IMPACTS OF COVID-19 ON ENVIRONMENTAL RULE OF LAW

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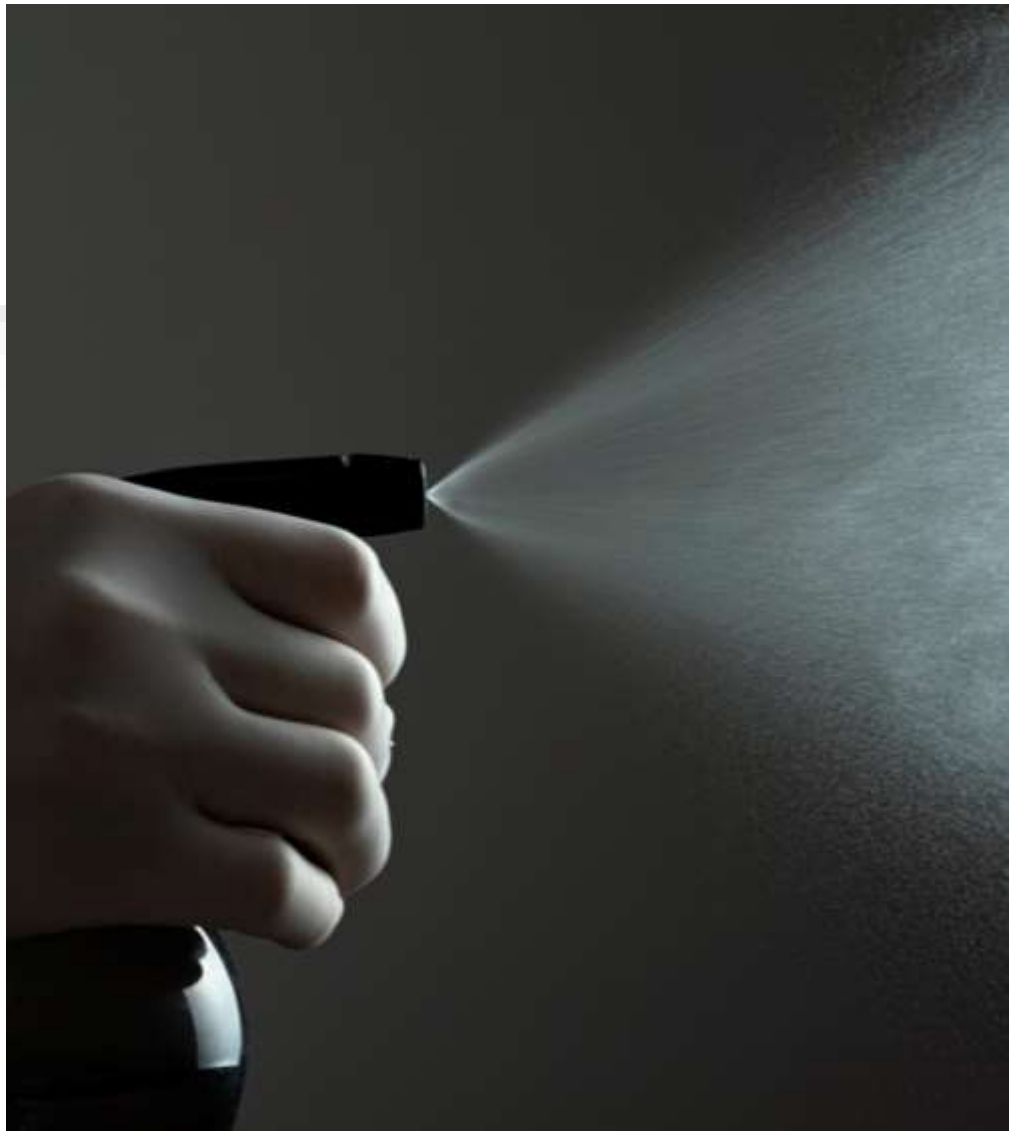
UNEP-ELI Series

ANTIMICROBIALS AND FIFRA

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) – Authorizes EPA to regulate any pesticide product that is sold and distributed in the U.S.

- Before any antimicrobial pesticide product can be lawfully sold or distributed, EPA performs a comprehensive scientific assessment of the product.
  - Product specific data (chemistry, efficacy and acute tox)
  - Generic data (human health and ecotox)
- The Agency evaluates the active ingredients, other ingredients in the product and the proposed use pattern to ensure that, when the product is used according to label directions, no unreasonable adverse effects on human health or the environment will occur.



ANTIMICROBIAL EFFICACY CLAIMS

- **Antimicrobial Pesticides**
  - Destroy or suppress microorganisms in the inanimate environment
  - Registrant must substantiate pesticidal claims with efficacy data
    - 40 CFR 158.2220 - Product performance (efficacy) data requirements

- **Public Health Claims**
  - Claim to control microorganisms affecting human health (e.g., SARS-CoV-2, MRSA)
    - Require efficacy data to be reviewed by EPA

PESTICIDE DEVICES

- Pesticide devices must work by physical means, must be an instrument or a contrivance and must not contain a substance.
    - E.g., UV lights, air filters (untreated)
- Devices require no pre-market review.
- Many devices being sold make public health claims.
- Companies cannot make false or misleading claims on their labels and must be able to substantiate any pesticidal claims.
    - Efficacy data are not submitted to or reviewed by the Agency.

For more information:
https://www.epa.gov/pesticides/pesticide-devices-guide-consumers

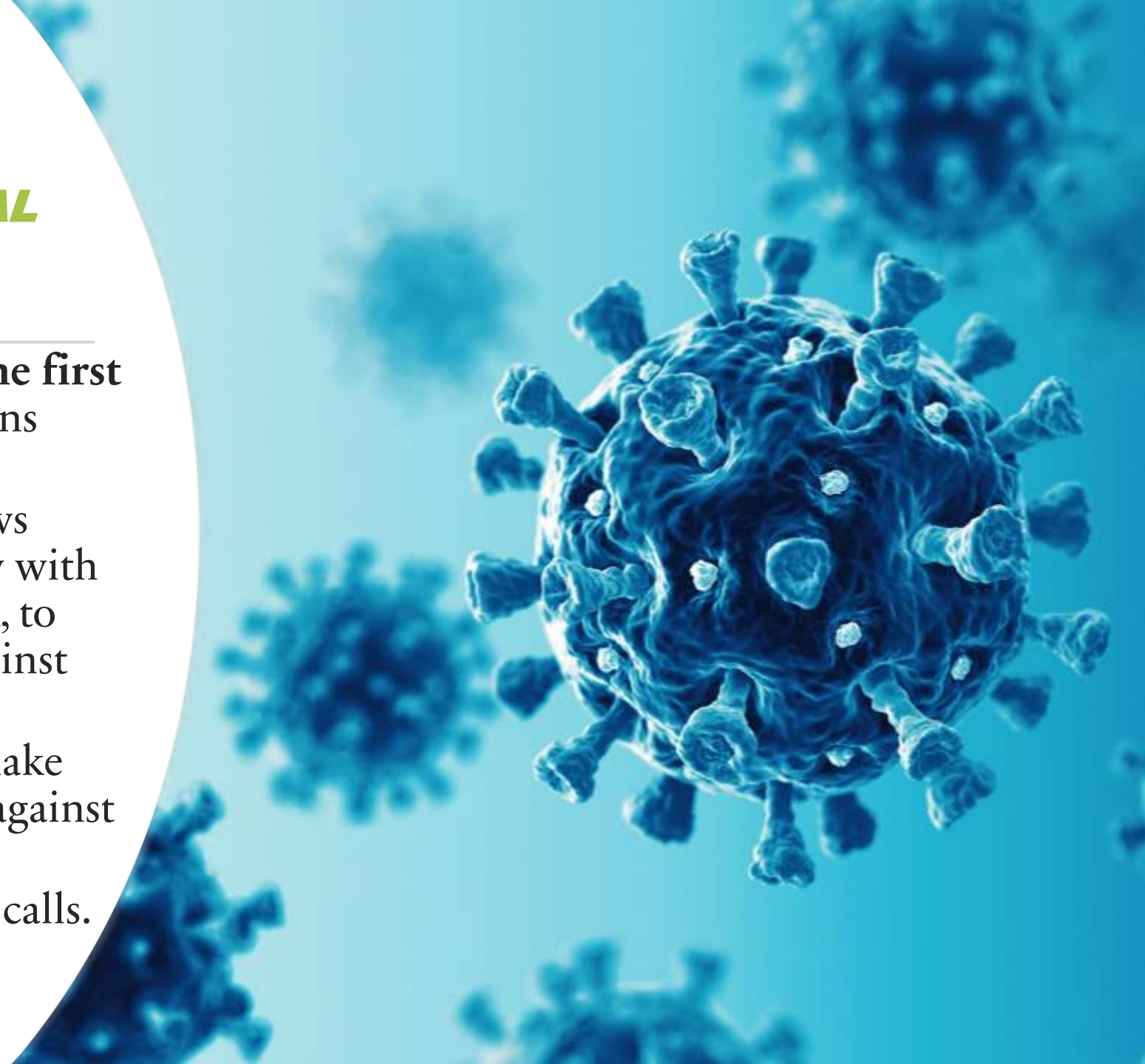
COVID-19 RESPONSE
ACTIVATED EMERGING VIRAL PATHOGENS GUIDANCE

In January 2020, EPA activated—**for the first time ever**—its Emerging Viral Pathogens Guidance for Antimicrobial Pesticides.

- Under this 2016 guidance, EPA allows manufacturers to provide the agency with data, even in advance of an outbreak, to show their products are effective against harder-to-kill viruses.

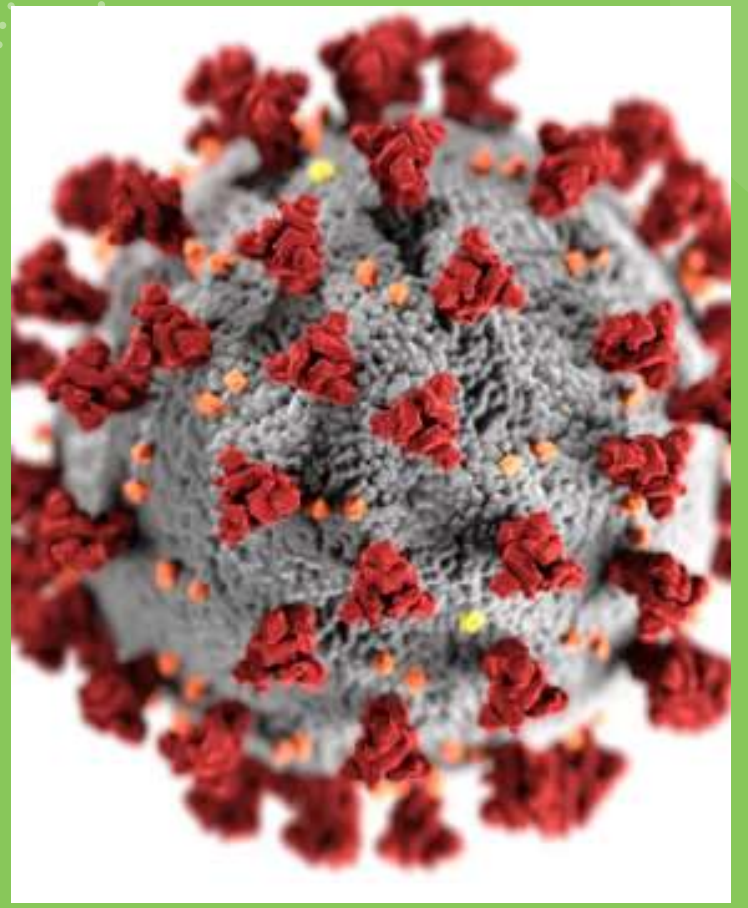
Once approved, these companies can make non-labeling marketing claims for use against the novel coronavirus.

- E.g., websites, social media, 1-800 calls.

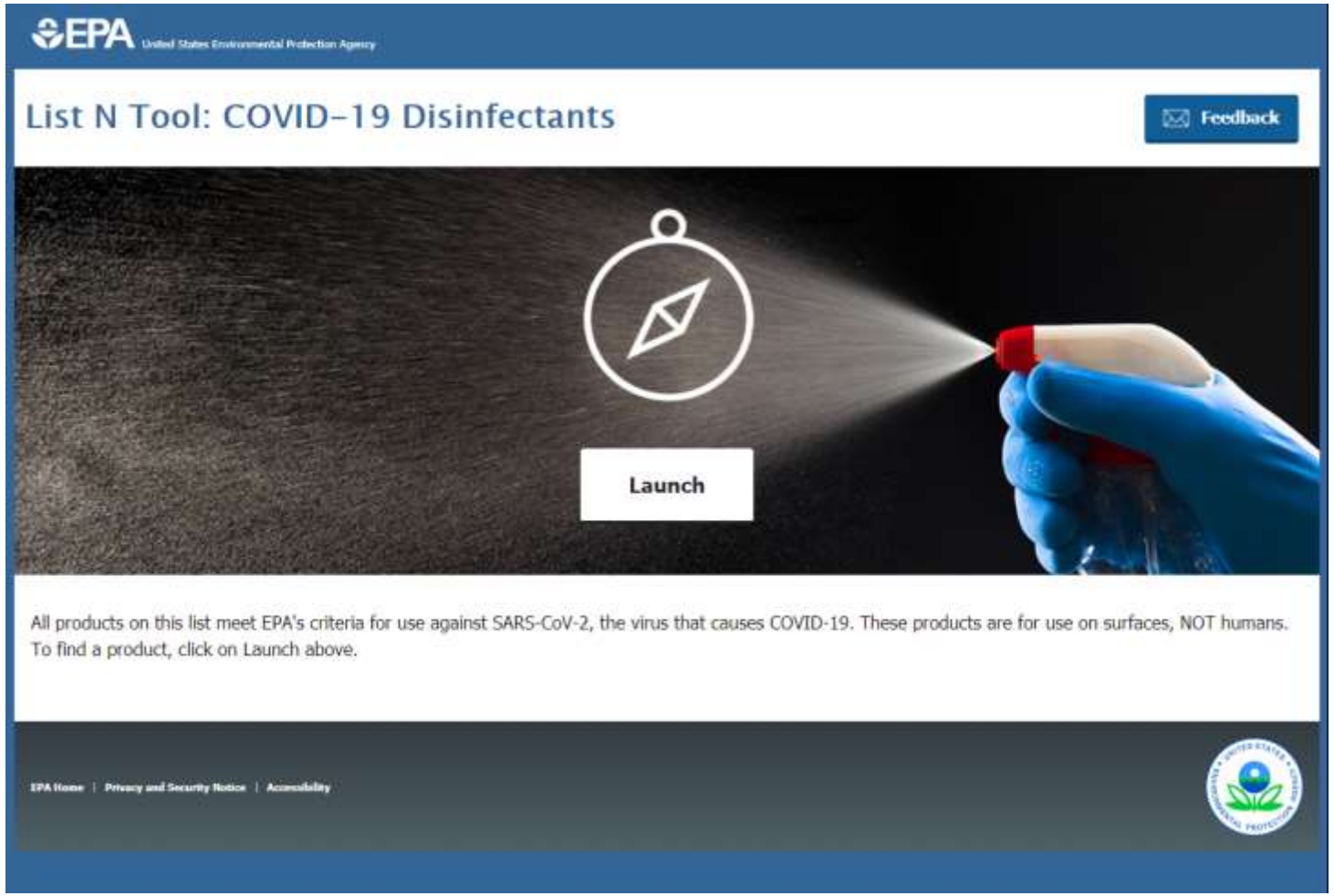


EPA DISINFECTANT LISTS AND LIST N

- EPA maintains lists of disinfectants for a number of pathogens including SARS-CoV-2 (https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants)
    - Lists are searchable and sortable
- List N includes registered liquid, wipe, spray and other products that are effective against SARS-CoV-2 because they demonstrated efficacy against SARS-CoV-2 or a pathogen that is harder to kill than SARS-CoV-2
    - 321 out of 691 products have been specifically been tested against SARS-CoV-2
- EPA's List N site has been viewed over 23 million times since it was first published in March 2020.



LIST N TOOL



Go to: https://cfpub.epa.gov/wizards/disinfectants/ or scan the QR code

COVID ADAPTATIONS

- Regulatory flexibilities
- Novel test methods and uses
- Best practices for applicators

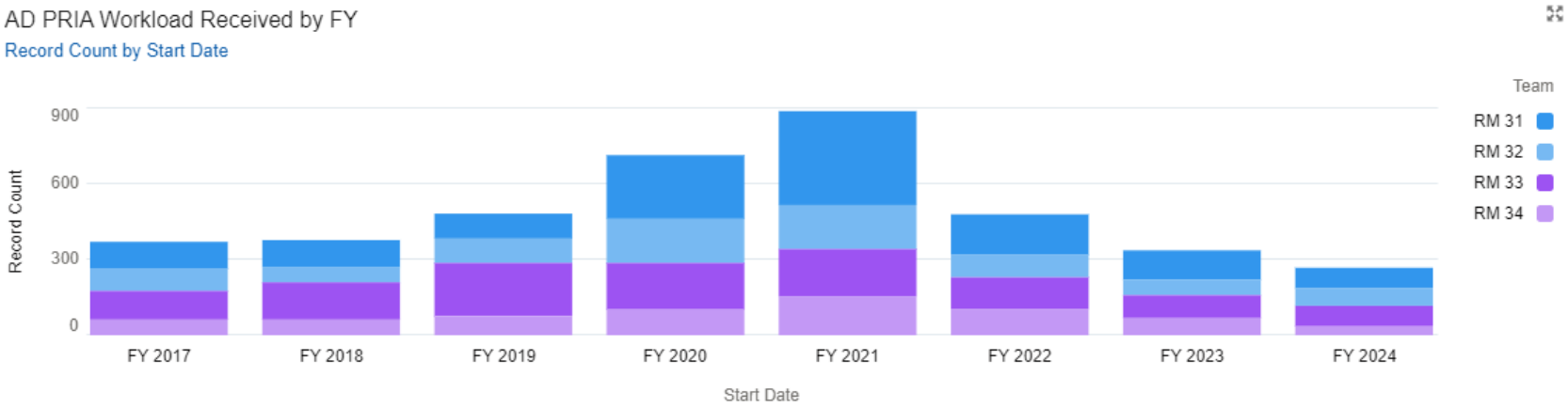
EXPEDITED REGISTRATION

In March 2020, EPA announced that it would expedite the review process for products that were eligible for emerging viral pathogen claims without requiring the review of new data. This allowed EPA to quickly add qualified products to List N.

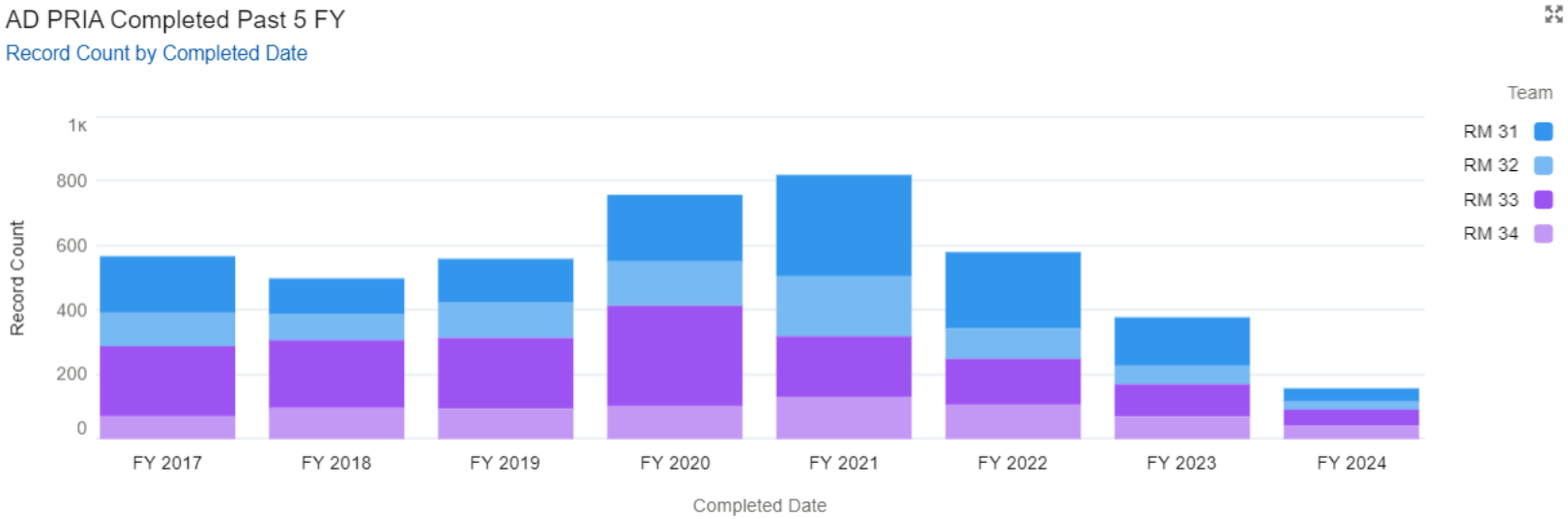
In May 2020, EPA expanded its expedited review program to include new products as well as amendments to existing product labels that require the review of new efficacy data.

In April 2021, EPA terminated expedited review of these actions.

AD Received and Completed PRIA Actions FY17-24



Received



Completed

SUPPLY CHAIN FLEXIBILITIES

PRN 98-10: Notifications, Non-Notifications and Minor Formulation Amendments

The temporary amendment to PRN 98-10, signed May 11, 2020—which included the provisions in the temporary amendments from March 30 and April 14, 2020—allowed registrants to notify EPA of certain formulation and manufacturing facility changes and immediately release the product for sale without waiting for EPA approval. In the temporary amendment, EPA emphasized that this regulatory flexibility was time-limited.

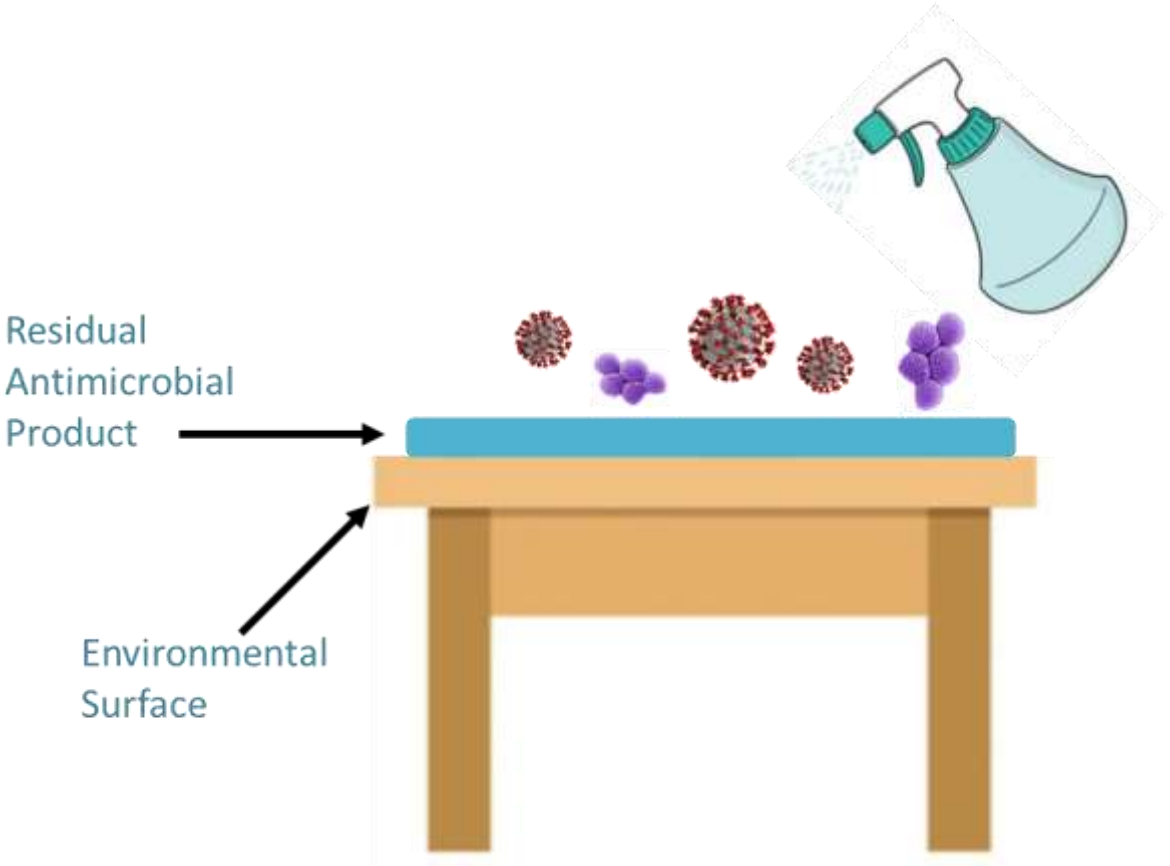
Additional Information

- Expedited Review for Products Adding Residual Efficacy

- To address reported supply chain issues, in Spring 2020, EPA created flexibilities for manufacturers by temporarily allowing registrants to notify EPA of certain formulation and manufacturing facility changes and immediately release the product for sale without waiting for EPA approval.
  - For certain active and inert ingredients, companies were able to switch suppliers without waiting for EPA approval.

- EPA terminated these flexibilities in March of 2023
  - https://www.epa.gov/pesticide-registration/prn-98-10-notifications-non-notifications-and-minor-formulation-amendments

DEVELOPMENT OF NOVEL PRODUCT TEST METHODS



- During and post-COVID there was interest in novel efficacy test methods
  - Residual ("long-lasting") Efficacy Guidance and Methods:
    - Guidance and Methods
  - Electrostatic spray (ESS)
    - Guidance
  - Products to treat air (chemical and filter)

NEW DATA DEVELOPMENT

- In July 2020, EPA began to expedite applications to add directions for use with electrostatic sprayers to products intended to kill SARS-CoV-2.
  - Electrostatic spraying has drawn increased interest because of the need to disinfect large indoor spaces or areas with many surfaces.
- In August 2020, EPA issued the first coronavirus emergency exemption (Section 18) to the state of Texas to allow use of a residual product as a surface coating that inactivates viruses and bacteria within two hours of application and continues to work against them for up to seven days.
  - Additional approvals followed for several other products: Coronavirus Section 18s
- In October 2020, EPA provided guidance and methods and announced expedited review for products making residual (long-lasting) efficacy claims.
  - The guidance and methods were finalized after review of public comment in October 2022
- Air treatment
  - In January 2021, EPA approved a Section 18 for a chemical air treatment to kill SARS-CoV-2 in the air
    - Announcement of Section 18
  - In October 2022, EPA approved the first air sanitizer to kill SARS-CoV-2 in the air
    - Announcement of air sanitizer
  - EPA is working on test methods for air filters treated with antimicrobials

GUIDANCE ON RESPIRATORY PROTECTION & RESPIRATORY FIT TESTING FOR AGRICULTURAL PESTICIDE HANDLERS

- In June 2020, EPA issued temporary guidance that outlines approaches to address the unavailability of required respiratory protection and respiratory fit testing for agricultural pesticide handlers.
    - https://www.epa.gov/pesticides/epa-releases-temporary-guidance-respiratory-protection-agricultural-pesticide-handlers
- The guidance aligned with OSHA memoranda on respirators while addressing EPA's responsibilities under FIFRA and the Agricultural Worker Protection Standard (WPS).
- Sunset in August 2021
    - https://www.epa.gov/pesticides/epa-sunsets-temporary-guidance-respiratory-protection-agricultural-pesticide-handlers

GUIDANCE FOR AGRICULTURAL AND HANDLER EMPLOYERS ON WPS PESTICIDE SAFETY TRAINING

- The Agency was aware that COVID-19 made it difficult for agricultural and handler employers to provide WPS pesticide safety training, as required by the WPS.
- In response, EPA issued guidance in June 2020 to inform agricultural and handler employers of flexibilities available under the WPS to allow continued protection for employees and agricultural production.
  - https://www.epa.gov/pesticides/epa-releases-guidance-pesticide-safety-training-requirements-during-covid-19

GUIDANCE FOR STATE, TRIBAL, AND FEDERAL CERTIFYING AUTHORITIES ON PESTICIDE APPLICATOR CERTIFICATION PROGRAMS

- EPA was also aware that state, tribal, and federal certifying authorities needed to make temporary changes to their existing pesticide applicator certification programs in response to the COVID-19 public health emergency.
- As a result, EPA issued temporary guidance in July 2020 to provide flexibilities that meet both the needs of applicators and the requirements of the Certification of Pesticide Applicators rule (40 CFR Part 171).
  - https://www.epa.gov/pesticides/epa-releases-temporary-guidance-regarding-certification-pesticide-applicators-during

Best practices for cleaning and disinfecting

https://www.epa.gov/coronavirus/cleaning-and-disinfecting-best-practices-during-covid-19-pandemic

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