6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5i, which categorically excludes from further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.
The Department also has general authority to issue regulations necessary to carry out section 41712. Many of the Department’s existing aviation consumer protection rules were issued under the authority of section 41712, including but not limited to the tarmac delay rule, the full-fare advertising rule, the prohibition on post-purchase price increases, and the rules on oversales and denied boarding compensation.

Section 41712 does not define “unfair,” “deceptive,” “or “practice.” On December 7, 2020, the Department issued a final rule titled “Defining Unfair or Deceptive Practices” (“UDP Final Rule”). In this rule, the Department noted that section 41712 was modeled on section 5 of the Federal Trade Commission (FTC) Act. The Department explained that while section 5 vests FTC with broad authority to prohibit unfair or deceptive practices in most industries, Congress granted the Department the exclusive authority to prohibit unfair or deceptive practices of air carriers and foreign air carriers. The Department noted that DOT and FTC share the authority to prohibit unfair or deceptive practices by ticket agents in the sole of air transportation.

Accordingly, DOT determined that it was appropriate to define the terms “unfair” and “deceptive” in ways that reflect both FTC precedent and DOT’s own long-standing interpretation of those terms. Specifically, DOT defined a practice as being unfair to consumers if “it causes or is likely to cause substantial injury, which is not reasonably avoidable, and the harm is not outweighed by benefits to consumers or competition.” DOT defined a practice as being deceptive to consumers “if it is likely to mislead a consumer, acting reasonably under the circumstances, with respect to a material matter. A material matter if it is likely to have affected the consumer’s conduct or decision with respect to a product or service.”

Like FTC, the Department stated that proof of intent is not necessary to establish either unfairness or deception. The Department found it unnecessary to define “practice.”

Among its major provisions, the UDP Final Rule requires DOT to employ its definitions of “unfair” and “deceptive” when issuing future rulemakings or taking future enforcement action. The rule provided, however, that if Congress directs DOT by statute to issue regulations specifically declaring a practice to be unfair or deceptive, then DOT may do so without reference to the general definitions. The rule also clarified that if a specific regulation already applies to the conduct at issue, then the Department may rely on the terms of that regulation.

On July 9, 2021, the President issued Executive Order 14036, “Promoting Competition in the American Economy.” That Order directed the Department to take a number of actions to protect aviation consumers, including that the Department start development of proposed amendments to its definitions of the terms “unfair” and “deceptive” in section 41712. Pursuant to the Executive Order, DOT stated that it would fulfill the requirements of the Executive Order by issuing an interpretive rule (i.e., this guidance document) that would clearly apprise the public of the Department’s interpretation of the definitions of the terms “unfair” and “deceptive.”

Guidance Regarding Interpretation of Unfair and Deceptive Practices

The purpose of this guidance document is to provide the public and regulated entities with greater transparency with respect to DOT’s Office of Aviation Consumer Protection (OACP)’s interpretation of the terms that are found in section 41712 and defined in the Department’s regulations at 14 CFR 399.79. This guidance document does not have the force and effect of law, is not legally binding in its own right, and will not be relied on by the Department as a separate basis for enforcement or other administrative penalties beyond the underlying authorities in statute and regulation.

Elements of Unfairness

In the Department’s final rule titled “Defining Unfair or Deceptive Practices” (“UDP Final Rule”), DOT defined a practice as “unfair” if it "causes or is likely to cause substantial injury, which is not reasonably avoidable, and the harm is not outweighed by benefits to consumers or competition.” We will address each element in turn.

1. “Causes or Is Likely To Cause”

In keeping with FTC precedent, DOT is of the view that a practice may “cause” harm even if it is not the only cause of the harm, and even if it is not the most proximate cause of the harm. Moreover, the Department is not required to wait for substantial injury to take place before taking action against an unfair practice. The Department may take action against practices which are "likely to cause” substantial injury as well.

When making such determinations, DOT examines not only the probability of the harm occurring, but also the magnitude of the injury if it does occur. As FTC has observed, “a practice may be unfair if the magnitude of the potential injury is large, even if the likelihood of the injury occurring is low.”

2. “Substantial” Injury

The UDP Final Rule uses the terms “harm” and “injury” interchangeably.

The Department did not define "substantial injury" in the UDP Final Rule, other than observing that the term "would necessarily exclude trivial or speculative" harm.

Substantial injury would be determined by the totality of the circumstances. As FTC has written, “it is well established that substantial injury may be demonstrated by a showing of a small amount of harm to a large number of people, as well as a large amount of harm to a small number of people.”

Substantial harm is typically of an economic nature. For example, the Department has found that delay in providing refunds to consumers constitutes substantial harm to consumers who did not receive the service they paid for and did not have...
access to their money for a significant time. However, it is well established that harm need not be financial in order to be substantial. For example, the Department found that delaying passengers on the tarmac for a substantial length of time without the opportunity to deplane or without adequate food, water, lavatory facilities, and medical attention imposes substantial harm. Substantial harm may also be found in intangible injury, such as to an individual’s privacy or reputation. Extended delays in obtaining relief, and the time and expense of pursuing a claim, can also constitute substantial harm.

3. Not Reasonably Avoidable

For a practice to be unfair, the harm must not have been reasonably avoidable by the consumer. For example, a lengthy tarmac delay imposes unavoidable harm because the passenger lacks the opportunity to deplane. It has also been the longstanding view of OACP that it would be an unfair practice for a carrier to fail to provide a refund, on request, for flights to or from the United States that were canceled or significantly changed by the carrier, in part because the harm was not reasonably avoidable by the traveler. We came to this conclusion even if the passenger purchased a “non-refundable” ticket. We concluded that a consumer acting reasonably would believe that he or she was entitled to a refund under U.S. law if the carrier cancelled or significantly changed the flight, regardless of the reason for the cancellation or significant change. We further concluded that a reasonable consumer would not believe that it is necessary to purchase a more expensive refundable ticket in order to be able to recoup the ticket price when the airline fails to provide the service paid for through no action or fault of the consumer, because reasonable consumers understand that “refundable” tickets are valuable because they ensure a refund if the passenger cancels the flight. The Department has issued a notice of proposed rulemaking that would propose to codify OACP’s interpretation that section 41712 requires airlines to provide prompt refunds when a carrier cancels or makes a significant change and the passenger does not take an alternative flight offered by the airline, including when the original ticket purchased is non-refundable.

The Department looks at this element from the perspective of an ordinary consumer acting reasonably under the totality of the circumstances. For example, we have found that a passenger who triggered an airline’s fraud-detection system and lost frequent flyer miles could have reasonably avoided that harm by not repeatedly entering fictitious information into the airline’s reservation system.

4. Harm Not Outweighed by Benefits to Consumers or Competition

Finally, the harm must not be outweighed by benefits to consumers or to competition. Like FTC, the Department recognizes that some practices may be harmful to consumers in some respects, but beneficial to consumers in other respects. For example, offsetting benefits may include lower prices or a wider availability of products and services resulting from competition. The Department seeks to regulate practices that are harmful to consumers in their net effects.

Importantly, the Department does not compare the harm to the consumer against the benefits that the airline or ticket agent may obtain from the practice. The Department’s determination to regulate an unfair and deceptive practice would also be informed by a regulatory impact analysis.

5. Public Policy Considerations

As we noted in the UDP Final Rule, DOT has a broad statutory responsibility to consider a wide variety of public policies enumerated by Congress. In fact, Congress has directed the Department in carrying out its aviation economic programs such as regulations under section 41712 to consider certain enumerated factors as being in the public interest. These factors include “the availability of a variety of adequate, economic, efficient, and low-priced services without unreasonable discrimination or unfair or deceptive practices” and “preventing unfair, deceptive, predatory, or anticompetitive practices in air transportation.” DOT considers public policy as established by both the Executive branch (e.g., regulation, Executive Order) and the Legislative branch (e.g., statute, sense of Congress) of the Federal Government as appropriate, when determining whether a practice is unfair.

As a public policy matter, the Department has found that discriminatory conduct in and of itself constitutes an unfair practice. In this regard, orders of the Department and its predecessor Civil Aeronautics Board (CAB) support the position that violations of statutes that prohibit discrimination constitute unfair and deceptive practices. For example, the CAB determined that unlawful disparate treatment of consumers by a carrier in its ticket-by-mail procedures based on the consumer’s ZIP code, which had the effect of discriminating against African-Americans in New York City, is an unfair practice.

26 See “Enhancing Airline Passenger Protections,” 74 FR 68983 (Dec. 30, 2009); available at https://www.federalregister.gov/documents/2009/12/30/FR-30615/enhancing-airline-passenger-protections (also noting that the rule was also premised on an airline’s statutory duty to provide “safe and adequate” interstate air transportation).
27 Mishandling the private information of consumers may be considered an unfair or deceptive practice within the meaning of section 41712. See https://www.transportation.gov/individuals/aviation-consumer-protection/privacy; see also LabMD at 19 (“the privacy harm resulting from the unauthorized disclosure of sensitive health or medical information is in and of itself a substantial injury under section 5(a),” even without further evidence that the information was used to cause further harm); Spokeo, Inc. v. Robbins, 578 U.S. 330 (2016) (“intangible injuries may nevertheless be concrete” for purposes of satisfying the case or controversy requirement of standing in Article III courts).
28 See FTC Policy Statement on Unfairness, available at https://www.ftc.gov/public-statements/1980/02/ftc-policy-statement-unfairness (FTC generally does not intend to second-guess the wisdom of consumer decisions, but it does intend to halt seller behavior that “unreasonably creates or takes advantage of an obstacle to the free exercise of consumer decisionmaking.”)
29 See Air Canada Order at 5.
30 See FTC Policy Statement on Unfairness, 14 CFR pt. 250, which also reflects this balance. The rule is carefully crafted to allow airlines to overbook flights in order to fill seats that would have otherwise gone empty due to “no-shows.” In exchange for this ability to overbook flights (which would otherwise be unfair or deceptive), the Department requires airlines to compensate and provide protections to passengers who were involuntarily denied boarding in accordance with the rule. See DOT Order 2020–6–5.
31 See Air Canada Order at 6 (finding that the practice of retaining passenger funds for canceled flights beyond the time frames allowed by law conveyed no benefit to consumers, even if the practice may have benefited the airline).
33 49 U.S.C. 40101(a).
34 52679 Federal Register
unfair practice. The Department has also consistently found that violation of the Air Carrier Access Act, which prohibits U.S. and foreign air carriers from discriminating against passengers with disabilities, is an unfair practice. Similarly, the Department has found that discrimination against individuals based on their race, color, national origin, religion, ancestry or sex is an unfair practice.

Elements of Deception

In the UDP Final Rule, DOT defined a practice as “deceptive” if it “is likely to mislead a consumer, acting reasonably under the circumstances, with respect to a material matter. A matter is material if it is likely to have affected the consumer’s conduct or decision with respect to a product or service.” We will address these elements in turn.

1. Likely To Mislead a Consumer

First, the practice must be likely to mislead the consumer. As FTC has explained, express misrepresentations, implied representations, and omissions are all potentially actionable. A failure to provide services as promised (whether by contract or otherwise) can also be deceptive.

The Department’s full-fare advertising rule is based on its authority to prohibit deceptive practices. Put simply, this rule requires advertised prices for air transportation to be the entire price to be paid by the customer to the carrier, or agent, for such air transportation. The Department based its rule on evidence that consumers believed that they were going to pay a particular advertised price for air transportation, only to find that the price was substantially higher due to additional taxes and fees. The rule also requires any charges that are listed as components of the entire price (e.g., taxes) not to be false or misleading.

We have also found that advertising a fare that is no longer available, or failing to have a reasonable number of seats available at the advertised fare, is deceptive.

3. Material Matter

The Department has adopted FTC’s standard that the deception must regard a “material” matter, which is a matter that is likely to have affected the consumer’s conduct or decision with regard to a product or service. In such a case, “consumer injury is likely, because consumers are likely to have chosen differently but for the deception.”

For example, the Department has found that the practice of mischaracterizing a carrier-imposed fee as a “tax” is deceptive. We concluded that a reasonable consumer may choose to pay a “tax” under the reasonable belief that a tax is unavoidable, but that same consumer may choose to shop elsewhere in order to avoid a carrier-imposed fee. We have also found that an airline acted deceptively when it promised a universally available discount for prepaid baggage fees, when that discount was not available if the customer purchased the ticket through a third-party website. In contrast, we have found that errors that appear only in post-purchase receipts are misleading, but not deceptive for purposes of section 41712, because there was no evidence in that case that an error in a post-purchase receipt influenced the consumer’s pre-purchase decision.

It is important to note that the “product or service” is not limited to the initial purchase, however. For example, we have found that an airline acted deceptively when it responded to consumer complaints about denied boarding compensation by stating that it complied with “DOT and FAA regulations,” when no such regulations existed. We found that such misrepresentations could have dissuaded consumers from pursuing valid complaints with the Department.

We have also found that misrepresentations relating to cancellation fees were deceptive within the meaning of section 41712.

Practice

FTC has the statutory authority to prohibit unfair or deceptive “acts or practices” in or affecting commerce.
Section 41712, however, refers only to “practices.” In the UDP Final Rule, we explained that our aviation consumer protection regulations are always directed to practices of an airline or ticket agent, rather than isolated acts of individual employees. We also explained that our enforcement efforts include a determination that the conduct in question reflects a practice or policy affecting multiple consumers, rather than an isolated incident. We concluded that “in general, the Department is of the view that proof of a pattern or policy affecting multiple consumers, conduct in question reflects a practice or ticket agent, rather than isolated acts of individuals. We also explained that our enforcement efforts include a determination that the conduct in question reflects a practice or policy affecting multiple consumers, rather than an isolated incident.

Effective Date

This guidance is effective August 29, 2022.

Issued on or about this 15th day of August, 2022, in Washington, DC.

John E. Putnam,
General Counsel, U.S. Department of Transportation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2021–F–0564]

Food Additives Permitted in Feed and Drinking Water of Animals; Fumonisin Esterase

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of fumonisins esterase to degrade fumonisins present in poultry feed. This action is in response to a food additive petition filed by Biomin Holding GmbH.

DATES: This rule is effective August 29, 2022. See section V of this document for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the final rule must be submitted by September 28, 2022.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 28, 2022. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting objections. 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 publically available, you should 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

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