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CAST Commentary

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FIFRA, ESA and Pesticide Consultation: Understanding and Addressing the Complexities

Introduction

For decades growers have been engaged in developing workable approaches to reducing impacts of pesticides on non-target species. These efforts not only yield positive benefits for the environment but often provide growers with substantial economic and ecological benefits that accrue from the conservation of beneficial species. Over the last several decades, the focus on pesticide use has shifted from optimizing on-farm pest management to the responsibilities and obligations created by label changes driven by the Endangered Species Act of 1973 (ESA) to pesticide actions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Recently fulfilling understanding and meeting those obligations of the ESA has become more difficult as advocacy organizations began filing procedurally based lawsuits against the EPA for perceived violations of the ESA, resulting in court rulings intervening in the FIFRA process. Judicial rulings are especially challenging for the EPA in assessing the impacts of pesticide use on listed (threatened and endangered) species while meeting court-ordered deadlines in shortened timeframes and with declining staffing levels.

Why has consultation among federal agencies addressing the Endangered Species Act of 1973 (ESA) proven to be such a difficult task in assessing the risk of pesticide use and delivering regulatory actions that protect species in a practicable manner that allows farmers to provide food security for the nation?

Identifying the Complexities

As the EPA rapidly implements pesticide label restrictions to protect listed species per court requirements, these restrictions are limiting the practical use of pesticides for the agricultural community. Label restrictions that, while well-intentioned, can be the product of an insufficient amount of on-the-ground data combined with what also can be overly protective assumptions where data are lacking, can severely limit a farmer's ability to manage pests effectively and efficiently. The EPA, the National Research Council (NRC) Committee and the agricultural community have all voiced concerns that must be understood if effective solutions

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are to be developed.

The EPA has identified at least six key challenges that they believe must be overcome (US EPA 2022b).

- First is the large and growing number of FIFRA actions that trigger ESA review, at a time when the Pesticide Program's staffing is roughly at the FY 2013 level. "Apart from the growing workload and backlog challenges, the Pesticide Program's staffing levels have declined from a high of 808 (2005) to 603 (2021)." Data from FWS or NMFS regarding the number of staff positions with responsibility for working with the USEPA on interagency ESA consultations are more difficult to determine.
- Second is that the current ESA-FIFRA process generally does not result in protections for Listed (threatened and endangered) species that are both practical for pesticide users to implement and timely to protect species.
- Third is that FIFRA registrations are often geographically broad, cover many pesticide uses, and affect many types of listed species. All of this creates unique scientific and practical challenges for the EPA's ability to meet its ESA obligations.
- Fourth is the need to better harmonize the FIFRA process with the ESA process. For example, the current FIFRA process assesses each pesticide on a chemical-by-chemical basis, but this approach is unsustainable across hundreds of pesticides. This is one reason that the entire ESA-FIFRA process currently spans at least four years for one pesticide.
- Fifth is a series of challenges related to data and scientific methods. For example, having better and more refined data on where species occur and how best to protect them from pesticide exposure would result in more effective and cost-efficient protection. However, gathering and analyzing these data would likely extend the ESA-FIFRA process even longer and require additional agency capacity. Thus, EPA needs to balance the benefits of more or better data, to expedite the ESA-FIFRA process.
- Finally, an effective ESA-FIFRA process requires strong working relationships among EPA, FWS, NMFS, and USDA. "All four agencies are working toward this goal but still have room for improvement."

Additionally, in its report "Assessing Risks to Endangered and Threatened Species from Pesticides" (a report requested by EPA, NMFS, and the FWS), the National Academies of Sciences, Engineering, and Medicine, National Research Council (NRC) Committee on Ecological Risk Assessment under FIFRA and ESA noted three major areas that would benefit from improvement (National Research Council 2013).

The first is a lack of a common approach, which the NRC noted: "has created scientific obstacles to reaching agreement between the EPA and the Services during consultation."

Second, is an improvement in "recognizing and analyzing uncertainty" by adopting a probabilistic risk assessment approach "that allows uncertainty in exposure and effect to be explicitly recognized and then combined in forming a risk estimate."

Finally, the report suggested that a unified definition of "best data available" should include stakeholder data.

The agricultural community has also identified areas of concern, some of which overlap with those discussed by the EPA and the NRC (Cranney 2023).

- The need for improved regulatory cooperation across agencies.
- The need for developing accurate maps for listed species ranges, habitats, and farm fields being treated with pesticides.
- The need to have regulatory decisions based on practical/historical pesticide use rates as typically applied.
- The need to have regulatory decisions based on more realistic predicted pesticide sensitivity levels of listed species.
- The need for scientifically sound and flexible mitigation measures that apply to variable crop production systems.
- The need for refining pesticide modeling to reflect likely pesticide exposures more accurately.
- Improved communication between federal agencies and agricultural stakeholders.

Addressing These Complexities from a Grower Perspective

Improved Cooperation Among Regulatory Partners: The EPA, NMFS, and the FWS must continue to work toward developing an agreed-upon, reliable, and efficient process for meeting ESA responsibilities. However, a decade after receiving the advice from the NRC that they solicited, the federal agencies continue to differ on key theoretical and analytical approaches to risk assessment, and significant logistical and legal issues remain. It is hard to envision how EPA will be able to meet its legally mandated timetables without changes in the process and without being forced by partnering federal agencies or the courts to implement mitigation practices that are overly restrictive to agricultural production. Several tactics to improve collaboration between agencies have been proposed by the agency (US EPA 2022), but it is not clear that all the regulatory parties agree. Nor is it clear that users have had a chance to review the impacts of interagency consultations, such as for herbicides. The potentially impacted parties must have a seat at the table since agencies are making a significant change in how ESA decisions will be made, thereby having significant impacts on pesticide user stakeholders.

Accurate maps for listed species range, habitats, and farm fields: Identifying specific locations where listed species and their habitats are located, and where these locations overlap with agricultural production is essential to protecting both species and minimizing undue disruption. By documenting species ranges, habitats, and agriculture fields, a scientific determination of sensitive sites can be achieved by fostering protections as needed. If pesticide restrictions are to be put in place, the overlap mapping process of listed species and pesticide use sites must be reasonably accurate. Currently, the process of using outdated species range maps, or maps based on habitat that may have historically occurred, lacks scientific merit as does aggregating mapped data on unrelated species, grouping crops without consideration of differences in use patterns, and other map consolidation shortcuts that remove precision in tradeoff for faster review processes.

Pesticide Usage Data

The incorporation of pesticide usage data is particularly important for a credible consultations process under the ESA, but, since the release of the NRC report in 2013, there has been little agreement among Federal Agencies involved in ESA risk assessments regarding what constitutes credible pesticide usage data. The datasets that are most highly valued by the EPA appear to be from the California Department of Pesticide Regulation Pesticide Information Portal or proprietary data from a commercial provider, Kynetec. User data collected by

USDA's National Agricultural Statistics Service (NASS) seems to be considered by EPA to be of lesser value, primarily due to its overall frequency of collection and how often certain use sites are surveyed (e.g., small acreage crops and non-agricultural use sites). NASS usage data for biopesticide and antimicrobial active ingredients are generally unavailable (US EPA 2022b). The Kynetec usage data is the most highly used private data source but is limited to those who purchase access, a cost that limits access for many. Data reconciliation becomes difficult when user data differs from that provided by Kynetec because users do not have access to the raw Kynetec data.

Determining the Sensitivity of Listed Species to Pesticides

Since protected species cannot be treated with pesticides to test for effects, it is understood that the EPA ESA pesticide risk assessment process must use an alternate methodology for the prediction of species sensitivity to a given pesticide. Since these values are determined by estimating the sensitivity of respective pesticides on surrogate species, the agency's typical approach of using the most biologically sensitive relationship currently documented can result in overly conservative estimates. This assessment process is extremely complex, but it is solvable through cooperative research that identifies and tests closely related surrogates (to the listed species) to observe their response to pesticides. The results of this effort could have monumental implications, offering a more realistic and data-driven approach to understanding the sensitivity of listed species to pesticide exposure.

Mitigation

There is great concern among many agricultural producers about ecological mitigation measures proposed recently by the EPA (US EPA 2022b). Agriculture is not monolithic. Great differences are seen in production practices in perennial (tree crops) versus annual cropping (most field crops) systems and production regions. Whereas annual cropping systems may deploy practices such as contour plowing, no-till, or alternate cropping in the same field, perennial crop producers are unable to employ the full range of these practices and question how existing sustainability practices will be valued.

Most cropland is used for producing livestock feed, feed exports, or is left idle to allow the land to recover. According to Bloomberg (Merrill et al. 2018), the total cropland in the United States was approximately 391.5 million acres. Of that total, 127.5 million acres were in livestock feed, 21.5 million acres were being cultivated for wheat exports, 62.8 million acres were devoted to other grains and feed exports, 13.6 million acres were used for cotton and non-food production, 38.1 million acres for ethanol, biodiesel production, and 52 million acres were idle. Approximately 77 million acres (less than 20% of the total U.S. cropland acreage) were used for human food production. Specialty crop production (fruits and vegetables, tree nuts, dried fruits, horticulture, and nursery crops, including floriculture) falls into this category. For most specialty crops, the average acreage farm size is far less than 100 acres.

Consequently, many specialty crop producers do not have as much flexibility or economic wherewithal as major commodity producers in terms of reducing planting acreage or installing new systems for producing their crops. Some of the EPA proposed ESA mitigation measures would require wholesale changes to established cropping systems with substantial adverse economic impacts on the affected growers. Regulatory agencies must consider the differences in farm size, production region, and production practices when proposing mitigation requirements on pesticide labels. These must be practicable for farmers to implement for their cropping system.

Specialty crop producers believe that most of the mitigation measures recently proposed by the EPA are not suitable for specialty crop production and that many of the mitigation measures identified may be more suitable for those farmers producing major crops such as corn, wheat, soybeans, and cotton. However, it is also apparent that major crop producers have significant concerns with the current proposed EPA mitigation measures (Culpepper and Randell-Singleton 2023).

Additionally, both specialty and agronomic crop growers are likely to lease land. These growers must secure the approval of the land-owner lessor to make changes to the leased land. Securing multi-year commitments from the lessor is particularly problematic. Consequently, mitigation measures that may involve substantial changes to the farm, especially those involving multi-year commitments are essentially not feasible for these growers.

Specialty crops must be approached individually when considering mitigation measures for pesticide runoff and erosion mitigation. These cropping systems are highly dynamic and complex and consist of many components such as diverse tillage practices, planting of grass strips, irrigation methods, seed/planting practices, fertilization, pest management practices, and harvesting procedures. Specific production practices are often conducted due to the sensitive and delicate nature of the crop, and many are not compatible with the mitigation measures being suggested by EPA (Culpepper and Randell-Singleton 2023).

Spray drift buffers to protect against the theoretical risk of off-site movement of the applied pesticide are notable features of endangered species protection. The EPA and its federal partners should join with the user community in the development of drift reduction technologies, especially for air blast sprayers, to offer greater options for mitigation. Currently, there is growing interest in adopting spray equipment technologies which may help to reduce drift. Increased federal and state research funding would enable the development of technology that would allow growers to reduce buffer zone sizes by documenting drift reduction. A commitment by the agency to support the development of drift reduction technology, consider the impact of those technologies in pesticide product risk assessments, and reflect that technology on pesticide labels would speed the adoption of proven new technologies, particularly in perennial crops.

Modeling

The EPA's heavy dependence on models that have not been validated across all the use scenarios where the output is applied concerns growers. Grower stakeholders expect that regulatory modeling, which could result in the withdrawal of products or cropland, would provide a level of accuracy at least equivalent to other models growers rely upon for pest control and crop production. Additionally, there are significant stakeholder concerns that modeling used to make regulatory decisions is in many cases not as robustly validated as the weather-based decision support tools routinely and voluntarily used by growers to support integrated pest management and other decision-making. Additionally, the federal agencies' decision to incorporate estimates of environmental contamination based on modeling data into ESA analyses when actual field monitoring data exists showing lower levels of contamination is of particular concern to the grower community. The below discussion highlights just some instances comparing field-validated models to those less robust.

To provide an example of validation that provides a level of certainty at the field level, currently growers use several Integrated Pest Management (IPM) predictive models to aid in improving pest management decision-making. Perhaps one of the most widely used models is the codling moth growth model which predicts population development in apple, pear, and walnut orchards (Jones et al. 2013). Developed by entomologists at Washington State University, the model demonstrates that it accurately predicts 1st egg hatch, a critical event in codling moth management. The reliability of the model provides growers confidence that pesticides can be accurately timed targeting specific codling moth life stages thereby enhancing control and reducing insecticide costs. Figure 1 shows the level of validation growers expect when predicting events that may have economic impacts on their operations. In the graph, the zero-day designation refers to the date on which the first egg hatch is observed in a heavily infested apple orchard. The blue bars note the often-significant difference between this observed egg hatch and the date on which the standard calendar timing (seven to ten days after petal fall) compared with the increased accuracy of the model in predicting egg hatch (black bars). Note that in six years of the ten for which data is presented egg hatch predicted by the model and observed egg hatch occurred on the same day. This level of granularity in validation is not a feature of most or all the ecological models used to project environmental contamination, yet the economic impacts may be further reaching.

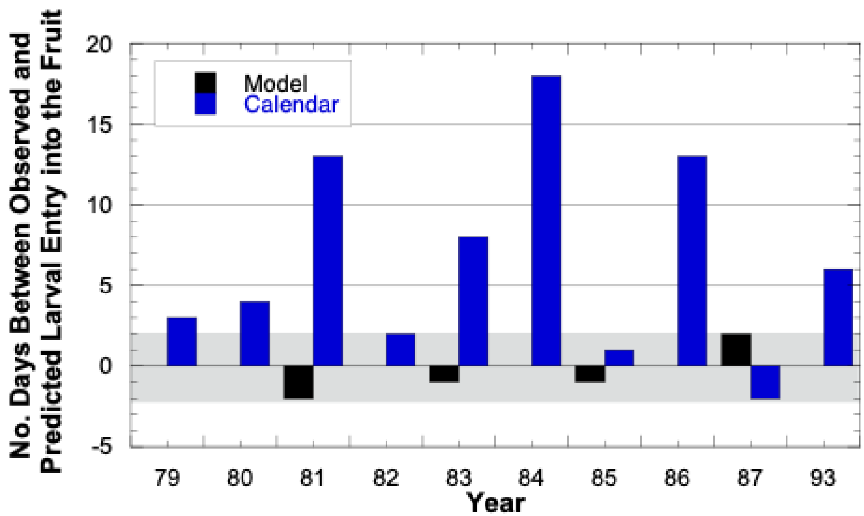

Figure 1. Calendar-based and degree-day model-based spray timing for codling moth compared with actual observations of first egg hatch in Wenatchee, Washington

As an example, Florida has many years of actual field-level monitoring data specific to atrazine. From 1996 to 2011, monitoring recorded a maximum of 23 ppb of atrazine (Perkins et al. 2021). However, the Watershed Regressions for Analysis Pesticides (WARP) model (Larson and Gilliom 2001) used by the EPA for estimating runoff into water complexes, predicted maximum likely detections (95% PI) in the 1,200 ppb range within these very same farmlands (https://www.regulations.gov/document/EPA-HQ-OPP-2013-0266-1665). Florida growers were put at risk of losing access to a valuable herbicide due to the WARP modeling overly conservative outputs. While this may be an egregious example, Florida growers do not have a clear understanding of the factors in the model that drove this difference.

Similar concerns exist in other cropping systems. For example, most of Oregon's pear production occurs in the Hood River Valley (Figure 2). Historically, chlorpyrifos had been one of the tools applied to the crop (USDA NASS 2010) for insect control. In a study conducted by Temple and Johnson (2011), the maximum measured chlorpyrifos detection in Neal Creek was 0.482 ppb (Figure 3). The low levels of chlorpyrifos detected in Neal Creek were likely the result of pest control applications using an air blast sprayer, with many acres across the landscape being treated at about the same time. The models used to generate potential concentrations in water for the various types of water bodies adjacent to orchard and vineyard crops provided estimates of 1-day chlorpyrifos concentrations [effective environmental concentration (EEC)] in surface water which ranged from just over 0.72 ppb to just under 59 ppb. The maximum

Figure 2. Blooming pear orchards in Hood River Valley of Oregon looking south up the Hood River toward Neal Creek drainage.

EECs were associated with applications modeled on tart cherries (Rossmeisel and Bohatty 2020).

In its 2013 report, the NRC (National Research Council 2013) notes that Bird and colleagues (2002) compared field data with AgDRIFT model evaluations for "161 separate trials of typical agriculture aerial applications under a wide range of application and meteorological conditions." The comparisons all relied on case-specific meteorological data (wind, temperature, and humidity) and application data, such as observed aircraft heights and nozzle equipment. With such inputs, the investigators concluded that the "model tended to overpredict deposition rates relative to the field data for far-field distances, particularly under evaporative conditions" by about a factor of three. However, the AgDRIFT estimates were in good agreement (to within less than a factor of two) with "field results for estimating near-field buffer zones needed to manage human, crop, livestock, and ecological exposure." Bird and colleagues (2002) concluded that "the model appears satisfactory for regulatory evaluations…. However, greater uncertainty in the output of the model will arise when it is applied as a general screening tool and case-specific input parameters, such as wind speeds and mode of application, are not known." (emphasis added). This would be the case when, as in the chlorpyrifos example above, a general screening tool such as AgDRIFT, is used to estimate drift from air blast sprayers.

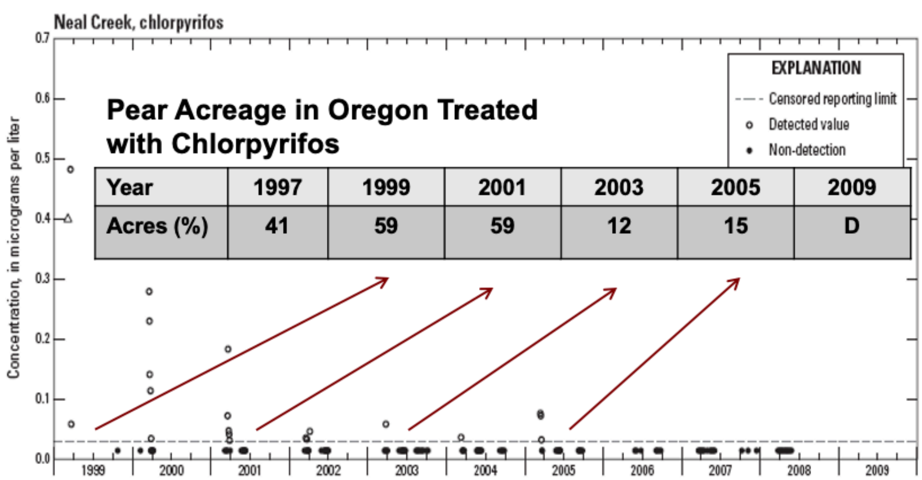

Figure 3. Detections of Chlorpyrifos in Neal Creek and acreage of pears treated with chlorpyrifos over 13 years.

For ground applications using air blast sprayers, AgDRIFT only allows for the use of simple deposition curves, and for Tier I screening-level assessments, the stochastic model of a young, dormant apple orchard is used as a surrogate for all crops, as it represents the worstcase scenario. Unfortunately, while available for aerial applications, a higher level (Tier III) approach is not available in AgDRIFT for air blast sprayer application, the most common way to apply pesticides in perennial fruit and nut crops.

When high-frequency water monitoring data from aerial applications of malathion to sweet cherry orchards near The Dalles, Oregon was compared to malathion concentration predictions made by using AgDRIFT, the predictions improved from a 43.6- to 45.7-factor overprediction with the Tier I screening-level parameterization to a 1.0- to 1.8-factor overprediction at the most refined Tier III parameterization (Winchell et al. 2018).

Over the past several years, grower groups representing producers of tree and vine fruits and nut crops on the U.S. West Coast have spent almost $500,000 to collect validation data in apples, almonds, citrus, and grapes to begin the development of a mechanistic model (Tier III) to assess drift more accurately in perennial fruit and nut crops (Willett and Thistle 2023, personal communication) but more resources are needed to complete the model. Even if the difference between the screening level model and a more refined estimate does not result in a 40x to 50x overprediction when using air blast sprayers, clearly more refined estimates are justified. Financial support to complete the development of a Tier III model for air blast sprayers would benefit the federal and state agencies in conducting more accurate assessments and would also benefit stakeholders who must live with the results of these drift assessments. In addition, more highly refined drift models for air blast sprayer applications in fruit and nut crops would help evaluate and support the adoption of proven drift reduction technology.

Communication - Bulletins Live! Two (BLT)

The EPA developed Bulletins Live! Two as a part of their Endangered Species Protection Program. These Bulletins set forth geographically specific (i.e., county, or sub-county) pesticide use limitations for the protection of threatened and endangered (listed) species and their designated critical habitat associated with that area. The approach using a resource such as BLT is meant to bring more specificity to mitigation needs, although there are numerous concerns from pesticide applicators' standpoints.

Few agricultural producers are familiar with BLTa name that lacks connection or meaning to its use and purpose for a pesticide applicator. It is incumbent on the EPA to connect more effectively with pesticide users, helping them understand the importance and relevance of the site. Additionally, access to BLT is only currently through a web browser on a desktop/laptop computer and not through a smartphone or tablet. To be accessible to all pesticide users, the program must be developed into some type of app that is accessible on mobile devices as well as computers. Access to a stable internet connection is paramount for BLT to be successful, as loading maps and other imagery can be cumbersome on less reliable internet connections.

If the decision is made to develop a mobile-accessible app, developers and the EPA would benefit from having practical input from both the Cooperative Extension System and growers. This web-based, technologically progressive approach for communicating targeted restrictions on pesticides will only be successful if applicators find the app easily understandable and available on customarily used hardware platforms.

Currently, the BLT process for accessing instructions for restricted products in some states is simple. However, when considering the nearly 1,200 registered active ingredients that could be added, the potential for confusion is a tremendous concern. This process of accessing mitigation information on BLT will likely get extremely complicated very quickly as new restrictions are added; thus, the EPA must first evaluate procedures with dozens, or even hundreds of active ingredients in each regional area. Also, concerning mapping, the ESA geographical areas which will be used to determine the mitigations listed within the BLT system should be further refined. In many instances, the available maps are developed on a county-level resolution or larger basis. This potentially overstates the affected area. Efforts should be undertaken to refine these maps to a sub-county, species-specific level. This would help ensure that needed restrictions are appropriately targeted, and an undue regulatory burden is not placed on growers to adopt application restrictions that are not necessary because the listed species are not impacted by that farm's operations.

The ideal user experience on BLT would include the ability to add multiple pesticide products into a single pesticide application event, allowing the user to provide either EPA registration numbers, pesticide chemical names, or product names. Also, a 9 to 12month time interval between implementing new restrictions on BLT and requiring pesticide users to follow them would provide stakeholders ample time to plan for planting and pest management needs.

Requiring pesticide applicators to access a webpage for specific instructions before applying a pesticide will be a significant change in standard practices for grower applicators. Reliance by the agency on web-based labeling is likely to expand over time, particularly since the introduction of many new pesticide products will include BLT references. Both EPA and registrants should ensure that the required label language regarding BLT is prominently displayed and highlighted to ensure that the important legal use information is not accidentally overlooked.

Conclusion

The challenges facing federal agencies tasked with assessing the risk of pesticide use and delivering regulatory actions to protect threatened and endangered species in a manner that minimizes the disruption to the agricultural production system are monumental. Progress has been made, but many challenges remain for the EPA to enact regulations that allow farmers to provide food security for the nation in a practicable manner. A risk assessment must be based on realistic pesticide use scenarios. Similarly, modeling predicting scientifically valid toxicity endpoints using appropriate pesticide exposure estimates when forming a risk is essential. Where the use of drift reduction technology is not captured on current pesticide labels (such as for air blast sprayers), the agency should seek to support and promote these methods. Ultimately, regulatory decisions delivered by the EPA to limit risk to listed species must also minimize the potential impacts to agricultural operations regarding the scope of their action and provide continued availability and application of important crop protection chemicals. And the burden of funding refinements and developing new tools to improve ecological exposure estimates should not completely fall on the regulated community. Only with these considerations can EPA ensure the development of an effective regulatory program.

As stated previously, agriculture is not monolithic, and a "one size fits all" approach in developing a regulatory response is not appropriate. The potentially impacted parties must have a seat at the table to better inform the EPA about making a significant change in how ESA decisions will be made.

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