Department of Health and Human Services

Food and Drug Administration

Import Tolerances for Residues of Unapproved New Animal Drugs in Food

Docket No. FDA-2001-N-0075

Final Regulatory Impact Analysis

Final Regulatory Flexibility Analysis

Final Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule will simply codify the procedures that are currently used for the import tolerance program, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before finalizing "any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Cost and Benefits

Firms are currently able to request that we establish or amend an import tolerance. The final rule will not change the current procedures for these requests. Thus, we only include the incremental costs of reading and understanding the final rule on import tolerance procedures.

In Table 1, FDA provides the Regulatory Information Service Center (RISC) and Office of Information and Regulatory Affairs Consolidated Information Center accounting information.

Table 1. Economic Data: Costs and Benefits Statement

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year					7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative	Codifying current practices of the import tolerance program could improve the efficiency of the system.						
Costs	Annualized Monetized $millions/year	<$0.0001	<$0.0001	<$0.0001	2020	7%	10 years	
		<$0.0001	<$0.0001	<$0.0001	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: No Effect Small Business: The final rule will not have a significant impact on a substantial number of small entities that manufacture unapproved drugs that are the subject of an import tolerance request. Wages: No effect Growth: No effect							

C. Comments on the Preliminary RIA and Our Responses

We received two public comments to the proposed rule that specifically address the Proposed Regulatory Impact Analysis (PRIA) of the proposed rule. Each of these comments address multiple issues within the analysis. We discuss these issues as separate comments.

Comment 1) We received comments that the final rule would affect consumer confidence in imported foods. One commenter claims that the rule would cause the "further erosion of the confidence that U.S. consumers have in catfish and catfish-like products due to on-going residues found of antibiotics and carcinogens in imports of catfish and catfish-like products." A second commenter also mentioned the loss of consumer confidence in the safety of imported foods due to the establishment of import tolerances.

Response 1) We disagree with both comments. The import tolerance system has been in operation for more than 20 years. Over this time, we have not established an import tolerance for an unapproved drug used in imported catfish, nor have we observed a loss of consumer confidence in the safety of imported foods attributable to an established import tolerance.

Comment 2) We received comments that the final rule would offer a production cost advantage to foreign producers. One commenter claims that the rule would result in the loss of hundreds of millions of dollars in lost sales to the domestic catfish industry. Another commenter suggests that similar issues will occur in other (non-fish) U.S. agriculture industries.

Response 2) We disagree with these comments. The commenters do not offer any data to substantiate their forecast that the final rule will cause millions of dollars in lost sales to domestic producers or provide any data to show that those import tolerances established to date have adversely effected domestic markets. Congress established import tolerances to facilitate international trade of foods of animal origin. The statute could benefit foreign producers of

foods, creating marginal transfers of sales of food products from one domestic food producer to foreign food producers. As discussed, however, the history of this program does not show a large influx of import tolerance requests for animal drugs for food products of animal origin. Because the final rule will not change the existing import tolerance procedures, we don't anticipate that the final rule will cause any changes in the behavior of domestic and foreign producers.

Comment 3) Another comment states that "FDA should account for costs consumers and manufacturers of competing animal drugs will incur in responding to requests for a tolerance". A second comment made a similar point.

Response 3) We disagree with these comments. We do not estimate any costs to consumers or manufacturers of competing animal drugs since they will not take part in responding to requests for an import tolerance. Only we will respond to a request for an import tolerance.

Comment 4) One comment to the proposed rule questions our estimate that we would receive about two import tolerance requests annually. The comment implies that we would receive many more import tolerances annually because of the rule.

Response 4) We disagree with the comment stating that we will receive more than about two import tolerance requests annually. Since 1996, we have received less than one import tolerance request annually, and do not believe that merely codifying the current practices will cause a significant increase in the number of requests submitted annually. Moreover, based on the history of the import tolerance system we change our estimate of the number of annual import requests that we use in our final analysis to about one every two years, with a small range around that figure.

Comment 5) We received a comment that we should include the costs of adding and conducting new tests in our import sampling and testing program to account for the rule's requirement for a practicable method to determine the quantity of an unapproved drug subject to an established import tolerance.

Response 5) We agree with the comment that the government incurs costs to validate the method for testing the level of an unapproved drug with an established import tolerance and to test for the unapproved drug under our import sampling and testing program. Because we have been accepting and processing import tolerance requests for over 20 years, these current validation and testing costs are not a result of the final rule.

Comment 6) One commenter requests that because some drug manufacturers may seek an import tolerance rather than a new animal drug approval, we should include lost revenues in the calculation of government costs due to this rule.

Response 6) We disagree that animal drug manufacturers seek import tolerances in lieu of new animal drug applications because we have no data or anecdotal evidence to suggest this has occurred over the last 20 years. Moreover, the commenter does not provide any data to support this claim. Because we expect the number of import tolerance requests to stay the same, we expect government costs to stay the same.

Comment 7) We received a comment to the proposed rule that addressed the benefits section of the analysis. It stated that we failed to identify any benefit accruing to consumers, and requested that we identify and quantify the benefits consumers would experience.

Response 7) We disagree with this comment. Codifying the current practices of the import tolerance procedures might improve the efficiency of the system for both industry and

government. However, the comment contains no data on benefits to consumers and we lack data to estimate any benefits to consumers.

D. Summary of Changes

The final rule is fundamentally the same as the proposed rule. However, we made organizational changes from the proposed rule to the final rule to clarify that the rule also pertains to import tolerances established by FDA on the Commissioner's initiative as well as those established by request.

II. Final Regulatory Impact Analysis

A. Background and Purpose of the Rule

We are finalizing procedures to establish, amend or revoke an import tolerance for a new animal drug that has not been approved or conditionally approved for use in the United States. Import tolerances provide a basis for legally marketing food of animal origin that is imported into the United States containing residues of unapproved new animal drugs. We have accepted and acted on import tolerance requests for about twenty years, as the import tolerance system was provided for by Congress in the 1996 Animal Drug Availability Act (ADAA). The final rule, therefore, sets forth in codified language the information that a requester would need to submit to support the establishment or amendment of an import tolerance. This information may include data submitted to appropriate regulatory authorities in any country where the new animal drug is used legally, or data available from a relevant international organization such as the Codex Alimentarius Commission. The final rule also requires that requests to establish or amend an import tolerance include a practicable validated method for measuring the residue level of the

new animal drug in the imported edible product derived from animals treated with the new animal drug. The final rule also allows for the public disclosure of requests to establish or amend an import tolerance, information supporting such requests, and notices establishing, amending, or revoking import tolerances. In addition, the final rule describes procedures for revoking an existing import tolerance if scientific evidence shows the tolerance to be unsafe or if information demonstrates that use of the new animal drug under actual use conditions results in food being imported into the United States with residues exceeding the tolerance.

As described in the preamble of the final rule, the 1996 ADAA created the import tolerance system. The first import tolerance was established in 1996, and seven additional import tolerances have been established since that year. This final rule merely describes the procedures by which import tolerances can be requested, established, withdrawn or revoked. It does not change any requirements for requesting an import tolerance and only codifies the existing import tolerance procedures.

B. Market Failure Requiring Federal Regulatory Action

Interested parties may currently submit requests for the establishment of import tolerances. Without regulation to specify the procedures interested parties should follow to submit requests, an institutional failure exists that could create inefficiencies. This final rule describes the procedures to submit requests to establish import tolerances that may be more efficient because the regulation specifies the information we require be submitted in such a request. In addition, the FD&C Act requires that we specify, by regulation, procedures to revoke an import tolerance. This final rule establishes such procedures and thus corrects the institutional failure.

C. Baseline Conditions

We base our estimate of the impact of the final rule on the average number of requests that we have received since the creation of the import tolerance system. We have received about 10 import tolerance requests since 1996. We assume the average number of requests will remain steady.

Because the baseline for this rule includes uncodified import tolerance procedures as currently administered, this rule does not impose new requirements on interested parties seeking to establish an import tolerance or new obligations on government resources required to review those import tolerance requests. However, we inadvertently included both industry and government costs attributable to the enacting legislation in our preliminary regulatory impact analysis. We exclude the costs of the enacting legislation from our final analysis.

D. Benefits of the Final Rule

As stated previously in this document, the final rule codifies procedures for the import tolerance process established under the 1996 ADAA. Codified procedures may clarify the import tolerance submission process for the establishment, amendment and revocation of these tolerances. This could result in improving the efficiency of the system to both industry and government. However, we lack data to quantify these efficiency gains.

E. Costs of the Final Rule

1. Industry Costs

a. Administrative Costs – Reading and Understanding the Final Rule

All entities affected by this final rule will incur the one-time cost for reading and understanding this rule. We use the time required to complete this activity to estimate the burden of this activity. To understand this rule, affected entities will read the preamble and codified which together contain almost 11,300 words. To estimate the time to read and understand the rule, Department of Health and Human Services (HHS) guidance (Ref. 1) recommends using reading speeds of 200 words per minute to 250 words per minute. Therefore, we estimate the time to read the regulation is about 45 to 60 minutes per person. Based on the small number of import tolerance requests that we have received since 1996, we estimate that we will receive about one import tolerance request every other year, or about 0.5 per year. Thus, we estimate that about 5 firms would need to read and understand this rule over the next 10 years.

To value the time for complying with reading and understanding the rule we use wages calculated from the Bureau of Labor Statistics' national industry-specific occupational employment and wage estimates for the pharmaceutical and medical manufacturing industry (Ref. 2).[1,2] To value the time associated with reading and understanding the rule, we use the average of the $73.41 hourly wage of management occupations (occupation code 11-0000) and the $66.89 hourly wage of legal occupations (occupation code 23-0000). We double this average hourly wage to account for benefits and overhead, yielding an average fully-loaded hourly labor cost of $140.30.

We estimate the cost for the one person to read the rule ranges from $105 to $130. Based on the small number of firms that we estimate could request an import tolerance per year, only

[1] May 2020 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 325400 – Pharmaceutical and Medicine Manufacturing. We use estimates from NAICS 325400 because detailed estimates for NAICS 325412 are not available, https://data.bls.gov/oes/#/home, accessed July 27, 2021.
[2] This wage is slightly higher than that of management occupations for NAICS 622110 – General Medical and Surgical Hospitals, but this difference does not significantly impact of the cost of the final rule.

about 5 firms would need to read and understand this rule over the next 10 years. The total costs for reading and understanding the rule range from around $530 to around $660. Table 2 includes a summary of these costs.

Table 2. One-time costs for reading and understanding the rule (2020 dollars)

	Low	Medium	High
Reading time (hours)	0.75	0.85	1
Wage ($ per hour)	$140.30	$140.30	$140.30
Affected entities	5	5	5
Number of people reading per entity	1	1	1
Total cost[1]	**$530**	**$585**	**$660**

[1] Totals may not equal estimates due to rounding.

We anticipate that requests to revoke or amend an import tolerance will occur infrequently. We recognize that requesters may incur some minor administrative costs for time spent in preparing a request to amend or revoke an import tolerance. We anticipate that the potential costs for these types of requests will be negligible.

III. Final Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to prepare a regulatory flexibility analysis if a rule is expected to have a significant economic impact on a substantial number of small entities. Although we believe it is very unlikely that significant economic impacts would occur, we do not completely rule out this possibility because of uncertainty in the type or size of entities that may request the establishment, amendment or revocation of import tolerances.

The Regulatory Flexibility Act requires a description of the small entities that would be affected by the rule, and an estimate of the number of small entities to which the rule would

apply. We expect that manufacturers of new animal drugs will make all or nearly all requests to establish import tolerances. Manufacturers of new animal drugs are classified in the North American Industrial Classification System (NAICS) under industry code 325412--Pharmaceutical Preparation Manufacturing. Since the publication of the proposed rule, Census data from 2017 has become available. Census data in this category show that 1,280 establishments manufacture pharmaceuticals in the United States (Ref. 3).

The Small Business Administration (SBA) defines those entities within NAICS code 325412 as small entities if they employ less than 1,250 employees (Ref. 4). Census data shows that between 976 and 999[3] of the 1,280 establishments within NAICS code 325412, or between 76 and 78 percent, would be considered small. The existence of some multi-establishment companies in this NAICS code would likely decrease the number of companies that would meet the definition of a small entity. Based on SBA size standards, a substantial number of pharmaceutical manufacturers would meet the criteria to be considered small entities.

For establishments with one to nine employees, the annual value of receipts averages about $1.6 million in 2017. For all establishments with 10 or more employees, it is much greater. For a manufacturer composed of only one establishment of one to nine employees, we estimate the one-time cost of $105 (= $140.30 per hour * 0.75 hours) to $140 (= $140.30 per hour * 1 hour) to read and understand this final rule would represent less than 0.01 percent of average annual revenues. Those establishments with more than 10 employees would incur compliance costs that represent significantly less than 0.01 percent of average revenues. Therefore, we

[3] The SBA standard indicates that a firm in industries identified by the NAICS codes 325412 would be considered small if they employ fewer than 1,250 employees. We are unable to perfectly break out the employment characteristics for firms with fewer than 1,250 employees. The range given is for the number of establishments with fewer than 1,000 employees and 1,500 as our lower and upper bounds, respectively.

certify that the final rule will not have a significant economic impact on a substantial number of small entities.

References

1. Guidelines for Regulatory Impact Analysis, HHS September 2016. http://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.

2. U.S. Bureau of Labor Statistics, Occupational Employment Statistics, May 2020, National Industry-Specific Occupational Employment and Wage Estimates, http://data.bls.gov/oes/, accessed July 27, 2021.

3. U.S. Census Bureau, Statistics of U.S. Businesses, 2017 SUSB Annual Data, https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html, accessed July 27, 2021.

4. U.S. Small Business Administration, "Table of Small Business Size Standards Matched to North American Industry Classification System Codes", August 19, 2019, https://www.sba.gov/document/support--table-size-standards.