

## PRE-PUBLICATION NOTICE

On January 19, 2021, **Andrew R. Wheeler**, the EPA Administrator, signed the following document:

Action: Advance notice of proposed rulemaking (ANPR)  
Title: Pesticides; Modification to the Minimum Risk Pesticide Listing Program and Other Exemptions under FIFRA Section 25(b)  
FRL #: 10016-29  
Docket ID #: EPA-HQ- OPP-2020-0537

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Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at <http://www.regulations.gov>.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 152**

**[EPA-HQ-OPP-2020-0537; FRL-10016-29]**

**RIN 2070-AK55**

**Pesticides; Modification to the Minimum Risk Pesticide Listing Program and Other Exemptions under FIFRA Section 25(b)**

**AGENCY:** Environmental Protection Agency (EPA)

**ACTION:** Advance notice of proposed rulemaking

**SUMMARY:** The Environmental Protection Agency (EPA) is soliciting public comments and suggestions about the petition process for exemptions regarding pesticides from registration and other requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), where the pesticides are determined to be of a character unnecessary to be subject to regulation under FIFRA. The Agency is considering streamlining the petition process and revisions to how the Agency evaluates the potential minimum risk active and inert substances, factors used in classes of exemptions, state implementation of the minimum risk program and the need for any future exemptions or modifications to current exemptions. EPA is also requesting comment on whether the Agency should consider amending existing exemptions or adding new classes of pesticidal substances for exemption, such as peat when used in septic filtration systems.

**DATES:** Comments must be received on or before [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2020-0537, through the Federal eRulemaking Portal at <http://www.regulations.gov>.

Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Due to public health concerns related to COVID-19, the EPA Docket Center and Reading Room are closed to the public with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For further information on EPA Docket Center services and the current status, please visit us online at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Charles Smith, Acting Director Biopesticide and Pollution Prevention Division, (7509P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-0291; email address: [BPPDFRNotices@epa.gov](mailto:BPPDFRNotices@epa.gov).

## **SUPPLEMENTAL INFORMATION**

### **I. Executive Summary**

#### *A. Does this action apply to me?*

You may be affected by this action if you manufacture, distribute, sell, or use minimum risk pesticide products. EPA has promulgated several exemptions for pesticide products of a character not requiring regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These exemptions are codified in 40 CFR 152.25. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, rather it provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Pesticide and other agricultural chemical manufacturers (NAICS codes 325320 and 325311), as well as other manufacturers in similar industries such as animal feed (NAICS code

311119), cosmetics (NAICS code 325620), and soap and detergents (NAICS code 325611).

- Manufacturers who may also be distributors of these products, which includes farm supplies merchant wholesalers (NAICS code 424910), drug and druggists merchant wholesalers (NAICS code 424210), and motor vehicle supplies and new parts merchant wholesalers (NAICS code 423120).

- Retailers of minimum risk pesticide products (some of which may also be manufacturers), which includes nursery, garden center, and farm supply stores (NAICS code 444220), outdoor power equipment stores (NAICS code 444210), and supermarkets (NAICS code 445110).

- Users of minimum risk pesticide products, including the public in general, as well as exterminating and pest control services (NAICS code 561710), landscaping services (NAICS code 561730), sports, and recreation institutions (NAICS code 611620), and child daycare services (NAICS code 624410). Many of these companies also manufacture minimum risk pesticide products.

- Government establishments engaged in regulation, licensing, and inspection (NAICS code 926150).

- Sewage treatment facilities collecting, treating, and disposing waste through sewer systems or sewage treatment facilities, (NAICS code 221320).

- Site Preparation Contractors NAICS code 238910; and septic tank pumping and cleaning services (NAICS 562991).

If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What is the Agency's authority for this action?*

This advance notice of proposed rulemaking (ANPR) is issued under the authority of FIFRA, 7 U.S.C. 136 *et seq.*, particularly FIFRA sections 3 and 25. Exemptions to the requirements of FIFRA are issued under the authority of FIFRA section 25(b). Eligible products may be exempt from, among other things, registration requirements under FIFRA section 3.

*C. What action is the Agency taking?*

EPA is considering whether regulatory and policy changes are needed to improve the exemption provisions in order to make the implementation of the process and evaluation of the exemption provisions more efficient. This ANPR initiates the rulemaking process by specifically soliciting public comments and suggestions about the petition process for exemptions regarding pesticides from registration and other requirements under FIFRA section 25(b), where the pesticides are determined to be of a character unnecessary to be subject to regulation under FIFRA. The Agency is considering streamlining the petition process and revisions to how the Agency evaluates the potential minimum risk active and inert substances, factors used in classes of exemptions, state implementation of the minimum risk program and the need for any future exemptions or modifications to current exemptions. EPA is also requesting comment on whether the Agency should consider amending existing exemptions or adding new classes of pesticidal substances for exemption, such as peat when used in septic filtration systems.

This ANPR asks the public to provide input on specific questions about the petition process and the evaluation of potential minimum risk active and inert substances, factors used in classes of exemptions listed at 40 CFR 152.25, state implementation of the minimum risk program and the need for any future exemptions or modifications to current exemptions. EPA is assessing whether changes to the exemption process could improve efficiency and enhance opportunities for reducing regulatory requirements.

EPA regulations at 40 CFR 152.20 provide certain exemptions for pesticides adequately regulated by another Federal agencies. 40 CFR 152.30 provides exemptions for pesticides that are context-specific (e.g., pesticides distributed or sold under an emergency exemption under FIFRA section 18); the exemptions in 40 CFR 152.30 are not limited to specific pesticides. Because the exemptions in 40 CFR 152.20 and 152.30 are in general not based on risk analysis of individual pesticides, they are not the subject of this ANPR.

*D. What are the incremental economic impacts of this action?*

This ANPR does not impose or propose any requirements, and instead seeks comments and suggestions that will help the Agency identify, develop and consider improvements to the FIFRA section 25(b) petition process and related requirements. If EPA decides to propose changes to the regulations, it will conduct the appropriate assessments of the costs and benefits of those changes and provide opportunities for public comment.

*E. What should I consider as I prepare my comments for EPA?*

*1. Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

*2. Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## **II. Request for Comment**

EPA invites public suggestions for improving the exemption provisions in order to make the implementation of the process and evaluation of the exemption provisions more efficient. EPA is particularly interested in public feedback on the questions posed in this document regarding the implementation and evaluation of the exemption provisions of the Minimum Risk Pesticide Listing Program and the other exemptions codified at 40 CFR part 152.25. Please provide EPA with your thoughts as well as a rationale supporting your suggestions. If you can, provide examples or describe situations. Commenters are encouraged to present any data or information that should be considered by EPA during the program review, and is particularly interested in information regarding the impacts of exemptions, both in terms of costs and costs savings. For instructions on how to submit comments see Unit I.E. and the ADDRESSES section of this document.

## **III. Background**

### *A. Brief Summary of the EPA's Use of the Authority in FIFRA Section 25(b)*

Under FIFRA section 25(b)(2), EPA may exempt from the requirements of FIFRA any pesticide that is “of a character unnecessary to be subject to [FIFRA].” Pursuant to this authority, in 1988 (53 FR 15952, May 4, 1988) (FRL-3266-9b), EPA promulgated 40 CFR 152.25(a) through (e) which provided the initial determinations that certain classes of pesticides would be exempt from FIFRA regulation. The classes include Treated articles or substances (40 CFR 152.25(a)), Pheromones and pheromone traps (40 CFR 152.25(b)), Preservatives for biological specimens (40 CFR 152.25(c), Vitamin hormone products (40 CFR 152.25(d)) and Foods (40 CFR 152.25(e)). The final rule was amended in 1994 (59 FR 2751, January 19, 1994)(FRL-4744-6) to include Natural Cedar (40 CFR 152.25(f)).

In 1996, EPA promulgated 40 CFR 152.25(g), which exempted from FIFRA any pesticide product consisting solely of specified ingredients that EPA determined to pose minimum risk to humans and the environment (61 FR 8876, March 6, 1996) (FRL-4984-8). This provision was later redesignated as 40 CFR 152.25(f) (66 FR 64759, December 14, 2001) (FRL-6752-1). In 2001, EPA also moved provisions related to vitamin hormone products to 40 CFR 152.6(f) (66 FR 64759, December 14, 2001) (FRL-6752-1). The exemption provision in what is now 40 CFR 152.25(f) was the start of the Minimum Risk Pesticide Listing Program, which covers the listing of active and inert ingredients as minimum risk substances that are available for use in minimum risk pesticide products. Currently, forty-four active ingredient substances and two hundred and eighty-seven inert ingredient substances, as well as commonly consumed food commodities, animal feed items, and edible fats and oils as described in 40 CFR 180.950 (a), (b) and (c), respectively, are included in the Minimum Risk Pesticide Listing Program.

The Minimum Risk Pesticide Listing Program (152.25(f)) has been amended several times over the years. The last amendment was in 2015 when EPA issued a final rulemaking entitled, Pesticides; Revisions to Minimum Risk Exemption (80 FR 80660) (FRL-9934-44) December 28, 2015). The 2015 amendment improved the clarity and transparency of the minimum risk exemption by codifying the inert ingredients list and by adding specific chemical identifiers, where available, for all eligible active and inert ingredients. The 2015 rule also modified the labeling requirements for the exemption to require products to list ingredients on the label with a designated label display name and to provide the producer's contact information on the product label. The specific chemical identifiers and the labeling changes were intended to make it easier for manufacturers, the public, and Federal, state, and tribal inspectors to determine the specific chemical substances that are permitted in minimum risk pesticide products and

provide more consistent information for consumers.

In the March 1996 final rule, EPA wrote that “In developing its list of exempted substances, EPA applied certain factors. Consideration was given to such factors as: 1) Whether the pesticidal substance is widely available to the general public for other uses; 2) If it is a common food or constituent of a common food; 3) If it has a nontoxic mode of action; 4) If it is recognized by the Food and Drug Administration (FDA) as safe; 5) If there is no information showing significant adverse effects; 6) If its use pattern will result in significant exposure, and 7) If it is likely to be persistent in the environment.” (61 FR 8876, March 6, 1996) (FRL-4984-8).

#### *B. Petition Process and Rulemaking*

Under the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, the public can petition EPA ask the Agency to consider whether a new substance should be added to the list of active ingredients eligible for the minimum risk pesticide listing exemption in 40 CFR 152.25(f)(1) or the list of inert ingredients in 40 CFR 152.25(f)(2). EPA reviews the petition and may grant or deny the petition request. If the Agency decision is to grant the petition, EPA would generally publish in the *Federal Register* a proposed rule (also known as a Notice of Proposed Rulemaking or NPRM). Supporting documents for a proposed rule are made available in the corresponding official docket created for the rulemaking and available through the Federal eRulemaking Portal at <http://www.regulations.gov>. Once the proposed rule publishes, the public has an opportunity to provide comments. EPA considers the comments received on the proposed rule, addressing comments and making revisions to the proposed revisions based on those comments, and issues a final rule. The rulemaking record is updated when the final rule publishes in the *Federal Register* and the regulatory provisions are codified in Title 40 of the *Code of Federal Regulations* (CFR). Petitions are considered by EPA on a case-by-case basis.

EPA invites the public to comment on the petition process and how it relates to the Minimum Risk Pesticide Program.

1. Do you have any suggestions for improving the processes for initiating a review of a substance or for implementing a decision that a substance may be used or may no longer be used in a minimum risk pesticide process? Please explain how changes could increase efficiencies.

2.

### *C. Evaluation of Minimum Risk Pesticide Ingredients*

As described in Unit III.B., the public can petition EPA under the APA to request that the Agency consider whether a substance should be added to the list of active or inert ingredients eligible for inclusion in minimum risk pesticide products. To determine whether to grant or deny that petition, EPA applies the risk assessment factors described in the March 1996 final rule, as well as additional factors currently relevant to pesticide risk assessment. The risk factors from March 1996 include: 1) Whether the pesticidal substance is widely available to the general public for other uses; 2) If it is a common food or constituent of a common food; 3) If it has a nontoxic mode of action; 4) If it is recognized by the Food and Drug Administration (FDA) as safe; 5) If there is no information showing significant adverse effects; 6) If its use pattern will result in significant exposure, and 7) If it is likely to be persistent in the environment.

Currently, the EPA's pesticide registration risk assessment process considers the original seven factors described in the previous paragraph as part of a weight-of-the evidence approach, but also routinely considers the following additional six factors to determine whether the substance in question: 1) Is likely to have carcinogenic or endocrine disruptor properties; 2) Is likely to cause human health developmental, reproductive, mutagenic, or neurotoxicity issues; 3) Is a known allergen or a known allergenic source or a potential allergen; 4) Is associated with

developmental toxicity/adverse effects to mammals, birds, aquatic organisms, insects, plants; 5) Produces or could produce toxic degradates; and 6) Has the potential to be contaminated with toxic or allergenic impurities.

EPA invites the public to comment on the factors described in this unit that are used to evaluate substances for consideration under the Minimum Risk Pesticide Listing Program.

1. Considering the previous discussion, are these factors appropriate for EPA to consider in determining whether a substance should be exempted from FIFRA regulation via the minimum risk exemption?

2. Are there other factors that should be considered? Please explain how these factors should be weighed in a minimum risk determination.

#### *D. Regulation of the Provisions on Exempted Classes of Pesticides*

In addition to substances that may be formulated into pesticide products, the regulations at 40 CFR 152.25 exempt several classes of pesticides from registration under FIFRA due to their unique and specific character. For example, under 40 CFR 152.25(b), pheromones need not be registered under FIFRA if, for example, they are formulated into traps. The pheromone compound itself must either be naturally produced by an arthropod or a synthetically produced compound which is identical or substantially similar to the naturally produced pheromone with only slight variations to the compound as allowed by the regulation (40 CFR 152.25(b)(2) or (3)). EPA has determined that such products pose little risk to humans or the environment, as exposure is expected to be low and not likely distinguishable from the highest levels encountered naturally on days of heavy arthropod presence.

Another category, under 40 CFR 152.25(e), exempts from FIFRA registration products consisting only of natural cedar in certain forms (blocks, chips, shavings, needles, etc.), if the

natural cedar meets certain criteria. To be eligible for this exemption, the product must be natural cedar or cedarwood and the product must not be treated, combined, or impregnated with any additional substances. Labeling claims for natural cedar or cedar wood products must be limited to specific arthropods or must exclude ticks if any general term such as “arthropods,” “insects,” “bugs,” or any other broad inclusive term, is used. Excluded from exemption are products formulated with cedarwood oil, a form of cedar more likely to be involved in accidental exposure via the eye, dermal or oral routes. For pests of significant public health importance, such as ticks, efficacy data and other registration data needs to be evaluated to ensure protection of human health and the environment.

In some situations, an exemption like those codified in 40 CFR 152.25(a) through (e) may be preferable to a listing under the Minimum Risk Pesticides Listing Program in 40 CFR 152.25(f). A minimum risk exemption would include all uses of a product consisting of eligible ingredients, provided that the labeling and other generic requirements are met. Other exemptions are more targeted as to the nature of the use, even as they are in some cases more general with respect to what ingredients are included. EPA believes that exemptions like those codified in 40 CFR 152.25(a) through (e) may be more appropriate for situations where the exemption sought is narrowly tailored to a specific use pattern or where the pesticide functions via complex chemical processes that do not lend themselves to identification and listing of active and inert ingredients.

As these examples show, EPA has exempted some minimum risks products with pesticidal properties and uses from FIFRA regulation separately from the list of minimum risk pesticide ingredients. These include, like cedar, unrefined natural products that lack a specific formulation and products with a specific form or application, such as pheromone traps. One example of an unrefined natural product which currently lacks a specific formulation is peat.

Peat is an accumulation of partially decomposed organic material found in peatlands or bogs, and has uses as fuel, in gardening, and in certain types of septic filtration systems. While the use of peat in septic systems may be intended for a pesticidal (antimicrobial) purpose, it has been suggested that registration of such uses may not be necessary in order to carry out the purposes of FIFRA. In the context of this ANPR, EPA is interested in comments about whether there may be criteria that could address such circumstances or if EPA should consider proposing the creation of an exemption from FIFRA registration for the specific use of peat in septic filtration systems. In considering such an exemption, because of the public health and environmental interests at stake, should EPA also consider which label and labeling claims might be considered false or misleading for these systems (i.e., they could not be marketed to perform controls that they cannot be shown to achieve), and whether such circumstances warrant the consideration of any other limitations on the exemption from FIFRA registration.

EPA invites the public to comment on the following questions on the current classes of pesticide exemptions found in 40 CFR 152.25 or on other aspects of the Minimum Risk Pesticides Listing Program.

1. EPA broadly requests comment on the utility, clarity, functioning, and implementation of the provisions in 40 CFR 152.25.

2. Are there other pesticidal substances or systems, like peat as mentioned above, that the EPA should consider adding as a new class at 40 CFR 152.25 for exemption from registration under FIFRA?

3. What other factors should EPA consider in determining whether a category or class of products should be exempted from FIFRA regulation? Please explain how these factors should be weighed in a determination.

### *E. Minimum Risk Pesticide Program Exemption*

Currently, to be eligible for the minimum risk exemption, a pesticide product must meet the following conditions:

**Condition 1:** The product's active ingredients must all be listed in 40 CFR 152.25(f)(1).

**Condition 2:** The product's inert ingredients may only be those that are:

- Listed in Table 2 of 40 CFR 152.25(f)(2)(iv); or
- A commonly consumed food commodity, animal feed item, or edible fat and oils as described in 40 CFR 180.950(a) through (c) as given in 40 CFR 152.25(f)(2)(i) through (iii).

**Condition 3:** All the ingredients (both active and inert) must be listed on the label. The active ingredient(s) must be listed by the label display name in 40 CFR 152.25(f)(1) and their percentage by weight in the product.

**Condition 4:** The product must not bear claims to control or to mitigate microorganisms that pose a threat to human health or claims to control insects or rodents carrying specific diseases.

**Condition 5:** The name of the producer or the company for whom the product was produced, and the company's contact information must be displayed prominently on the product label.

**Condition 6:** The label cannot include any false or misleading statements.

A pesticide product that meets all of these conditions is exempt from federal regulation under FIFRA. EPA does not review products that claim to meet the criteria set by 40 CFR 152.25(f), and companies do not report such products to EPA. However, states may enforce and often have their own requirements regarding minimum risk products. In 2019, a majority of states required products that are exempt from federal regulation under 40 CFR 152.25(f) to

adhere to some form of state regulation, varying from a simple fee to complete state registration.

The states have reported that the regulation of federally exempt products has presented some challenges for the states. EPA's previous response to the state concerns prompted the 2015 rule change to the federal program. The 2015 amendment codified the inert ingredients list by adding specific chemical identifiers, where available, for all eligible active and inert ingredients. The 2015 rule also modified the labeling requirements for the exemption to require products to list ingredients on the label with a designated label display name and provide the producer's contact information.

EPA invites the public to comment on the following questions on the Minimum Risk Pesticide Listing Program or the minimum risk exemptions and solicits comments on other aspects of the Minimum Risk Pesticide Listing Program.

1. Have the changes to the federal program in the 2015 rule, which provided specific chemical identifiers and the labeling changes, made it easier to identify specific chemicals used in minimum risk pesticide products?

2. Are there state challenges to implementing the minimum risk program you would like to share with EPA? Do you have suggestions for improvements to the program to address these issues?

#### **IV. Next Steps**

EPA intends to review all the comments and information received in response to this ANPR, as well as previously collected and assembled information, to help determine whether to propose any additions or modifications to the Minimum Risk Pesticide Listing Program or related policies and to the class exemptions or the other provisions at 40 CFR 152.25. In addition to comments received in response to this ANPR, EPA may seek additional information from

states, industry or other stakeholders. Should EPA decide to move forward with changes to the program, the next step would be to identify, develop and evaluate specific options for amending the current regulations in 40 CFR 152.25, and issue a proposed rule for public review and comment. During the development of the proposed rule, the Agency may also engage stakeholders or provide other opportunities to comment on EPA's proposal.

#### **IV. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review.*

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

*B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs*

This action is not subject to the provisions in Executive Order 13771 (82 FR 9339, February 3, 2017) because it does not impose or amend regulatory requirements.

*C. Other Regulatory Assessment Requirements*

Because this action does not impose or propose any requirements, and instead seeks comments and suggestions for the Agency to consider in possibly developing a subsequent proposed rule, the various other review requirements in statutes and Executive Orders that apply when an agency impose requirements do not apply to this ANPR. Should EPA subsequently determine to pursue a rulemaking, EPA will address the statutes and Executive Orders as applicable to that rulemaking.

As part of your comments on this ANPR, please include any comments or information that you believe could help the Agency assess the potential impact of a subsequent regulatory action with regard to the following:

Potential economic impacts on small entities pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

Potential applicability of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (15 U.S.C. 272 note);

Potential environmental health or safety effects on children pursuant to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997);

Potential human health or environmental effects on minority or low-income populations pursuant to Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994); and

Potential impacts to state and local governments or tribal governments.

The Agency will consider such comments during the development of a subsequent rulemaking as it takes appropriate steps to address any applicable requirements.

Administrator’s Digital Signature on Document identified as FRL-10016-29, entitled  
“Pesticides; Modification to the Minimum Risk Pesticide Listing Program and Other Exemptions  
under FIFRA Section 25(b)”

**List of Subjects in 40 CFR Part 152**

Environmental protection, exemptions from pesticide regulation and minimum risk  
pesticides.

Dated: \_\_\_\_\_.

**Andrew Wheeler,**

*Administrator.*