

Agency	Law	Name/description	CFR Citation	2017		2018	
				Min penalty (rounded to nearest dollar)	Max penalty (rounded to nearest dollar)	Min penalty (rounded to nearest dollar)	Max penalty (rounded to nearest dollar)
OWCP	Black Lung Benefits Act.	Failure to secure payment of benefits for mines with fewer than 25 employees.	20 CFR 726.302(c)(2)(i).	136		139	
OWCP	Black Lung Benefits Act.	Failure to secure payment of benefits for mines with 25–50 employees.	20 CFR 726.302(c)(2)(i).	272		278	
OWCP	Black Lung Benefits Act.	Failure to secure payment of benefits for mines with 51–100 employees.	20 CFR 726.302(c)(2)(i).	409		417	
OWCP	Black Lung Benefits Act.	Failure to secure payment of benefits for mines with more than 100 employees.	20 CFR 726.302(c)(2)(i).	544		555	
OWCP	Black Lung Benefits Act.	Failure to secure payment of benefits after 10th day of notice.	20 CFR 726.302(c)(4).	136		139	
OWCP	Black Lung Benefits Act.	Failure to secure payment of benefits for repeat offenders.	20 CFR 726.302(c)(5).	409		417	
OWCP	Black Lung Benefits Act.	Failure to secure payment of benefits.	20 CFR 726.302(c)(5).		2,795		2,852.

Signed at Washington, DC, this 22nd day of December, 2017.

**R. Alexander Acosta,**

Secretary, U.S. Department of Labor.

[FR Doc. 2017–28224 Filed 12–29–17; 8:45 am]

**BILLING CODE 4510–HL–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 573**

[Docket No. FDA–2017–F–2130]

**Food Additives Permitted in Feed and Drinking Water of Animals; Formic Acid as a Feed Acidifying Agent in Complete Poultry Feeds**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA, we, the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of formic acid as a feed acidifying agent in complete poultry feeds. This action is in response to a food additive petition filed by BASF Corp.

**DATES:** This rule is effective January 2, 2018. Submit either written or electronic objections and requests for a hearing by February 1, 2018. See section

V of this document for information on the filing of objections.

**ADDRESSES:** You may submit objections and requests for a hearing as follows:

*Electronic Submissions*

Submit electronic objections in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2017–F–2130 for “Food Additives Permitted in Feed and Drinking Water of Animals; Formic Acid as a Feed Acidifying Agent in Complete Poultry Feeds.” Received objections will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies in total. One copy will include the information you claim to be

confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of objections. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your objections and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper objections received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6729, [chelsea.trull@fda.hhs.gov](mailto:chelsea.trull@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In a document published in the **Federal Register** of May 30, 2017 (82 FR 24611), FDA announced that we had filed a food additive petition (animal use) (FAP 2301) submitted by BASF Corp., 100 Park Ave., Florham Park, NJ 07932. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of formic acid as a feed acidifying agent in complete poultry feeds.

**II. Conclusion**

FDA concludes that the data establish the safety and utility of formic acid as an acidifying agent in complete poultry feeds and that the food additive regulations should be amended as set

forth in this document. This is not a significant regulatory action subject to Executive Order 12866.

**III. Public Disclosure**

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

**IV. Environmental Impact**

The Agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment, nor an environmental impact statement is required.

**V. Objections and Hearing Requests**

Any person who will be adversely affected by this regulation may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

**List of Subjects in 21 CFR Part 573**

Animal feeds, Food additives. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

**PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS**

■ 1. The authority citation for part 573 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348.

■ 2. In § 573.480, revise paragraph (b) introductory text and paragraph (b)(5)(iii)(B) to read as follows:

**§ 573.480 Formic acid.**

\* \* \* \* \*

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine and poultry feeds at levels not to exceed 1.2 percent of the complete feed.

\* \* \* \* \*

(5) \* \* \*

(iii) \* \* \*

(B) Contact address and telephone number for reporting adverse reactions or to request a copy of the Safety Data Sheet (SDS).

\* \* \* \* \*

Dated: December 26, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-28251 Filed 12-29-17; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 864**

[Docket No. FDA-2017-N-6780]

**Medical Devices; Hematology and Pathology Devices; Classification of the Whole Slide Imaging System**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the whole slide imaging system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the whole slide imaging system’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.