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The Implementation of the Food Quality Protection Act (FQPA) in Increasing the Safety Standards for New Pesticides Used on Foods

Saad Nasser AlQahtani*

Abstract

This paper examines the Food Quality Protection Act (FQPA) and its impact on enhancing safety standards for pesticides used on food in the United States. Initially, the study explores the Delaney Clause – a strict standard prohibiting carcinogenic food additives – which FQPA replaced with a more flexible "reasonable certainty of no harm" criterion. This shift allows the Environmental Protection Agency (EPA) to assess pesticide risk with consideration of potential benefits, even if a substance is carcinogenic at high doses. The paper also critiques the EPA's implementation challenges, including reliance on quantitative risk assessment (QRA) and cumulative risk assessment, which quantify risks of multiple chemical exposures but face informational and regulatory limitations. Recommendations focus on refining judicial review and integrating cumulative risk assessment to strengthen the FQPA's capacity to safeguard public health, especially for vulnerable populations, such as children. This study underscores the importance of regulatory clarity and rigorous assessment methods in pesticide management.

Keywords: Food Quality Protection Act (FQPA), pesticide regulation, environmental protection agency (EPA), delaney clause, reasonable, certainty of no harm, quantitative risk assessment (QRA), cumulative risk assessment, carcinogenic additives

INTRODUCTION

To meet the growing food demand, the use of pesticides played a major role in reaching that goal. Although pesticides have a positive effect on protecting crops against insects and pests, it also proved to be harmful and toxic for humans, animals and the environment. In other words, pesticides are designed to kill regardless of what they are used on. These pesticides are formulated to intentionally attack and destroy living organisms. It is estimated that over a billion pounds of chemical pesticides are spread over all farms, schools, parks and many other places in the U.S. It has also been estimated that more than half of American food contains chemical residue. In short, since humans occupy a web of the nature, poisoning pests could eventually backfire and poison people [1].

***Author for Correspondence**
Saad Nasser AlQahtani
E-mail: Mr-Saad2@hotmail.com

Assistant Professor, Department of Law, College of Business Administration, Prince Sattam Bin Abdulaziz University, Al-Kharj, Saudi Arabia.

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Many laws have been enacted to address this issue, such as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug, and Cosmetic Act (FFDCA), and the Food Quality Protection Act of 1996 (FQPA), as pesticide overuse has become a major concern to the public. This essay will focus only on the FQPA, as this act amended the FIFRA and FFDCA by increasing the safety standards for new pesticides used on foods. More specifically, this essay will analyze the implementation of the FQPA and the standards that have been covered by this law [2].

The paper will discuss in the first section the Delaney standard which has been removed by the FQPA. This standard simply means that the EPA would prohibit any carcinogenic food additives. This means that risk-benefit analysis has no room for food that is carcinogenic, and the EPA has not choice other than prohibiting that pesticide. The Delaney clause faced many criticisms as this clause applies only to processed foods, not raw foods. The second section will discuss the FQPA act and the reasonable certainty of no harm standard. This standard has replaced the Delaney clause. The standard means that the EPA would not ban a pesticide even if it was carcinogenic if it is reasonably certain that no harm would occur in exposing to this chemical especially if the risk is low. However, many criticisms have faced this standard, such as the unclear meaning of the term "reasonable certainty of no harm" [3].

The third section will focus on the other standard required by the FQPA which is the application of QRA. This assessment means that the EPA must transfer the dangers and risks into numbers, and then assessing whether the pesticide causes more harm rather than benefit. However, this assessment seems to assume that many assumptions are not accurate, such as the belief that it is accepted socially for governments to decide which amount of exposure is toxic for human and the environment. The last section would cover the final standard required by the FQPA to be applied which is the cumulative risk assessment. It means the combined risks from aggregate exposures to multiple agents or stressors [4]. This assessment came from the fact that the single-stressor assessment has faced many criticisms in terms of its effectiveness as it does not reflect the real world as hazards are usually combined with each other and do not exist individually. Although this assessment is important, the EPA did not use it in its decisions but rather it has been used as an informational instrument to increase awareness only [5].

Many recommendations have been given to improve the efficiency of the act. The first recommendation is the need to improve the judicial review of uncertainties, and it is suggested that courts can use a centralized administrative group which aims to assess whether orders adopted by the EPA are reasonable [6]. The second recommendation is applying the precautionary principle as it aims to minimize or avoid harm when there is a lack of full scientific certainty. The last recommendation is the application of cumulative risk assessment in making decisions due the fact that it studies the various stressor interactions with each other and how these interactions would be considered dangerous to human health. Its importance also comes from the fact that chemicals do not function separately but rather they integrate and combine with each other [7].

Prior FQPA: The "Delaney Clause" Standard

The Delaney clause is a provision of the FDCA that prohibits any carcinogenic food additives. This clause is a result of public concerns related to their health regarding pesticides. According to the Consumer Expenditure Survey (CE) of the Bureau of Labour Statistics, US consumers spent on average, $6,129 on food in 2010. This means that almost 15% of the average household annual expenditure goes towards food. It is estimated that over a billion pounds of chemical pesticides are spread across all farms, schools, parks and many other places in this nation [8]. The Delaney clause became famous as it prohibited the use of any additives that were found to cause cancer. In other words, risk-benefit analysis has no room for carcinogenic foods, and the EPA has no choice other than to prohibit that pesticide. The Delaney clause also prevented any food that had been proven to lead to cancer in animals, as animals are a main source of human nourishment, and any harm to animals would lead to harming people [9].

If the food is not carcinogenic but might lead to other risks, then an approach adopted by the Delaney clause will be applied to determine whether the EPA can approve the pesticide. First, the assessment begins with understanding the extent to which the given pesticide is putatively dangerous. The inherent characteristic that pesticides are formulated to kill almost always leads to an affirmative answer. The second step of the assessment examines the response which aims to identify the relationship between the level of exposure and the effects caused by this exposure. This assessment is not applied to humans, but to animals due to ethical reasons. The last step is the exposure assessment determines the amount

of contact between humans and the residue. This process might involve a great deal of conjecture, although exposure assessment made it easier for food additives to be introduced into the food supply [10].

However, this solid clause seems to have some contradictions in its application. The Delaney clause applies only to processed foods, not raw foods. In other words, raw foods are exempt from the application of the Delaney clause and therefore will not be banned, even if they are considered carcinogenic. It is questioned whether raw foods are assisted under risk-benefit analysis or whether raw foods are always exempt from any assessment and therefore cannot be banned. This contradicts with the fact that the Delaney clause aims to protect people from carcinogenic foods, as it would be logical to ban any food that leads to cancer, whether raw or processed. The Delaney clause became a dubious regulatory approach, although many argued that this clause was a response to the scientific understanding of that time. Others argued that the Delaney clause must be more flexible, as carcinogenic exposure does not always lead to getting cancer. In short, the Delaney clause seems to contradict itself and applies only to processed foods, therefore people are still vulnerable to carcinogenic raw foods [11].

Another major criticism of the Delaney clause is that it does not offer extra protection to children. It is well known that children are more vulnerable to disease than adults, and their immune system is weaker. Many laws, as it will be covered below, such as the FQPA, provides infants with more protection due to the weaknesses of their body. Although the Delaney clause is an iron clause that prohibits any food leading to cancer, it does not take children into consideration and thus treats them as adults. It is evident that the Delaney clause does not acknowledge children in calculating and measuring uncertainties. It does not consider the peculiar metabolic intricacies of a child's developing body [12].

The FQPA and the Reasonable Certainty on No Harm Standard

The FQPA enacted by congress adopted many implementations, of which include the "reasonable certainty of no harm". This standard replaces the Delaney clause as section 405(b)(2)(C)(ii) of the FQPA states "there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue". The term "reasonable certainty of no harm" replaces the word "safe" in the Delaney clause, which has specific statutory implications that are integral to the meaning of sections 402 and 408 (as amended by section 405 of the FQPA) of the FFDCA. A key purpose of the FQPA is to provide a room for tolerances to not ban any food that contains a very low risk of cancer but could provide numerous benefits. In other words, the act will ensure that food is reasonably safe and will not prevent food with low risks of cancer from being consumed due to the benefits [13].

The FQPA and its standard also provides a special consideration to the health of children and infants. The act states that the EPA must "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue". This means that the EPA must collect data about infant and child consumption and then decide the best method to provide more protection in comparison to adults. Therefore, the EPA must not simply examine adult vulnerability to pesticides and then provide extra protection based on this data, but rather, the protection must be based on infant bodies. Moreover, the EPA was instructed by the FQPA to include an additional default ten-fold safety factor to account for known vulnerabilities or uncertainty in the data relevant to infants and children. The provision allows some discretion for the EPA to increase the margin of safety only if, based on reliable data, such margins will be safe for infants and children [14].

Although the FQPA abolished the Delaney clause, the reasonable certainty of no harm standard seems to be vague. The meaning of the word "safe" is not clear, nor is the extent to which pesticides must be present in a food to consider it unsafe. The act also provides the word "certainty", and it is questioned how much certainty is required to apply the law. Due to the shortage of precedent for the decision rule, the act is considerably ambiguous. The act also suggests that the EPA is not entitled to ban any food

unless it has reasonable data and evidence that the food is certainly not safe. In other words, people will be exposed to the unsafe food if the EPA does not provide the requirements of the act to prohibit a food. It also means that even if the food is proven not to be safe, the EPA cannot ban it unless the harms exceed the benefits, which contradicts with the wide discretion power given by the law to ban unsafe foods in the light of uncertainty. In short, the EPA will approve any food that leads to cancer if it passes risk assessment analysis as it will be explained below [15].

Many scholars argue that the intention of the reasonable certainty of no harm standard and the FQPA in general is not mainly to protect human health, but rather to achieve other goals. Politically, it has been argued that politicians aim to achieve a compromise between public health and business goals. The evidence of this stems from the fact that Vice President Al Gore sent a memorandum to the EPA requiring them to work with the U.S department of agriculture and its stakeholders to achieve an acceptable implementation of the FQPA without harming agricultural or business concerns. The EPA responded by establishing The Tolerance Reassessment Advisory Committee (TRAC) to ease any necessary transition to new rules and to not jeopardize agriculture and farming communities. The members represent all public interest groups, users, growers, the pesticide industry, environmental groups and many other groups, such as academia. However, the environmental group resigned, arguing that the committee failed to protect the public health. This clearly shows the tendency towards protecting agriculture and business concerns, and this could be seen through the involvement of the agriculture department in the application of the FQPA as it applied many practises to protect only farmers, such as exemptions from major environmental statutes, including significant parts of the Clean Air Act and Clean Water Act [16].

The EPA failed in implementing the FQPA in many respects, such as reviewing existing pesticides. The FQPA law required the EPA to review 10,000 existing pesticide tolerances by the year 2006. The law aims that the EPA would review existing pesticide tolerances in different steps starting with the review of 33% of these pesticides and aims to complete its review by August 2006. The EPA has been remiss in implementing the FQPA and instead of reviewing what was required, it revoked tolerances that were no longer in use and reassessed tolerances that pose little or no risk. This clearly shows that the EPA is not capable of implementing many requirements by the FQPA, which makes one question whether the law is impractical or whether the EPA is the main reason of its failure. It could be argued that due to the unclear goal of the FQPA, as this law represents a compromise between industry interests and the desires of environmental and children's advocacy groups, the EPA could not function properly. This argument is supported by the fact that the FQPA is required to work along with the agriculture administration in implementing the law, which takes some power away from the EPA in implementing the law [16].

The second failure of the EPA in implementing the FQPA was not applying the additional ten-fold safety factors to protect children. It is essential to consider the timing of exposure to toxic substances, not just the dose as it tends to be the most sensitive periods for inducing epigenetic effects. Moreover, it has been argued that many threats to children's health occur due to the gap in overseeing pesticide use. The application of the use of pesticides is not regulated by the federal government, but in theory it left the application of the act to the states. These states did not adequately fill this regulatory gap and thus a great deal of pesticides can be used in unsafe ways and in higher concentrations than expected or needed [17].

Even in those decisions where the EPA applied extra protection for children, some issues arose due to the impracticality of gathering data from pesticide registrants. For instance, the EPA was required to collect all data regarding the developmental neurotoxicity studies for all organophosphate and carbamate pesticides since they cause many types of disorders in children, such as asthma, immune disorders, autism, and ADHD. Unfortunately, these studies are not required for food using pesticides, nor for the development of the toxicity in two generations of production. Moreover, the collected data

only provides the toxicity of the pesticide in a specific amount of time. To explain this, pesticide registrants would only provide data for the toxicity of the pesticide for a pregnant rat or rabbit before it gave birth. In other words, the study does not evaluate postnatal toxicity. This means that the EPA will gain insufficient data, and accordingly, will not be able to provide the correct amount of protection to children [18].

The third failure by the EPA in implementing the FQPA was by not assessing the effects of pesticides on adults and children. This means that pesticide registrants would not be required to examine the toxicity of their pesticide after being consumed by adults and children. More specifically, commercially available pesticides before the enactment of FQPA did not receive after-the-fact oversight to ensure their safety and compliance. Even new pesticides introduced after the act underwent only limited screening, and significant gaps were noted in the assessment process, such as the lack of comprehensive neurodevelopmental toxicity testing, even for those known to be neurotoxic. Many pesticides are tested only on adult animals, even if there is evidence that the pesticide would also affect non-adult consumers. If infant animals were tested, the long-term effects of pesticide are not required to be examined and analyzed [19].

Another main criticism of the implementation of the "reasonable certainty of no harm" standard under the FQPA is the fact that courts require quantitative risk assessment (QRA) to decide whether the EPA was reasonable in banning a pesticide. This means that the EPA must translate all risks into numbers otherwise the court might not accept their evaluation. This could be seen as a serious shift from the discretion doctrine given to the EPA in requiring them to provide specific numbers which leads to not having the power to protect consumers in the light on uncertainty. In other words, if uncertainty arose, the EPA would not be able to ban nor prohibit the pesticide, even if it would be harmful due to the court requirement in adopting the analysis. The next para will explain the meaning of QRA and its main issues, which made the EPA less effective in protecting both adults and children from pesticides [20].

Quantitative Risk Assessment (QRA)

A QRA is defined as "the characterization of the potential adverse health effects of human exposures to environmental hazards". A QRA has two main purposes; the assessment of the risk of any environmental hazards, which leads decision makers to set up an acceptable level of risk and assessing the risk of different environmental contaminants and then prioritizing which risk needs to be regulated based on the quantitative assessment of risk. In other words, QRA is the science of transferring the dangers and risks into numbers, and then assessing whether the pesticide causes more harm rather than benefits, to make a wise decision in prohibiting the pesticide or allowing it to be consumed [21]. Courts have forced the EPA to use QRAs to accept its decisions in banning pesticides, as prohibiting pesticides shall not be allowed without a QRA. This requirement can be seen on many occasions, such as in the Natural Resources Defense Council (NRDC) v. EPA, when the Second Circuit found that EPA had failed to explain how their pesticides are harmful. In other words, the court refused to accept speculation by the EPA and required it to adopt QRA methods to make its decision. Another case which supports the above-mentioned claim could be seen in AFL-CIO v. OSHA, when the Eleventh Circuit stated that without a QRA, the court would not be able to evaluate or answer the extent to which the EPAs claim about the dangers of pesticides is true or exaggerated [22].

A QRA involves many steps, beginning with hazard identification, followed by dose response assessment and finally exposure pathway assessment. Hazard identification simply means the capability to assess if a given chemical is putatively dangerous. This means that the EPA must determine whether the substance is not safe and generally involves the risk of cancer, or whether the substance is safe to identify the threshold. In other words, a threshold must be identified using a QRA to enable the EPA to assess the risk of pesticides which lead to hazard identification. The aim of the "hazard identification" step is that the EPA puts the threshold limit below the toxicity level, which the chemical will not cause an adverse effect. This step is not straightforward, as complexity might occur in determining the

threshold level in a chemical that leads to a potential endocrine disruption [23]. This complexity is a result of the limited knowledge about the mechanism of toxicity. Moreover, complexity can also be seen in another example, such as exposing to EDC. The impact of the EDC on humans differs based on genetic backgrounds. This would be seen as a challenge for the EPA to clearly identify the dangers of using QRA, and at the same time consider different impacts of pesticides on different people [24].

The second step of a QRA is dose response assessment, which is the assessment of the probability in how disease would change and develop with various exposures. The researcher would examine the relationship between a dose and the level effect. This kind of assessment requires the researcher to examine both high-doses and low-doses to examine its effectiveness from animals to humans. However, this assessment might not measure the risk of the dose but rather whether the dose is high or low. In other words, scientific risk assessments do not provide a complete, true, and accurate quantification of risk but rather estimate the level of expected risk. The fact that an animal's developmental or gestational period differs from a human's is considered a key limiting factor. This creates uncertainties in relating data generated by animal testing to humans. Nevertheless, this test is only one step of the QRA process that the EPA requires as a means of implementing the law. Dangerous chemicals are more likely to be more toxic in high doses rather than low doses, and the few chemicals that go against this rule are, arguably rare and not common [25].

The exposure assessment measures and identifies the way people may be exposed to pesticide residue. In this step, the QRA can identify the quantity of pesticide residue present in food and the probability of its consumption. This is performed by statistically analyzing the total exposure of a pesticide based on the registrant's proposed. Nevertheless, some argue that assessing all elements other than the chemical in the pesticide is not only difficult but virtually impossible [26].

However, QRAs seem to assume many assumptions which calls into question its credibility. The first assumption is that the risk assessment will accurately assess whether the chemical will have a detrimental impact on a person's health. This assumption is inaccurate as there is insufficient data to accurately assess the exact expected risk which leaves room for speculation and estimation. This means that if the data says that a particular chemical causes high dose administered to mice, then a judgment must be made regarding the translocation of this data into a dose-response curve for humans. This shows clearly that a personal, unscientific judgment is involved in the decision making and thus might not be always the accurate decision.

The second assumption QRAs rely on is whether meaningful risk assessment is possible. To explain this, to identify and know all possible Endocrine Disrupting Chemicals (EDCs), thousands of chemicals must be examined and subject to costly screen testing. The cost of only one compound test is approximately $200,000. If this substance is suspected to cause disease or risk for humans, then additional tests will occur for this substance which can cost upwards of over a million dollars. This cost only determines whether one compound is safe, taking into consideration many factors that might affect the toxicity of this compound, such as the length of exposure. If the EPA decided to fully ensure that all chemicals in existence are safe by conducting all the necessary tests, then the cost could be more than 10 billion dollars. As a result, only a tiny number of pesticides used in commercial production have been subjected to rudimentary toxicity testing [27].

The last assumption that QRAs rely on, which might be the most problematic and controversial, is the belief that it is socially accepted for governments to decide which amount of exposure is toxic for humans and the environment. The problem stems from the fact that lawmakers can create the safety threshold not based on social demand, but on their own determination of the amount of exposure that is accepted for societies to be exposed to. It has been argued that these statistics and standards were decided based on scientific research, and the findings are apolitical. However, it has also been argued that scientific research is not authentic if it is linked to politics or business. In other words, if science was involved in business, then these businesses will ensure that the scientific results will not harm them

and thus these studies would lose their objectivity. This could be seen in many examples, one of which happened in California where the U.S. Bureau of Reclamation and the California Department of Water Resources requested the reinitiation of the Endangered Species Act consultation on the coordinated long-term operation of the Central Valley Project and State Water Project. The service reported that these projects would be harmful for the environment. Several months later, scientific findings changed, and the service found that after applying two scientific research endeavours, the projects will not jeopardize, threaten or endanger species or adversely modify their designated critical habitats. These results came from different scientific teams which many organizations have argued that, since the first scientific team did not reach the results wanted from law makers, they were simply changed [28].

The above-mentioned assumptions in the use of QRA made the results and findings questionable, due to their lack of reliability and malleability. It has been argued that these assumptions are rooted in the decision maker's point of view, rather than on the scientist's experience. This means that even when scientists try to make such determinations, this would not make them devoid of policy implications. It has also been argued that these assumptions are based on personal values and beliefs that cannot be easily disentangled. This would eventually lead to inaccurate results which would cause many health problems due to its inefficiency. The National Research Council (NRC) argued that economic interests and external pressures on the EPA made the risk assessment less efficient [29].

Cumulative Risk Assessment

Cumulative risk assessment is defined as "the combined risks from aggregate exposures to multiple agents or stressors". It simply means that the cumulative risk assessment test considers the combination of many chemicals and how they integrate, and which are considered toxic. In other words, the cumulative risk assessment does not focus only on one single chemical or pollutant, but rather a combination of these chemicals that can lead to harmful effects. Unfortunately, the cumulative risk assessment has not been used heavily by many agencies, such as the EPA. The EPA approach was focused on assessing one in a single exposure medium. For instance, the EPA would assess the risk of DDT inhaled in the air in one separate test and would test the DDT risk ingested in the water in another test. These tests would be made product by product and not combined [30].

Furthermore, the single-stressor assessment has faced many criticisms in terms of its effectiveness. It is argued that the single assessment test does not reflect the real world. In the real world, hazards are usually combined with each other and do not exist individually. It is also argued that communities in real the world do not expose one stressor, but rather they are exposed to many stressors at the same time. Thus, assessing single stressors individually without combining them together in a cumulative risk assessment would not be affective for communities. The FQPA, unlike previous food laws, adopted the cumulative risk assessment test in 1996 which shows the importance of the test to protect human health. The need for cumulative risk assessment is urgent since more than 85,000 chemicals are distributed in the market in the U.S., and yet there have been no cumulative risk assessments for these chemicals combined with each other [14].

The cumulative risk assessment has many features, and among these features is the cumulative assessment study on how stressors combine and interact with each other. This means that this assessment is not a catalogue discerption of different stressors and the risks that these stressors would provide to a population. The cumulative risk assessment could also be seen as the process that studies whether the impacts given by stressors are additive or synergistic. The term additive means they can identify which chemicals can operate by similar modes of action. Then, it would determine the total risk and whether it can be calculated by adding up the individual risks posed by each of the chemicals over all identifiable exposure pathways. The term synergistic means they can identify whether many stressors can combine, and whether this combination is worse than if the stressors were not combined. This is important since some stressors might not be dangerous individually but can be toxic if combined with others.

The second feature of cumulative risk assessment is that it is not restricted to chemical stressors, but also physical, biological, or social stressors. For instance, the assessment of living near the airport and its risk would include the evaluation of a chemical stressor (the air pollution), and the non-chemical stressor (the noise), as they can both affect health, such as causing hypertension. Scientists also argue that stressful social environments can make the population more sensitive to exposures which are unhealthy. It is also important to understand that the cumulative risk assessment focuses also on the population level. This means that this assessment would be beneficial to anyone concerned with questions related to public health. It is certain that the main purpose of this assessment is to promote public safety. This goal was proven by the studies enacted by the EPA using the cumulative risk assessment, as the EPA tested the health effects of humans from 177 hazardous air pollutants using the cumulative risk assessment. The test takes into consideration cancer risks and non-cancer hazards, such as neurological effects. By using this assessment, the EPA could identify the pollution risks. This conclusion came from cumulative risk assessment after relying on atmospheric dispersion models and human activity pattern data [15].

However, the cumulative risk assessment has not been used heavily by agencies. In fact, laws do not force this test to be applied. The FQPA is one example of laws that adopted the cumulative risk assessment method and ordered the EPA to adopt it. Nevertheless, there are many issues in implementing this test due to two main issues. The first issue is based on the informational challenges to risk characterization. The second is the few regulatory provisions that require the cumulative risk assessment.

First, it is admitted that cumulative risk assessment is a difficult process as it requires researchers to properly model and synthesize several data sets which can pose some challenges. The difficulty can be seen clearly in the evaluating process of the health impact of the stressor, as well as the ways to add up the risk. This means that researchers must understand how chemicals work and interact with each other which could be seen as a challenge due to the large amount of chemicals approved in the U.S. market. In some cases, individual risks are added to determine the joint risk while in other scenarios, these risks operate synergistically in a way that the parts are better than the sum. The EPA developed a methodology based on simplifying this process by assuming additivity because synergistic interaction is still unknown and undeveloped. For instance, in assessing organophosphate pesticides, the EPA made assumptions about their toxicity based on the available studies and data in the agency. The EPA acknowledged the difficulty to prove dose additivity at human exposure levels since studies based on individual chemicals are not designed to address the issue of dose additivity. The EPA would also consider the timing of exposure in its assessment, as exposure in one chemical makes the individual more susceptible to future exposure to a second chemical [20].

Second, it is admitted that there is a need for regulatory drivers for cumulative risk assessment for this assessment to be adopted in agencies' decisions. It is argued that the risk assessment has lagged the science. The reason for this is since agencies, such as the EPA, have not adopted any policies to consider cumulative risk assessment when making environmental decisions. Although there are guided documents which support the use of this assessment, cumulative risk assessment has only been used largely in the context of informational measures. Even in the FQPA, where it requires the EPA to use cumulative risk assessment, it has only been used as an informational instrument. This means that this assessment has not been used as the main methodology of assessment, but rather as a secondary rule which, ironically, aims only to educate individuals in the community.

It has been argued the cumulative risk assessment would be more effective if it relies only on mandatory disclosure not as a legal force mechanism that forces agencies to adopt such an assessment. This argument found some traction in some executive orders, such as "Executive Order 13563" adopted by the Obama administration which says that each agency shall reduce regulatory burdens and adapt flexible methods which gives the public the freedom of choice. Thus, it is increasingly recognized that

information disclosure is often a far less expensive and more efficient strategy than command-and-control as it would enable the public to assess government regulations as well as oversee them. It is also argued that any system that functions democratically requires information to be disclosed by the public with reliance on the public opinion in determining whether these results are harmful.

However, the idea of using cumulative risk assessment as an informational mechanism has been criticized by many scholars. It has been argued that the effectiveness of disclosure mechanisms will not be effective for the public due to the lack of knowledge that would prevent them from interpreting the results properly. Professors Ben-Shahr and Schneider argue that mandatory disclosure of large amounts of complex information be given to unspecified members of the public to make a complex decision is unreasonable. They argue that using cumulative risk assessment requires one to be a specialist, which makes the disclosure approach a fundamental failure which cannot be fixed [22].

Suggestions and Recommendations

After discussing the implementation of the FQPA and its issues, many recommendations can be given in order to use the law in its full capacity. The first recommendation is the need to improve the judicial review of uncertainties, as courts refuse that the EPA would make regulations based on uncertainties and requires that all orders must be proven by Quantitative Risk Assessment. This goes against the intent of congress as the FQPA aims to protect human health considering existing uncertainties through complex methodologies. It is suggested that courts use a centralized administrative group which aims to assess whether orders adopted by the EPA are reasonable. This group would include specialists in many fields, such as science, risk analysis, economics, and administration. The reason for this is the fact that courts must not prevent agencies from making orders based on uncertainties, and thus require them to prove all their orders through QRAs. Rather, agencies may place orders based on uncertainties and this group will help the court determine whether these decisions are reasonable or not. Four decades ago, the District of Columbia Circuit says that "such proof may be impossible to obtain if the precautionary purpose of the statute is to be served".

The Second recommendation is introducing the precautionary principle. This principle aims to minimize or avoid harm when there is a lack of full scientific certainty. This lack of certainty would make the precautionary approach effective as it provides some steps that must be adopted in these circumstances. "According to the Commission, the precautionary principle may be invoked when the potentially dangerous effects of a phenomenon, product or process have been identified by a scientific and objective evaluation, and this evaluation does not allow the risk to be determined with sufficient certainty". It means that when applying the precautionary principle, there must be a proportionality between the measures taken and the chosen level of protection which is also consistent with similar situations and finally review of the measures in the light of scientific developments. This means that the precautionary approach requires the use of science judgments based on individual risks [25].

The last suggested recommendation is the need for engaging cumulative risk assessment in the decision making as a mandatory requirement from the law to all agencies. The FQPA has recognized the importance of cumulative risk assessment and ordered the EPA to use this method. However, this assessment method has not been used in most cases, but rather, it has been used as an informational instrument. The need for this assessment in decisions is important since it studies the various stressor interactions with each other and how these interactions would be considered dangerous to human health. The fact that chemicals do not function separately but rather they integrate and combine with each other means that combination assessment would be more realistic in answering questions related to human health and what stressors can be more serious than others. It could then be suggested that cumulative risk assessment must be adopted in the EPAs decisions, as the FQPA aims to protect human health, and this measurement could lead to the aim placed by the law [25–30].

CONCLUSIONS

The paper has examined and discussed the implementation of the FQPA and the extent to which this law is effective in protecting human health. The first section covers the Delaney clause which was the

standard applied prior to the FQPA. The Delany clause prohibits any carcinogenic food additives which means that if the food leads to cancer, the EPA will have no choice other than to prohibit the product. The second section focuses on the FQPA and its implementations. More specifically, it covered the "reasonable certainty of no harm" standard which replaced the Delaney clause as, now, i.e., the FQPA allows the EPA to permit carcinogenic food if the risk is low in comparison to its benefits. The third section covers the QRA analysis required by courts to implement the reasonable certainty of no harm standard. The last chapter shed light on cumulative risk assessment which considers the combination of many chemicals and how they integrate, thus being considered toxic.

It could be argued that, generally, the FQPAs goals are well established, but nevertheless the implementation of the law seems to make the goal more challenging. The FQPA gave the EPA wide discretion to ban pesticides which lead to harming people, and especially children. This discretion has been delegated to the EPA considering uncertainty. However, the courts seem to refuse this discretion and forces the EPA to use QRA analysis in its decisions in prohibiting pesticides. This means that the EPA would not be able to ban a product unless its harm is proven, which means that people would consume these pesticides, and the EPA has no power to ban them even though the pesticide is most likely harmful. Moreover, the implementation of the cumulative risk assessment does not seem to be effective, although this test is significantly important as in the real world, hazards are usually combined and do not exist individually. Thus, assessing single stressors individually without combining them in a cumulative risk assessment would not be affective for communities. Nevertheless, the law has some advantages to grant more protection for society, but the implementation of the laws need for repairs and shift from trying to comprise between human health and agricultural concerns would lead to demolishing the main goal of the law, which is protecting human health.

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