a full pesticide evaluation by the US EPA can take 10-15 years.

Finally – and perhaps the most dangerous mechanism – is the inclusion of a 'risk-benefit analysis' as part of the approval process. This mechanism allows industry to make the case for the 'benefits' of a pesticide (for example to yield, consumers, etc.), measuring these against the risks associated to using that pesticide. Such a mechanism allows economic interests (as estimated by the company seeking authorisation) to rival scientific evidence, and leaves the door open to even greater corporate influence within the approvals process. Introducing socio-economic elements into a risk assessment distorts the process and undermines the focus on protecting health and the environment.

The complexity, inefficiency and ineffectiveness of the US system is a function of its risk-based approach. A system where risks are truly assessed and managed effectively would be too costly and burdensome. In contrast, the risk-based system in the US has led to an altogether convoluted and incomplete system which is highly susceptible to industry manipulation and has resulted in unacceptable levels of risk to both human health and the environment

Outcomes of the different approaches

The case studies above demonstrate that there is a vast difference between the level of protection against pesticide hazards provided in the EU and in the US. The partial hazard-based system in the EU allows for less error as it is binary: either a substance meets the cut-off criteria or it doesn't. In contrast, the US risk-based approach opens the door to more ambiguity and assumption and as a result, less scientific confidence. To accommodate a slow, complex and unwieldy risk-based system, the US has had to put in place temporary authorisations and allow for data waivers in risk assessments just to make the approvals system viable.

Differences between the two approaches are also evidenced in costs to healthcare and environment, and the findings detailed below are a conservative estimate of the comparisons.

In the US, the government's own Centre from Disease Control and Prevention reported that in 2012, pesticide exposures were the tenth leading cause of poisoning reported in the US. Neurotoxic organophosphate pesticides (bensulide, dicrotophos, phorate, terbufos, and tribufos) are still allowed for agricultural use, resulting in around 2,000 incidents of poisoning per year from 2012-2016.[32] And this is widely recognised to be a significant underestimate - many pesticide poisonings among farmworkers go unreported because a significant proportion are undocumented and fear losing their jobs or being deported if they report a pesticide incident.[33, 34]

The financial costs of such lax regulations are huge. The overall health costs of pesticide exposure in the US are estimated to total US $200 million per year from 2005-2009.[35] Furthermore, while there is no official data on the overall combined external costs of pesticide use in the US, one study estimated the following costs; "public health, $1.1 billion year; pesticide resistance in pests, $1.5 billion; crop losses caused by pesticides, $1.4 billion; bird losses due to pesticides, $2.2 billion; and groundwater contamination, $2.0 billion".[36]

It is clear that the regulatory system under a risk-based approach allows for many more hazardous pesticides to be released into the environment than those which are approved in the UK currently. This in turn has resulted in high rates of acute pesticide poisoning in the US and the healthcare costs therein. Other external costs associated to loss of soil fertility or biodiversity are also likely to be high. Additionally, the EPA's seeming inability to efficiently process pesticide active ingredients for approval has legitimised a loophole in the system which has resulted in potentially harmful pesticides being widely used even though they have only been partially assessed.

Comparatively, the US takes more risks than the EU within their pesticides regime. Whilst, in theory, the level of risk can be reduced by restrictions on use, in reality, the system and its implementation is insufficiently robust to mitigate risks effectively. Instead, the risk-based approach provides a lower level of protection, resulting in higher external costs and more harmful impacts on human health and the environment.

Conclusions and recommendations

Although the current EU system is only partially hazard-based as it still allows for the authorisation of hazardous pesticides, on balance, it provides a much higher level of protection for the environment and human health than risk-based systems adopted elsewhere. This is in large part due to the cut-off criteria, which block the authorisation of pesticides with characteristics that the EU has deemed too hazardous to be used safely – even with in-use mitigation measures.

Minimising risk by taking a hazard-based approach reduces the burden on the regulator, as it decreases the number of hazardous pesticides that are approved for use which in turn can reduce the risk of backlogs in the risk-assessment process. A risk-based system on the other hand will require an increased level of monitoring and enforcement. A system which does not adequately monitor and evaluate risks can neither claim to be scientifically rigorous nor be demonstrated to be effective.

A risk-based system would also increase the regulatory burden on government bodies as well as farmers and other pesticide users, who will be tasked with managing the risks from highly toxic pesticides – such as known carcinogens or reprotoxins. If one of the UK government's policy aims is to reduce the burden of agricultural regulation on farmers then a shift to a risk-based regulation will undermine the achievement of this goal. Abandoning the existing cut-off criteria would require the introduction of more, not less regulation as farmers would be required to undertake further training and manage extra controls for a wider range of pesticides. Meanwhile, regulating bodies would see increased workloads from a rise in exposure assessments, hazard risk characterisation and post registration monitoring and enforcement. The UK does not currently have a comprehensive post-authorisation monitoring system for pesticides but would need to introduce such a system, at potentially huge effort and cost, before considering any shift towards a risk-based system.

External financial and ecological costs also occur when the likelihood of exposure is increased. In future, the UK government should be looking to minimise costs and risks wherever possible, including any potential costs resulting from pesticide exposure. By maintaining a hazard-based approach based on precaution, external costs such as healthcare for acute and chronic pesticide poisoning; loss of soil fertility; loss of biodiversity including pollination services; reduced water quality; crop damage from pesticide drift and lost trade with EU countries, to take a few examples, could all be minimised or even avoided altogether.

Recommendations for the UK Government:

Any new UK system for pesticide regulation should aim to at least maintain, but ideally increase, the level of protection for human health and the environment. It is clear that the most reliable, efficient – and cost effective – way of doing this is to focus on eliminating hazards from pestcides at source rather than in use. As it develops its standalone approach to regulating pesticides, we therefore urge the UK Government to do the following:

- Maintain the UK's current hazard-based approach for pesticide approvals.
- Maintain the precautionary principle as the basis upon which all pesticide-related decisions are made and strengthen its implementation.
- Maintain the existing UK/EU 'cut-off criteria' and commit to a process and timetable for strengthening and expanding the definitions for the criteria.
- Do not introduce socio-economic considerations into the risk assessment process for active substances or pesticide products.
- Tighten the emergency use derogation process to ensure that a proper assessment is made based on the hierarchy of control and that emergency-use derogations are only granted when there is no acceptable alternative.
- Continue the "candidates for substitution" system whereby hazardous pesticides are identified and less toxic alternatives to them are sought as a matter of priority.

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Pesticide Action Network UK

PAN UK is based in Brighton. We are the only UK charity focused solely on addressing the harm caused by chemical pesticides.

We work tirelessly to apply pressure on governments, regulators, policy makers, industry and retailers to reduce the impact of harmful pesticides.
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