Docket Number EPA-HQ-OPP-2020-0587
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Indaziflam Preliminary Work Plan

Registration Review: Initial Docket Case Number 7288

December 2020

Approved by: _____

Elissa Reaves, Ph.D.
Acting Director
Pesticide Re-evaluation Division

Date: 12-16-2020

Table of Contents

References:

This Preliminary Work Plan summarizes the Environmental Protection Agency's current position based on the following documents:

1. *Indaziflam: Human Health Risk Assessment in Support of Registration Review.* Health Effects Division. September 22, 2020.

2. *Indaziflam: Round 2 Registration Review Combined Problem Formulation and Draft Risk Assessment*. Environmental Fate and Effects Division. October 10, 2020.

3. *Indaziflam (080818) Use and Usage Memorandum to Support the Preliminary Work Plan for Registration Review.* Biological and Economic Analysis Division. December 10, 2020.

These and other supporting documents for the indaziflam registration review case may be found in the docket EPA-HQ-OPP-2020-0587 at www.regulations.gov.

OVERVIEW

The docket for indaziflam is now open, initiating the first public comment period for this registration review case (docket number EPA-HQ-OPP-2020-0587). Indaziflam is a fluoroalkyltriazine herbicide. Indaziflam prevents the germination of seeds of annual sedges, grasses, and broadleaf weeds by inhibiting cell wall biosynthesis and affecting meristematic stem growth. The Weed Science Society of America (WSSA) places indaziflam in herbicide mechanism of action (MOA) Group 29, which represents cellulose biosynthesis (CB) inhibitors.

Products containing indaziflam are registered for use in a variety of agricultural, non-crop, and residential settings for the preemergent control of annual sedge, grass, and broadleaf weed species. Registered formulations of indaziflam include: flowable concentrate, water dispersible granule, wettable powder, granular, liquid soluable concentrate, and ready-to-use spray.

This Preliminary Work Plan (PWP) document explains what the EPA knows about indaziflam, highlights anticipated data and assessment needs, identifies the types of information that would be especially useful to the agency in conducting the review, and provides an anticipated timeline for completing the registration review for indaziflam.

The registration review process was designed to include a public participation component to solicit input from interested stakeholders and the general public. The agency intends, by sharing this information in the docket, to inform the public of what it knows about indaziflam and what types of new data or other information would be helpful for the agency to receive as it moves toward a decision on indaziflam. The agency encourages all interested stakeholders to review the PWP and Appendix and to provide comments and additional information that will help the agency's decision-making process for this chemical. In addition to general areas on which persons may wish to comment, there are some areas identified in the PWP and Appendix about which the agency specifically seeks comments and information. Interested stakeholders could include: environmental non-profit or interest groups; pesticide manufacturers; agricultural labor or commodity groups; commercial, institutional, and other users of pesticides; or, the public at large.

The PWP begins by listing the anticipated data needs for indaziflam. Next, it discusses the statutory and regulatory authority for registration review. Then, the document provides chemical facts, use and usage information, recent actions, the anticipated risk assessments, and a projected registration review timeline for indaziflam. Finally, the Appendix to this document includes identification and discussion of some areas that are considered generally in registration review along with some additional chemical case-specific information.

ANTICIPATED DATA NEEDS

The agency anticipates calling-in data in support of the indaziflam registration review. These data are needed to assess the potential risks to the environment. The EPA will issue a data call-in (DCI) to obtain these data. For pollinator data requirements, the need for the higher-tiered studies will be determined after review of the Tier I studies. For more information on the agency's

approach see the June 2014 *Guidance for Assessing Pesticide Risks to Bees*. The planned studies to be required are listed in Table 1, below.

For additional discussion of the anticipated data needs, see the *Indaziflam: Round 2 Registration Review Combined Problem Formulation and Draft Risk Assessment.*

Table 1: Anticipated Data Needs for the Indaziflam Registration Review

Guideline Number[1]	Study Title	Test Material	Estimated Timeframe (Months from receipt of DCI)
Anticipated Data Needs for the Parent Indaziflam			
850.6100	Environmental chemistry methods (ECM) and associated independent laboratory validation (ILV) for soil	TGAI	12
850.1400	Fish early-life stage (saltwater)	TGAI	12
Pollinator Data Requirements[2]			
Non-guideline (OECD Test Guideline 245)	Honeybee adult chronic oral toxicity (Tier 1)	TGAI	12
Non-guideline (OECD Guidance Document 75)	Semi-field testing for pollinators (tunnel or colony feeding studies) (Tier 2)[2]	TGAI or TEP[3]	24
Non-guideline	Field trial of residues in pollen and nectar (Tier 2)[2]	TEP	24
850.3040	Field Testing for Pollinators (Tier 3)[2]	TEP	24

TGAI = technical grade active ingredient; TEP = typical end-use product

[1] OCSPP Harmonized Test Guidelines – Master List https://www.epa.gov/sites/production/files/2019-10/documents/ocspp-testguidelines_masterlist-2019-09-24.pdf

[2] The need for higher-tier tests for pollinators will be determined based upon the results of lower-tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

[3] TGAI if colony feeding study, TEP if a tunnel study.

STATUTORY AND REGULATORY AUTHORITY

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically re-evaluates

pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. Registration review is a revolving process, with chemicals going through the process no later than 15 years after either the date on which the initial registration review is completed or the date products containing the active ingredient were first registered. The publication of this PWP initiates the first round of registration review of indaziflam. The agency may issue an interim decision so that it can (1) move forward with aspects of the registration review that are complete and (2) implement interim risk mitigation. The agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively referred to as, "the Services") to improve the consultation process for national threatened and endangered (listed) species for pesticides in accordance with the Endangered Species Act (ESA) § 7. Therefore, although EPA has not yet fully evaluated risks to federally-listed species, the agency will complete its listed species assessment and any necessary consultation with the Services for indaziflam prior to completing registration review. Likewise, the agency will complete endocrine screening for indaziflam, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review.

The regulations governing registration review begin at 40 CFR § 155.40. The agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the agency will develop a Final Work Plan (FWP) with an anticipated schedule for completing the registration review of indaziflam.

CHEMICAL AND REGULATORY INFORMATION

Table 2 provides a summary of the chemical identification and pesticide facts for indaziflam.

Table 2: Chemical Facts for Indaziflam	
PC code	080818
Case Number	7288
CAS Number	950782-86-2
Year first registered	2010
Pesticide Type	Herbicide
Chemical class	Fluoroalkyltriazine
Registration Review	This is the first time that indaziflam has entered into registration review.
Cumulative group	Not applicable. Indaziflam has not been identified as a member of a cumulative group that shares a common mechanism of toxicity.

Table 2: Chemical Facts for Indaziflam	
40 CFR Citation	Tolerances for indaziflam are established in 40 CFR §180.653
Non-pesticidal uses	There are no identified non-pesticidal uses of indaziflam.
Pesticide Re-evaluation Division, Chemical Review Manager	Kent Fothergill
Registration Division, Product Manager	Emily Schmid

USE AND USAGE INFORMATION

Indaziflam is a preemergent herbicide registered for use in agricultural, non-crop, and residential settings for control of broadleaf, grass, and sedge weeds. In the absence of data to the contrary, the agency assumes that indaziflam is systemic in plants.

Table 3 summarizes the use and usage information for indaziflam. Please see *Indaziflam (080818) Use and Usage Memorandum to Support the Preliminary Work Plan for Registration Review* in the indaziflam registration review docket for more details.

Table 3: Indaziflam Use and Usage Information	
Summary of Use	Preemergent (weed) herbicide, WSSA Group 29
Use Sites	Citrus, pome, and stone fruit crops; cane and bush berries, small fruit vines; tree nuts; tropical and subtropical fruit; coffee; conifer and Christmas trees; hops; residential and golf course turf; sod farms; pasture and rangelands; ornamentals; residential, recreational and agricultural buildings (outdoor use); commercial buildings (indoor and outdoor uses); fence and hedgerows; greenhouses (indoor use); commercial and industrial yards and lots and utility/electrical areas (outdoor use); pervious and impervious paved areas; railroad and roadside rights-of-way; woodland; nature areas; and animal habitat.
Summary of Usage	Based on pounds of active ingredient applied, tree nuts (almonds, hazelnuts, pecans, pistachios, and walnuts) account for the largest amount of usage of indaziflam from 2012-2019[1]. The second and third largest usage reported, based on pounds of active ingredient applied, were in grapes (table, wine, and raisin) and pome fruit (apples and pears), respectively, from 2012-2019[1]. Reported usage in citrus and stone fruits were similar in pounds active ingredient applied, and account for the fourth largest amount used in 2012-2019[1]. Minimal usage was reported in blueberries, kiwi and olives from 2012-2019[2, 3]. No recent national-level non-agricultural usage data is available.
Formulation Type(s)	Flowable concentrate, water dispersible granule, wettable powder, granular, liquid soluable concentrate, and ready-to-use spray.

Table 3: Indaziflam Use and Usage Information	
Application Method(s)	Typically applied to soil or ground surfaces by application methods such as: aerial equipment, ground boom sprayer, vehicle drawn/mounted spreader, manually and mechanically pressurized hand sprayers, push-type spreaders, and shaker cans. Some granular formulations can be applied over existing turf foliage.
Technical Registrant(s)	Bayer
No. of Registrations	3 Section 3 technical registration; 32 Section 3 end-use registrations; 3 Section 24(c) (special local needs—SLN) registrations
Restricted Use	No

[1] Kynetec USA, Inc. 2020. The AgroTrak® Study from Kynetec USA, Inc. Access Database. [Accessed December 2020].
[2] United States Department of Agricultural National Agricultural Statistics Service (USDA NASS). 2020. QuickStats. Available at: https://quickstats nass.usda.gov/ [Accessed December 2020].
[3] California Department of Pesticide Regulation California (CDPR) Pesticide Use Reports Data Archives. 2020. Available at: ftp://transfer.cdpr.ca.gov/pub/outgoing/pur_archives/. [Accessed December 2020].

Guidance for Commenters: Additional areas of *use and usage related information* requested for this registration review, and of particular interest to the EPA, are described below.

- Certain indaziflam labels are unclear with respect to application parameters such as the size of the treated area, the extent of a treated "spot," retreatment intervals, or maximum annual application rates. Without further information, the EPA expects to use conservative assumptions to approximate these parameters in order to conduct a quantitative risk assessment. However, the agency will work with registrants to clarify information on indaziflam product labels, especially the maximum annual application rates for non-agricultural uses including golf courses, turf, and ornamental lawns.
- Confirmation of the following label information: sites of application; formulations; application methods and equipment; maximum application rates; frequency of application, application intervals, and maximum number of applications per season; and geographic limitations on use.
- Use distribution (*e.g.*, acreage and geographical distribution of relevant use sites).
- Median and 90th percentile reported use rates (lbs ai/A) from usage data – national, state, and county.
- Information on the extent to which indaziflam exhibits systemicity (*e.g.*, translaminar, acropetal, basipetal) in plants.
- Typical application timing (date of first application and application intervals) – national, state, and county.
- Usage/use information for non-agricultural uses.
- Typical application interval (days).
- State or local use restrictions.
- Foreign technical registrants not listed above who supply technical indaziflam to the US market.

RECENT ACTIONS

Products containing indaziflam were first registered in 2010 for use on residential and commercial areas (lawns, ornamentals, and hardscapes such as patios, walkways, *etc*.), turf (parks, cemeteries, golf courses, sod farms, sports fields, and commercial lawns), field grown ornamentals and Christmas trees, commercial nursery and landscape plantings, and forestry. In 2011, products containing indaziflam were registered for use on food crops: citrus, stone, and pome fruit, grapes, tree nuts, pistachios, and olives.

In 2011 tolerances were established in or on citrus fruit; pome fruit; stone fruit; tree nuts; pistachio; grape; and olive; each at 0.01 mg/kg (parts per million; ppm) and almond, hulls at 0.20 ppm (PP 9F7589). Additionally, Bayer CropScience LP requested an import tolerance for sugarcane, sugar, refined at 0.01 ppm (76 FR 18899).

In 2017 new uses of indaziflam were approved: lowbush blueberries and expansions for Crop Groups 23 (tropical and subtropical fruit, edible peel group) & 24 (tropical and subtropical fruit, inedible peel group).

In 2019, the following pesticide products were voluntary cancelled: EPA Reg. No. 72155-89, 72155-90, 72155-104, and 72155-105, which were all lawn products co-formulated with other herbicides (84 FR 9329).

In 2020 permanent tolerances were established and new uses were registered on Crop Group 17 (forage and hay) and sugarcane, and tolerances were established for ruminant commodities (85 FR 37760).

SUMMARY OF RISK ASSESSMENTS FOR REGISTRATION REVIEW

The agency completed a combined scoping document and human health risk assessment on September 22, 2020 and completed a combined problem formulation and ecological risk assessment on October 10, 2020 for registration review. These documents are available in the docket (EPA-HQ-OPP-2020-0587). These combined documents were completed because the agency concluded that the current database is adequate for human health and for certain taxa. The human health risk assessment did not identify any uncertainties or risks of concern. The ecological risk assessment identified potential risks of concern to vascular aquatic plants and terrestrial plants (monocotyledonous and dicotyledonous). There is uncertainty in the potential for adverse effects to adult bees from chronic exposure and for estuarine/marine fish with chronic exposure. Additional data were requested to address these uncertainties, listed in Table1, and a revised ecological risk assessment will incorporate these data. Once the revised ecological risk assessment has been completed, the agency can move forward with its registration review decision.

Table 4 summarizes the conclusions of the registration review risk assessments based on the Environmental Fate and Effects Division (EFED) Combined Problem Formulation and Draft Risk Assessment and the Health Effects Division Combined Scoping Document and Human Health Risk assessment.

Table 4: Summary of Risk Assessments for the Indaziflam Registration Review[1]		
Type of Risk Assessment	**Conducted?**	**Notes**
Ecological and Environmental Fate		
Comprehensive ecological (species to be assessed include terrestrial and aquatic organisms), including endangered species	Yes	Risks of concern were identified for non-listed aquatic vascular plants and terrestrial monocotyledonous and dicotyledonous plants. Data gaps were identified for terrestrial invertebrates and estuarine/marine vertebrates and will be addressed. An assessment of potential risks to Federally listed threatened/endangered ("listed") species is pending the completion (see Appendix).
Incidents	Yes	For a discussion of reported ecological incidents for indaziflam, see page 15 of the *Indaziflam: Round 2 Registration Review Combined Problem Formulation and Draft Risk Assessment.*
Human Health		
Dietary		
Food	No	No changes since previous assessment[2]. Risks of concern were not identified (risk estimates < 100% of aPAD & c PAD). Acute and chronic (food + drinking water) dietary exposure assessments were conducted incorporating tolerance-level residues and 100% crop treated assumptions. The highest aPAD was 20% for the infants <1 year old subgroup. The highest cPAD was 20% for children 1-2 years old.
Drinking water	No	No changes since previous assessment[2]. Risks of concern were not identified, there is no need to update (see above).
Occupational		
Handlers (mixers, loaders, applicators)	Yes	Combined MOEs (Margin of Exposure) range from 150 to 2,100,000 which are > Level of Concern (LOC = 100), thus no risks of concern were identified.
Post-application	Yes	Dermal MOEs range from 17,000 to 46,000 which are > Level of Concern (LOC = 100), thus no risks of concern were identified.
Residential		
Handlers	Yes	MOEs range from 380 to 3,300 for various application methods which is > LOC, thus no risks of concern were identified.
Post-application	Yes	Dermal MOEs range from 810 to 45,000 which is > LOC. Incidental oral MOEs range from 3,100 to 2,500,000 which is > LOC. No risks of concern were identified.
Other		
Aggregate	Yes	Evaluates the combined risk from dietary and residential exposures. MOE range from 360 to 2,600

		which is greater than LOC, thus no risks of concern were identified.
Cumulative	No	EPA has not made a common mechanism of toxicity finding as to indaziflam and any other substances and indaziflam does not appear to produce a toxic metabolite produced by other substances.
Tolerances	No	No tolerance changes are anticipated as part of registration review.
Incidents	Yes	For a discussion of reported human incidents for indaziflam, see page 40 of the Scoping Document and the *Indaziflam. Human Health Risk Assessment in Support of Registration Review.*

LOC=level of concern; MOE=margin of exposure; NA=not applicable
[1] EDSP screening has not been completed, please refer to appendix
2 Indaziflam. Human Health Risk Assessment in Support of the Proposed New Uses on Grasses, Sugarcane, Wildlife Management, and Rights-of-Way. Health Effects Division. April 17, 2020

Guidance for Commenters: Additional *ecological information* needed for this registration review, and of particular interest to EPA, is described below.

- Scientific studies as described in Table 1, above.
- Ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency.
- Water quality monitoring data (see Appendix for further details).
- Information on the systemicity of indaziflam in plants.

Guidance for Commenters: Additional *human health information* is not needed for this registration review. The Human Health DRA is complete and no further information is likely to be needed.

TIMELINE

The EPA has created the following estimated timeline for the completion of the indaziflam registration review in Table 5 below.

Table 5: Projected Indaziflam Registration Review Timeline

Activities	Estimated Date
Opening the Docket	
Open Docket and 60-day Public Comment Period	December 2020
Close Public Comment	February 2021
Case Development	
Final Work Plan	September 2021
Issue Data Call-In (DCI)	October-November 2021
Data Submission	October-November 2023
60-day Public Comment Period for Revised Ecological Draft Risk Assessment	June 2024

Table 5: Projected Indaziflam Registration Review Timeline	
Activities	**Estimated Date**
Registration Review Interim Decision	
60-day Public Comment Period for Proposed Interim Registration Review Decision	March 2025
Interim Registration Review Decision and Begin Post-Decision Follow-up	October 2025
Total (years)	5

NEXT STEPS

After the 60-day public comment period closes, the agency will review and respond to any comments received and then issue a Final Work Plan for the registration review of indaziflam.

Appendix – Additional Areas Considered in the Indaziflam Registration Review

PUBLIC COMMENTS AND FEEDBACK:

Guidance for Commenters: The areas below highlight topics of special interest to the agency where your comments, data submissions, or reference to sources of additional information could be of particular use.

Trade Irritants:

Through the registration review process, the agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. The agency will work to harmonize tolerances and international maximum residue limits (MRLs) and may modify tolerance levels to do so, when possible. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of MRLs or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Water Quality:

Indaziflam is not identified as a cause of impairment for any water bodies listed as impaired under § 303(d) of the Clean Water Act.[1] In addition, no Total Maximum Daily Loads (TMDL) have been developed for indaziflam.[2] More information on impaired water bodies and TMDLs can be found at the agency's website.[3] The agency invites submission of water quality data for this pesticide. Refer to the *OPP Guidance for Submission of State and Tribal Water Quality Monitoring Data*[4] for information on how the EPA's Office of Pesticide Programs uses water monitoring data in pesticide risk assessment and the information that would be useful to include in submissions of water quality data.

Environmental Justice:

The EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to indaziflam compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

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[1] https://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885

[2] http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES

[3] http://www.epa.gov/owow/tmdl/

[4] http://www2.epa.gov/pesticide-reevaluation/opp-guidance-submission-state-and-tribal-water-quality-monitoring-data

ENDANGERED SPECIES:

In 2013, the EPA, along with the Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the United States Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides.[5] These Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations that discussed specific scientific and technical issues related to the development of pesticide risk assessments conducted on federally threatened and endangered species.

Since that time, EPA has conducted biological evaluations (BEs) on three pilot chemicals representing the first nationwide pesticide consultations. These initial consultations were pilots and were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, advancements to the initial pilot interim methods have been proposed based on experience conducting the first three pilot BEs. Public input on those proposed revisions is currently being considered.

Also, a provision in the December 2018 Farm Bill included the establishment of a FIFRA Interagency Working Group to provide recommendations for improving the consultation process required under section 7 of the Endangered Species Act for pesticide registration and Registration Review and to increase opportunities for stakeholder input. This group includes representation from EPA, NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). Given this new law and that the first nationwide pesticide consultations were envisioned as pilots, the agencies are continuing to work collaboratively as consistent with the congressional intent of this new statutory provision. EPA has been tasked with a lead role on this group, and EPA hosted the first Principals Working Group meeting on June 6, 2019.

Given that the agencies are continuing to develop and work toward implementation of approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the planned ecological risk assessment supporting the registration review of indaziflam will not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although the EPA has not yet completed effects determinations for specific species or habitats, for its evaluation in support of registration review, the EPA will assume, for all taxa of non-target wildlife and plants, that listed species and designated critical habitats may be present in the vicinity of the application of indaziflam. This will allow the EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. Once that occurs, these methods will be applied to subsequent analyses for indaziflam as part of completing this registration review.

[5] https://www.epa.gov/endangered-species/draft-revised-method-national-level-endangered-species-risk-assessment-process

ENDOCRINE DISRUPTOR SCREENING PROGRAM:

As required by FIFRA and FFDCA, the EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, the EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for indaziflam, the EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA § 408(p), indaziflam is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

The EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where the EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA § 408(p), the agency must screen all pesticide chemicals. Between October 2009 and February 2010, the EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013,[6] and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Indaziflam is not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit the EPA website.[7]

In this PWP, the EPA is making no human health or environmental safety findings associated with the EDSP screening of indaziflam. Before completing this registration review, the agency will make an EDSP FFDCA § 408(p) determination."

[6] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[7] https://www.epa.gov/endocrine-disruption