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Many baby formula plants weren't inspected because of COVID

U.S. News World News June 13, 2022

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FILE - Baby formula is displayed on the shelves of a grocery store in Carmel, Ind. on May 10, 2022. A bill introduced early June, 2022, would require the Food and Drug Administration to inspect infant formula facilities every six months. U.S. regulators have historically inspected baby formula plants at least once a year, but they did not inspect any of the three

U.S. News World New

WASHINGTON (AP) — U.S. regulators have historically inspected baby formula plants at least once a year, but they did not inspect any of the three biggest manufacturers in 2020, according to federal records reviewed by The Associated Press.

When they finally did get inside an Abbott Nutrition

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found standing water and lax sanitation procedures. But inspectors offered only voluntary suggestions for fixing the problems, and issued no formal warning.

Inspectors would return five months later after four infants who consumed powdered formula from the plant suffered bacterial infections. They found bacterial contamination inside the factory, leading to a four-month shutdown and turning a festering supply shortage into a full-blown crisis that sent parents scrambling to find formula and forced the U.S. to airlift products from overseas.

The gap in baby formula plant inspections, brought on by the COVID-19 pandemic, is

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government
 watchdogs
 investigating the
 series of missteps
 that led to the
 crisis. A recent bill
 would require the
 Food and Drug
 Administration to
 inspect infant
 formula facilities
 every six months.
 And the
 government's
 inspector general
 for health has
 launched an
 inquiry into the
 FDA's handling of
 Abbott's facility,
 the largest in the
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Abbott resumed production at the plant early this month under a legally binding agreement with the FDA, but the shutdown and nationwide shortage exposed how concentrated the industry has become in the U.S., with a handful of companies accounting for roughly 90% of the market.

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As COVID-19 swept across the U.S. in early 2020, the FDA pulled most of its safety inspectors from the field, skipping thousands of routine plant inspections.

The FDA did conduct more than 800 “mission critical” inspections during the first year of the pandemic, the agency said in a statement.

Regulators



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they carried a specific safety risk or were needed to produce an important medical therapy.

Only three of the nation's 23 facilities that make, package or distribute formula made the cut. The FDA resumed routine inspections in July 2021.

The inspection records reviewed by the AP show gaps as large as 2 1/2 years between FDA's 2019 inspections and when regulators returned to plants owned by the three leading formula manufacturers: Abbott, Reckitt and Gerber.

In fact, the FDA still has yet to return to one key plant owned by Reckitt and two owned by Gerber, according to agency records. All those facilities are operating around

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“The FDA would have had more chances to catch these issues if they’d been

inspecting during the pandemic,” said Sarah Sorscher, a food safety specialist with the Center for Science in the Public Interest.

She acknowledged the difficult trade-off the FDA faced in pulling its inspectors to reduce their exposure to COVID-19.

“Certainly there was a price to pay for protecting their workers during that time.”

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Baby formula manufacturers were “consistently identified as a high priority during the pandemic,” and there is currently no backlog of



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inquiries about the gaps. The agency said it skipped about 15,000 U.S. inspections due to COVID, but it has already made up about 5,000 of those, exceeding its own goals.

Under current law, the FDA is only required to inspect formula facilities every three to five years, but the agency has consistently inspected facilities annually — until the pandemic.

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“Our top priority now is addressing the urgent need for infant formula in the U.S. market, and our teams are working night and day to help make that happen,” FDA stated.

But outside experts say the gap in inspections speaks to a blind spot in the government’s response effort, which was successful at preventing



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supplies.

FDA
Commissioner
Robert Califf says
regulators knew
shutting down

Abbott's plant
would create
supply problems,
but there was little
evidence of
urgency between
when inspectors
shuttered the
plant in February
and recent
emergency
measures to allow
more imports
from abroad.

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Longtime food
safety specialists
see a deeper
problem at the
highest levels of
the FDA, where
physicians and
medical scientists
for decades have
prioritized
oversight of drugs
and medical
products over
food.

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"It's very

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engaged at all in
this area because
they don't have
the background,
the knowledge and
the experience in

it," said Steven
Mandernach,
executive director
of the Association
of Food and Drug
Officials, which
represents state-
level inspectors.

The FDA shares
oversight of food
production and
safety with the
U.S. Department
of Agriculture.

FDA inspections
of food facilities
peaked in 2011 and
have declined
most years since,
despite increased
funds and powers
by Congress. The
FDA said that
while U.S.
inspections have
declined, foreign
facility inspections
have increased.

There's no
certainty that
extra inspections
during COVID-19
would have
prevented the
contamination

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shut down. And Abbott says that its products have not been directly linked to the

infections, two of which were fatal.

But the plant did have earlier problems, including a 2010 formula recall due to possible contamination with insect parts.

“I think facilities that had known problems that could cause a food safety risk should have been part of FDA’s mission critical work,” Mandernach said. “And this facility would have been among those.”

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Not having regular inspections — or even the threat of them — can lead to changes in culture at plants



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“If you’re driving
 down the highway
 and you know the
 state troopers
 have been
 furloughed, might
 you go a little
 faster than if you
 knew there was a
 trooper on duty?”
 Mandernach
 asked.

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