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CAST Commentary

January 2024

Improving the FIFRA/ESA Process by Addressing Key Obstacles and Incorporating Better Data and Tools

Current Practice and Its Limitations

In the United States, pesticide active ingredients are registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (CFR 2014), as administered by the United States Environmental Protection Agency (EPA). However, federal regulatory actions undertaken by the EPA (e.g., a pesticide registration) must also be in compliance with the Endangered Species Act (ESA) (USFWS 1973), as administered by the United States Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS) (collectively the "Services"). This process necessitates that the EPA generate a "biological evaluation" (BE; essentially a generic endangered species risk assessment, typically at the national level) and consult with the Services in cases where the proposed regulatory action is deemed to likely adversely affect (LAA) listed species (as opposed to no effect [NE] or not likely to adversely affect [NLAA]). Subsequently, the Services issue a biological opinion (BO; essentially a species-specific assessment, typically at the local or regional level of analysis) concluding jeopardy, or no jeopardy, and likely to adversely modify critical habitat or not. Pesticide labels under FIFRA are then modified to reflect the outcome of this process. Within this BE/BO consultation cycle there are necessary procedural steps that could result in potential non-compliance; for example, if the EPA fails to consult or if the Services fail to assess.

In 2020 EPA released the "Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides" detailing a three-step framework where Step 1 involves a deterministic process (geospatial overlay of threatened and endangered ("listed") species critical habitat and range with a crop use footprint for a given active ingredient) to differentiate may affect (MA) from NE, and Step 2 describes a risk assessment methodology to delineate may affect calls between LAA and NLAA (US EPA 2020). Step 2 is intended to refine conservative assumptions employed in Step 1 and utilize probabilistic analyses, though conservative assumptions are still prevalent throughout. Steps 1 and 2 comprise the BE, which focuses on the

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individual, whereas Step 3, the BO is the domain of the Services and focuses on the population to determine jeopardy and adverse modification (J/AM) of critical habitat. In the cases considered to date, Step 1 has typically resulted in wholesale inclusion of listed species considered in the BE given that the range of listed species overlaps with land identified as "cropland" by ~96% (329 million acres) in the contiguous United States (Brain et al. 2023). Step 2 is a conservative deterministic (with some probabilistic elements) risk assessment that relies on prescribed models, model inputs, and endpoints from standard test species intended to be broadly representative of taxa generically.

The number of species listed as threatened or endangered has risen steadily from 70 in 1967 to more than 1700 currently, an increase of nearly 25-fold (US FWS 2023). Moreover, land allocation to listed species designated critical habitat (identified in the Environmental Conservation Online System database) accounts for 114,082,035 acres, with an additional 3,634,870 acres being proposed. The extensive overlap between listed species critical habitat and range with cropland is primarily an artifact of imprecise range maps, which vary considerably in resolution and size, from less than one acre (narrow ranges) to over 800 million acres (US FWS 2020). Some ranges cover nearly 50% of the total land acres in the contiguous United States, and the vast majority (~84%), have ranges ≥25,000 acres. Thus, not surprisingly, when a geospatial proximity analysis of listed species range relative to cropland is conducted, per Step 1 of the EPA's Revised Method (US EPA 2020), nearly all species are routinely flagged in this low-resolution capture. Although the EPA has detailed refinements in the recently released Herbicide Strategy (US EPA 2023), the approach is still highly prescribed, extremely conservative, and does not provide accommodation for higher-tier data or methodologies. This increases the likelihood of erroneous risk conclusions in the resulting BEs, which are then transmitted to the Services for concurrence. In an attempt to ensure compliance with ESA requirements, the EPA has recently proposed an a priori picklist or menu of mitigations whereby growers and applicators can select from a menu of practices intended to minimize potential pesticide exposure to listed species (e.g., US EPA 2023). However, there are technical, practical, and financial challenges associated with this approach. The fundamental weakness is the lack of calibration regarding the menu of mitigations relative to conservatively projected risks to listed species, resulting in potentially onerous and unwarranted demands for applicators and growers. For example, how much do cover crops reduce exposure relative to a vegetative filter strip, and how wide does a filter strip, buffer or setback need to be to reduce exposure sufficiently? There has been little evaluation of proposed picklist/menu mitigations and no calibration of their effectiveness relative to offsetting potential risks. Although we agree that up-front mitigations may offer a viable strategy, they need to be grounded in solid science.

Fundamental Obstacles That Need to be Addressed

Fundamentally, there are at least three major obstacles that are critically limiting effective implementation of the FIFRA/ESA consultation process. The first is a prevalent and persistent lack of staff and resources for the EPA and Services to do the necessary work. The second is excessive litigation. The third is key differences in the objectives of FIFRA and ESA. Without giving EPA and the Services resources to actually do what they're currently obligated to do by law, and without somehow stopping the all-too-frequent lawsuits against every registration action, there is little hope for substantive progress. Over and above these changes, action by Congress to modify one or both of the statutes so that they can operate more seamlessly should not be beyond the realm of possibility.

Obstacle 1 - A lack of resources has forced a reliance on screening-level risk assessments in Steps 1 and 2. This is not the requisite level of analysis needed to adequately characterize potential exposure and effects to listed species and adequately and accurately inform and calibrate proposed a priori mitigations intended to offset species exposure/risk.

Consideration and integration of higher-tier data and methodologies are essential, and the current procedure to develop BEs does not provide necessary flexibility to consider non-standard data and methods. Every pesticide active ingredient is unique, and although all conventional pesticides must at a minimum reflect the mandatory standard data requirements under 40 CFR Part 158 (CFR 2014), non-standard higher-tier data exist for many compounds. Not making use of available higher-tier data means that the assessments are not based on the best available science.

An additional consequence of resource limitations is that the consultation process, including the associated analyses, reporting, and reviewing, has been far too slow. This can have undesirable consequences for growers in delaying the registration or re-registration of products on which they depend (to grow more crops on less land) as well as manifesting in unnecessary mitigations. Moreover, from a listed species perspective it can also have undesirable consequences in delaying actions that might be needed to ensure continued species protection.

Obstacle 2 - Litigation as the driver of the FIFRA/ESA consultation process forces action—even if not the most scientifically supported action—in the interest of demonstrating compliance. Given the complexity of the FIFRA/ESA interface, it is inevitable that multiple stakeholders with diverging perspectives and priorities have a significant interest in the outcome of regulatory decisions. But contentious legal battles are not likely to result in stakeholder consensus; they rather lead to further delays in the consultation process and registrations of new active ingredients. The result is negative impacts on growers, listed species, or both. This is broadly a consequence of the litigious nature of the U.S. pesticide regulatory framework. Pesticides are an easy target given that they have a contentious origin (Brain and Anderson 2020), plausible biological relevance (BCPC 2018; Carson 1962; Fukuto 1990), and an easily exploited legal construct in the United States, e.g., citizen suit provisions (see Clean Water Act (CWA): US EPA 2002; Endangered Species Act (ESA): USFWS 1973). Replacing litigation as the driver behind the consultation process with a multi-stakeholder approach that embraces consensus-oriented dialogue, explication, and mediation would likely be much more desirable for all parties.

Obstacle 3 - In working through the ESA consultation process, it has become obvious that the objectives (i.e., protection goals) of FIFRA (i.e., ensuring no adverse effects to non-target species or critical habitat from registering a pesticide) and ESA (i.e., ensuring that listed species are not further impacted from any human-related cause) are very different. Registration/re-registration of a pesticide active ingredient under FIFRA takes the benefits of the product into consideration, whereas ESA does not. Also, FIFRA is designed to assess risk to all non-target species from one pesticide at a time, whereas ESA is designed to assess all potential risks to one listed species (population) at a time. Finally, FIFRA considers risk at a national level for the purpose of product registration and labeling, whereas ESA generally considers risk at a regional level for the purpose of developing recovery plans at the local level.

If under FIFRA, a pesticide is determined to have no significant adverse effects on non-target species, it should, in principle, not have any adverse effects on listed species. Because only a small subset of species are tested under FIFRA, legitimate questions can be raised about whether these tested species are sufficiently representative of listed species to ensure the latter's protection. Are there any reasons to expect listed species to be more vulnerable to the effects of pesticides than non-listed species? In particular, are they likely to be more toxicologically

sensitive? Are there features of their biology that would exacerbate the population-level impacts of pesticide impairments to survival, growth, or reproduction (i.e., the most common toxicity test endpoints), thus making their populations more vulnerable to the same levels of pesticide exposure as non-listed species?

In that ESA is focused on ensuring protection of listed species, it would seem essential to assess the potential risks of pesticides in a more holistic context that includes other potential factors that are impacting endangered species. However, the present consultation process is solely focused on assessing the risks of pesticides to listed species independent of other potential anthropogenic drivers. More effective protection of listed species would benefit from a greater separation of the FIFRA and ESA processes in which risk assessments under FIFRA focus exclusively on potential risks of pesticides to all species (including listed species), and risk assessments under ESA focus on relative risks of all potential stressors (including pesticides) to listed species. In this scenario, EPA could still provide input to ESA assessments, in the form of information produced under FIFRA, which the Services would subsequently consider relatively, within a broader anthropogenic context.

How Science Can Better Inform Assessments Under FIFRA and ESA

In what follows, we propose a way forward that leverages recent developments in the science to streamline the FIFRA/ESA process, achieve greater consensus among stakeholders, and more effectively balance the need to secure the human food supply with the need to protect the environment, and endangered/threatened species.

Considering how science can help to improve and streamline risk assessments under FIFRA and ESA, it is essential to recognize that science changes as understanding increases and technology improves. This implies that our regulatory processes should also change to reflect scientific progress. Regulators have been reluctant to make changes to historical practices, despite acknowledged improvements in the science for (perhaps justifiable) fear of litigation. Despite numerous advances in the science, procedures used by the EPA for ERAs (including endangered species assessments) have not substantively changed in decades. They rely heavily on highly prescribed and standardized screening-level risk quotients and levels of concern and often use worst-case assumptions that can be compounded, leading to overestimates of risk (Raimondo and Forbes 2022). This methodology is employed by design, for efficiency, consistency, and reproducibility; however, such an approach lacks flexibility to consider and incorporate non-standard, and often novel higher-tier data and approaches. This approach needs to be reformed. Engaging all stakeholders more productively is one way to achieve this. Regulatory actions should not be considered in a vacuum; rather the process should assess potential risks judiciously, accordingly, and relatively in order to identify the most significant factors contributing to species decline. If pesticides are among the most significant contributing factors, then we should explore a priori mitigation options or conservation offsets. However, such options should be thoroughly and rigorously vetted to consider geographic appropriateness, feasibility, likely grower adoption, economic considerations, and potential benefits to listed species.

Risk assessments are characterized by both uncertainty (e.g., lack of knowledge, measurement errors) and variability (e.g., differences in species sensitivity, differences in exposure scenarios). Science can help to distinguish between these so that we can reduce uncertainty and incorporate variability for more robust assessments. Science can

also provide data, theory, and tools to more quantitatively and robustly link what we measure (e.g., individual survival, growth, or reproduction) with protection goals (e.g., the persistence of listed species populations).

One question that is often posed in the context of ESA is what constitutes "best available data"? Not all research and studies are created equal, so how do we decide which studies and which data constitute "best available"? Klimisch and colleagues (1997) developed a system that considered the reliability, relevance, and adequacy of studies, where adequacy is defined as the "usefulness of data for risk assessment." This system categorizes studies using four reliability codes: (1) reliable without restrictions (preferably Good Laboratory Practice (GLP) studies), (2) reliable with restrictions (open literature articles, mostly non-GLP studies), (3) not reliable, and (4) not assignable. Studies rated as "reliable without restrictions" and "reliable with restrictions" may be used in a risk assessment. Relative scoring criteria and rubrics have also been developed and employed to evaluate the strength of methods, which facilitates identifying the most reliable endpoints for use in risk assessment (e.g., Hanson et al. 2019) and similar approaches exist for assessing the consistency of results (e.g., Hanson and Brain 2021). Moreover, quantitative weight of evidence approaches also exist to compare and contrast data based on a priori scoring criteria (e.g., Van Der Kraak et al. 2014). Data quality and relevance should be a fundamental tenant in any step of any ERA. If meaningful and accurate estimates of risks are to be developed, then the approach must have broad agreement across stakeholders on the specific criteria (related to quality and relevance) determining best available data. Granted it must be acknowledged that any evaluation of data quality necessitates some degree of expert judgment, regardless of how objective and quantitative the criteria. This potential subjectivity can introduce elements of bias; however, this can be addressed through transparent, consistent, and systematic application of data quality and relevance standards that are agreed-upon and validated. A useful template to evaluate, at least the basic elements of study quality, is provided by the Health Effects Division (HED) of the Office of Pesticide Programs within the EPA (US EPA 2012).

In principle, ERAs use a tiered approach that starts with worst-case assumptions about exposure and effects at initial (screening-level) tiers. If the screening-level ERA finds potential risks to be unacceptable, exposure and/or effects estimates are refined to more realistic (i.e., less worst-case) values, providing more accurate estimates of risk. This is laid out in elaborate detail by the EPA's overview document for threatened and endangered species evaluations (US EPA 2004). Because obtaining more realistic estimates of exposure and effects generally requires more information and resources, using a tiered approach makes sense. However, there are two ways that the tiered approach can go awry: if the initial screening-level ERA is not sufficiently worst-case, resulting in inherently 'risky' chemicals entering the marketplace; or if the higher tier ERA is not effective in screening out low-risk chemicals, resulting in the need for resource-intensive higher-tier assessments for too many chemicals, potentially requiring unnecessary restrictions on their use or keeping them out of the marketplace all together. The latter was the situation for the first three national level FIFRA/ESA BEs performed by EPA for chlorpyrifos, diazinon, and malathion (https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-risk-assessment-methodology-endangered; accessed July 19, 2023). Step 1 used a deterministic geospatial overlay of listed species critical habitat and range with a crop use footprint for widely used active ingredients, and nearly all species had to proceed to Step 2. Step 2 assessed pesticide exposure at the national level and pesticide effects using the lowest available individual-level toxicity data. In these cases, neither the Step 1 nor Step 2 ERAs were capable of eliminating the vast majority of listed species from detailed consideration by the Services in Step 3 (i.e., only 3% of 1,835 listed species were eliminated in Steps 1 and 2 for chlorpyrifos and malathion with 21% eliminated for diazinon).

National screenings are not likely to be helpful at eliminating listed species from further consideration (especially for widely-used products, as was the case in these assessments). Assuming that effects on survival, growth, or reproduction of a single individual of a listed species population are likely to adversely affect the population is very conservative, and therefore not surprising that very few species were screened out from further consideration. In short, the tiered approach in these cases was ineffective and resulted in nearly all species having to proceed to more intensive Step 3 assessments, which, at least in theory, are intended to assess population-level impacts.

Ecological risk assessments are generally intended to protect populations and ecosystems and not individuals (Suter 2020). Even for threatened and endangered species, for which it might be argued that the loss of any individuals is to be avoided, risk assessments are intended to determine conditions under which species populations are likely to decline (i.e., to be in jeopardy). This implies that any measure of chemical effects used in ERAs needs to either be a direct measure of population-level impact or linked quantitatively to such impacts (Raimondo and Forbes 2022). There have been numerous advances over the last couple of decades in the science of population modeling. These include guidance on model development, documentation, and evaluation (Raimondo et al. 2021), case studies (Hommen et al. 2015), and advances in the technology facilitating more sophisticated modeling approaches. Although population modeling has yet to make it into EPA's standard toolbox to any meaningful extent, increasing acceptance of population modeling for pesticide risk assessments in Europe is a sign of progress (EFSA 2014).

Admittedly, developing population models for non-target species requires a certain amount of data, and lack of data for many species is a real challenge. This is especially true for listed species because of restrictions in collecting or working with them, and they certainly cannot be used in toxicity tests. Ongoing research into traits-based approaches is exploring how particular life-history, physiological, behavioral, or ecological traits may influence the vulnerability of species to pesticides and other stressors. This work should help to identify species that can represent larger groups of species sharing similar traits. Population models could be developed for vulnerable representatives of larger groups with the expectation that estimates of risk based on the model outputs would be protective of species sharing similar traits.

For example, freshwater mussels are among the most critically imperiled taxa globally, with 91 of nearly 300 species listed as threatened or endangered under the ESA (USFWS 2018). Using literature data on five life-history traits (maximum life span, age at maturity, mean fecundity, maximum adult size and glochidia size) for 55 species, including 15 listed species, Moore and colleagues (2021a) grouped the species into three life-history categories (equilibrium, opportunistic, periodic). Listed species occurred in both the equilibrium and periodic categories, but not the opportunistic category. Population models are being developed for one or more data-rich representatives from each category to use in assessing risks of pesticides and other stressors to species for which data are lacking. Exploring how perturbations of individual-level responses (as would typically be measured in toxicity tests) extrapolate to population-level impacts for the different categories will improve understanding of how data measurements are linked to protection which could potentially result in ERAs that are better informed by the science.

Traits-based analyses can also be used to explore whether listed species share particular traits that make them especially vulnerable to pesticides and other stressors

and how they differ from non-listed species. Using a combination of phylogenetic and life-history analyses, Rueda-Cedial and colleagues (2022) found that listed terrestrial plant species were distributed widely across plant phylogeny and life-history clusters. This indicates that listed plant species do not share a common evolution or life-history traits that would make them uniquely vulnerable. It also suggests that non-listed species (that have fewer restrictions and are often more data-rich) may be suitable representatives for listed species in the context of ERA.

Additional tools, approaches, and resources include field studies, probabilistic geospatial frameworks, several higher-tier aquatic exposure models, as well as monitoring data. Field drift bioassays, when available, should be evaluated and used to refine buffer predictions (Brain et al. 2017, Brain et al. 2019, Moore et al. 2021b, Perkins et al. 2022). Such studies better reflect how non-target plants (or organisms in general) experience off-field exposure and empirically define a conservative buffer distance directly without the need for extrapolation. Probabilistic geospatial frameworks, such as the Automated Probabilistic Co-Occurrence Assessment Tool (APCOAT) (Dunne et al. 2023) (which is a freely available: https://www.stone-env.com/our-expertise/environmental-systems-modeling/apcoat) can also be useful. APCOAT generates batches of probabilistic maps and statistical summaries of species distributions, pesticide use, and co-occurrence. With respect to aquatic exposures, the Pesticide in Water Calculator (PWC) represents a simplistic, generic, farm pond that does not consider inflow or outflow to derive an extreme exposure scenario. Examples of available watershed models that could be used in refined pesticide risk assessments for listed species include the Soil Water Assessment Tool (SWAT) (Neitsch et al. 2005), the Agricultural Policy Extension (APEX) model (Steglich and Williams 2008), and the Pesticide Root Zone Model-Riverine Water Quality (PRZM-RIVWQ) model. The Vegetative filter strip modeling system (VFSMOD) (Muñoz-Carpena and Parsons 2004) specifically predicts the effects of vegetative filter strips and can be linked between PRZM and VVWM. Monitoring data should also be leveraged where possible in conjunction with the seasonal wave with streamflow adjustment and extended capability (SEAWAVE-QEX) tool developed by the USGS (Vecchia 2018).

The EPA's "Revised Method for National Level Listed Species Biological Evaluation of Conventional Pesticides" (USEPA 2020) outlines changes that have been made to the 2013 Interim Method (https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report; accessed July 19, 2023) that was applied to the first three national-level BEs (for chlorpyrifos, diazinon, and malathion). In this document, the EPA commits to applying current methods and best available data as the biological opinions evolve and to continue methodological discussions with the Services and USDA (USEPA 2020, p. 8). The recently released Herbicide Strategy also indicates that "In fulfilling the requirements of ESA section 7(a)(2), EPA must use the best scientific and commercial data available" (USEPA 2023). Although certain improvements have been made, for example regarding probabilistic methods and weight of evidence, overall improvements in the scientific basis of the approach appear minimal, and consideration of higher-tier data and newer methodologies is notably lacking.

Streamlining the Process with More Science and More Stakeholder Involvement

There are a number of ways that better use of science can streamline the FIFRA/ESA process. The first is ensuring that the criteria used to screen out low-risk cases are indeed effective screens. As the first three biological evaluations for organophosphates clearly demonstrated, national-level exposure assessments are unlikely to screen out species from further consideration for widely used pesticides. A solution to this would be to develop agreed-upon

regional scenarios that are tailored to ESA needs. Since preventing decline of listed species populations is the goal of ESA, choosing methods that more directly reflect population-level impacts could save time and effort. A multi-stakeholder initiative to develop a suite of standardized population models, using all of the guidance now available, for a handful of representative species, would be another way to streamline the process. While both of these efforts would take considerable time and energy, they could have the benefit of engaging all of the relevant stakeholders in a constructive dialogue that, over time, could lead to greater consensus building and less litigation.

Over a shorter timescale, it may be feasible to distribute the ERA workload to speed up the process. This could mean engaging the Services at an earlier stage than current practice, skipping the current Step 1 and possibly 2 to free up EPA resources to focus on higher tier, population-level assessments, and/or having registrants produce the ERAs for EPA/Services to review, consistent with EU/EFSA approach. This should be possible given that ESA applicants for other types of actions (developments, bridges, roads, pipelines etc.) generate and submit such assessments, rather than these being conducted by the action agency (EPA) or the Services.

With respect to prioritization, under ESA all listed species are created equal by design. In reality, the degree of imperilment and the relative drivers of listed species decline vary considerably. For the FIFRA/ESA process, it may be helpful to rank-order species relative to the unique and individual threats posed by agriculture (i.e., pesticides). To some extent recovery plans and 5-year reviews issued by the Services do reflect an element of prioritization, which reflects a species expert judgment call, however, this is not reflected in the EPA's BEs at this time. Prioritizing more time and effort to assessing potential risks of pesticides to listed species in the middle of the corn belt and less to remotely located and geographically isolated species, would be in keeping with the tiered philosophy of ERA.

Relative Threat of Pesticides and Other Stressors to Listed Species

Acknowledging that comparison of the relative drivers of listed species decline is not within the remit of the Section 7 ESA consultation process and would require Congressional debate, context warrants consideration. The FIFRA/ESA process is solely focused on assessing the risks of pesticides to listed species, ignoring both the other facets of agriculture (e.g., land use change, fertilizers) and, more importantly, other potential human stressors (e.g., invasive species, climate change, urbanization [homes, malls, recreation, highways], point-source industrial pollution etc.) that may be contributing to species decline. The available literature indicates that many of these other anthropogenic stressors represent primary threats to listed species and far surpass any potential impacts of pesticides. For example, based on data generated by Pimentel (2000) and compiled by the USFWS (2017) cats (domestic and feral) account for 72% of all bird mortalities in the United States annually (Brain and Anderson 2019; Figure 1), with a further (combined) 25% attributable to collisions with buildings, structures, and vehicles etc., and only 2% attributable to "poisons" (not broken out by household, industrial, or agricultural). Similar trends are evident when mammals and fish are considered (Brain and Anderson 2020; Brain and Prosser 2022). Consequently, a prudent question to ask would be whether we are judiciously focusing our efforts relative to the potential risks presented accordingly. The data suggest, for example, that spay, and neuter programs would be far more effective in reducing listed bird declines in the US than upfront pesticide mitigations, but that is not the reality reflected in existing practice. Clearly spay

and neuter programs and awareness are beyond the purview of FIFRA but are within the scope of ESA, given the remit is to recover and preserve listed species, whatever the source contributing to their imperilment. Thus, it appears that the current FIFRA/ESA consultation process focuses maximal effort on a minimal contributor to potential jeopardy of listed species. Taking a more holistic approach to assessing potential risks would, not only better reflect our existing scientific knowledge, but would lead to more effective and pragmatic strategies to protect listed species.

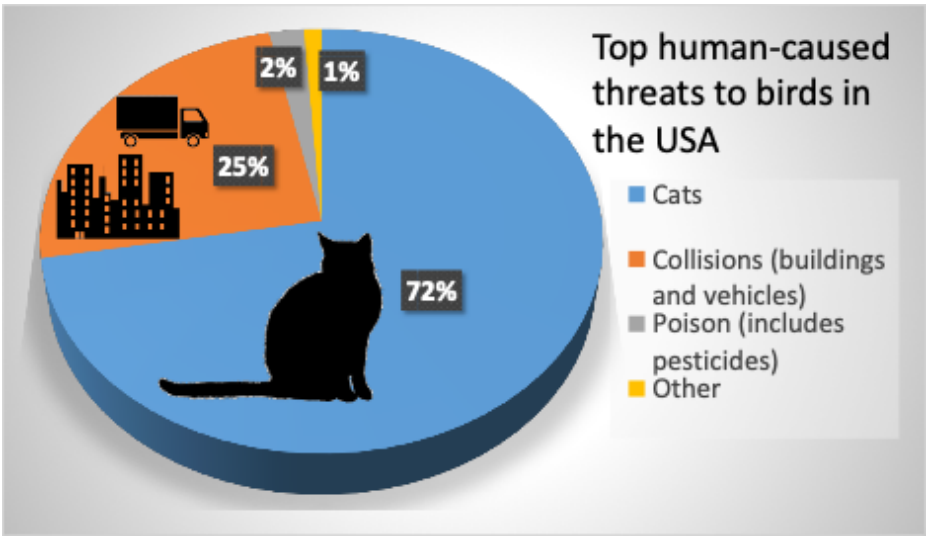

Figure 1. Anthropogenic contributions to avian declines in the United States (redrawn from Brain and Anderson 2019).

In the United States the number of acres characterized as "land in farms" have decreased by ~23% over the past 70 years, and "cropland" has shrunk by ~17%, yet the U.S. population has more than doubled during this timeframe, and agricultural productivity has increased three-fold (Brain et al., 2023). Habitat loss is the single most significant factor contributing to listed species decline, and agricultural expansion was the primary driver up to 1950. However, both habitat and farmland are now being consumed by urbanization, which is increasing at a rate of change of 858,504 acres per year (Brain and Anderson, 2019). Growing more food from less land has been made possible by synthetic pesticides and fertilizers and regulatory decisions that do not reflect the best available science will compromise these tools, stress land use and food security, and will not likely improve listed species status.

Conclusions and Recommendations

There are legitimate concerns that the FIFRA/ESA consultation process – constrained as it is by law - is missing the forest for the trees by focusing solely on pesticide risks to listed species when the science points to other major drivers that need to be addressed for effective species protection and recovery. Attempting to find shortcuts through mitigations that are not sufficiently informed by science may give the sense that actions are being taken, but the overall effectiveness of such actions is questionable. As the science continues to advance, better data and tools are becoming available to inform FIFRA/ESA risk assessments than those currently being used. The EPA appears to be committed to "continue to evolve as EPA gains experience and as scientific methods and data improve" (USEPA 2020, p. 8). Improving upon existing approaches will likely involve a more proactive, transparent, and consensus-driven engagement of multiple stakeholders and a shift away from litigation as the primary consultation driver. Achieving a more efficient FIFRA/ESA consultation process and more accurate ERAs that continuously improve as the science advances should be in the best interests of all stakeholders.

Several immediate steps that could be taken include:

1. Contextualizing risks posed by pesticide active ingredients relative to other more prominent drivers could better inform strategies for supporting listed species recovery and viability.

2. Changing the existing screening-level approach for BEs (Steps 1 and 2) to reflect a truly tiered system would save resources for where they are really needed. Although there is obvious utility in screening-level assessments, these are intentionally very conservative and may point to a priori mitigation strategies that are not feasible in practice. Flexibility and expert judgment are necessary to incorporate higher-tier data and methodologies, which can be accomplished through a tiered framework that has been publicly vetted.

3. Setting the tiers appropriately to reduce the number of species that need to proceed to Step 3 would improve efficiency. Reliance on a screening-level risk assessment that results in inordinate numbers of listed species (i.e., LAA designation) being referred to the Services for J/AM analysis is highly challenging and slows the overall process. Greater integration of state-of-the-art tools and methodologies through transparent and multi-stakeholder collaborative engagement would reduce uncertainty, facilitate realistic a priori mitigation options, better inform which species should proceed to J/AM analysis, and ameliorate litigation pressure.

4. Although resource allocation to support the EPA and the Services is the domain of Congress, there are collaborative opportunities to reduce the burden of Section 7 consultations. Registrants can provide support in the form of data, methods, tools, and assessments. Potential concerns of bias can be addressed through transparent data evaluation criteria and by pursuing a multi-stakeholder approach that also includes non-government organizations (NGOs).

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