Proposing Solutions and Regulations to Toxins Found in Tampons					
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Introduction

In the August, 2024 issue of Environment International Jenni Shearston (a postdoctoral scholar at the UC Berkeley School of Public Health) and others reported on finding toxic metals and metalloids in tampons. This work, funded by the National Institute of Environmental Health Sciences, followed on a 2022 review the group had conducted that found other constituents of concerns, but was considered to be the first to reveal the presence of heavy metals and related substances. With the personal risks being prominent, as well as what it poses for menstruators everywhere, the team chose to research what is known about the cause of this problem and what can be done about it - how the presence of these toxins can be prevented. For these reasons, this project aims to analyze and investigate the discovery of tampon products containing metals and metalloids. With the perspectives of sources and experts, this report explores the relationship between women's reproductive health and public health policies.

The team reached out to Professor Wendy Heiger-Bernays (an emerita clinical professor in the Department of Environmental Health at the BU School of Public Health, focusing on molecular toxicology) and has decided to create a conceptual framework that allows us to connect hazard and risk.

It's important to note that there are two kinds of studies:

- I. A study that looks at the presence or absence of toxic substances in materials.
- II. A study that analyzes exposure or outcome. This evaluates the conditions in which the hazards enter the body, but also how much. This examines the prevalence of the health outcomes.

Hazard does not equate to health risk, however, the risk will be higher the more we're exposed to toxic materials. This allows the public to understand where interventions should take place. By doing so, the team is able to focus on a consumer's right to know about their products and provide directions for future work.

¹ "Tampons as a Source of Exposure to Metal(Loid)s - ScienceDirect," accessed January 28, 2025, https://www.sciencedirect.com/science/article/pii/S0160412024004355.

Summary of Original Study

The study, conducted by Jenni Shearston (a postdoctoral scholar at the UC Berkeley School of Public Health), Kristen Upson, Milo Gordon, Vivian Do, Olgica Balac, Khue Nguyen, Beizhan Yan, Marianthi-Anna Kioumourtzoglou, and Kathrin Schilling was titled "Tampons as a source of exposure to metal(loid)s" and published in August issue of the journal Environment International. This study focused on assessment of hazards.

Notably, authors note the following:

- 1. Measurable concentrations of all 16 metals that were assessed.
- 2. Several metals known to cause toxicity at low doses, including lead, were detected.
- 3. Tampon use is a potential source of exposure to metals in menstruating people.
- 4. The highest concentration was found for zinc (geometric mean = 52,000 ng/g)
- 5. A geometric mean lead concentration of 120 ng/g was found in the study's samples.
- 6. Detected concentrations of several toxic metals, including elevated mean concentrations of lead (geometric mean [GM] = 120 ng/g), cadmium (GM = 6.74 ng/g), and arsenic (GM = 2.56 ng/g).
- 7. Metal concentrations differed by region of tampon purchase (US versus European Union/United Kingdom), by organic versus non-organic material, and for store- versus name-brand tampons.
- 8. Most metals differed by organic status of the tampon; lead concentrations were higher in non-organic tampons, while arsenic concentrations were higher in organic tampons. No category consistently had lower concentrations of all or most metals.

The study did not reveal the brands tested; however, it stated that it tested the most commonly used tampons—the brands you'd find at your supermarket. These findings were extremely concerning. They raised the question: What does this mean for the consumer?

The study's results raised concerns. Menstruators widely use tampons; they are well embedded in the daily routines of people's lives. Between 52–86% of people who menstruate in the United States use tampons². Consumers deserve to use clean, safe, and non-toxic products,

² Citation here

which compelled the establishment of this written report. By creating a conceptual model, hazard and risk are connected to evaluate this issue and establish solutions.

Reviewing the EPA's Role

Shortly after, the team decided to research the Toxic Substance Control Act (TSCA), which mandates the EPA to regulate, report, and add testing requirements for chemicals used in production and manufacturing.³ The goal was to determine whether or not the manufacturing of menstrual products is subject to the regulations of this act. The same goal was applied to the Consumer Product Safety Commission (CPSC), which is responsible for setting safety standards for certain products.⁴ After going through the TSCA Inventory and the statements within the CPSC, there was limited discussion regarding menstrual products. This is mainly due to the fact that menstrual products are considered to be medical devices and are regulated through the Federal Food and Drug Administration.

Following this, the team looked into the EPA's Toxic Release Inventory with the help of EPA official Christian Rascher and Heather Tenney of the Toxics Use Reduction Institute at UMass Lowell. Looking into the company profile of Procter and Gamble, the corporation responsible for a variety of tampon products, a multitude of chemicals were listed. It is important to note that although a variety of chemicals were listed, only the ones that are intentionally used are labeled. This may imply that the metals and metalloids are unintentionally added, or somehow unknowingly enter the product throughout the manufacturing process.

Consultation with Wendy Heiger-Bernays, PhD

The team reached out to Professor Wendy Heiger-Bernays, an emerita clinical professor in the Department of Environmental Health at the BU School of Public Health, who focuses on molecular toxicology and impact of chemicals on the public's health. The intention was to learn how toxins like lead could impact the body, especially in the amounts cited in the research.

³ "Summary of the Toxic Substances Control Act | US EPA," accessed December 9, 2024, https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act.

⁴ "About Us | CPSC.Gov," accessed December 9, 2024, https://www.cpsc.gov/About-CPSC.

⁵ "Facility Profile Report | TRI Explorer | US EPA," accessed December 9, 2024, https://enviro.epa.gov/triexplorer/release_fac_profile?TRI=18629PRCTRROUTE&TRILIB=TRIO1&V_NA_INDI_CATOR=.&FLD=&FLD=RELLBY&FLD=TSFDSP&OFFDISPD=&OTHDISPD=&OTHOFFD=&Y_EAR=2020.

One question was asked: How "dangerous" and "harmful" are these concentrations if these metal(loid)s are absorbed into the body, especially given the frequent use of tampons?

Professor Heiger-Bernays responded: "We would need to know something about the ability of the metals to move from the tampon into the highly vascularized mucosal tissue of the vagina. So these are two sub-questions - are the metals "fixed" or grown into the cotton fibers or are they available chemically to move from the tampon? And the second question is - if the metals are available, how efficiently are they absorbed? And if there is absorption, then how can we predict the concentration in the person's bloodstream (not menstrual blood)? But does menstrual blood hasten the release? Slow it down? And then, if people use the for say - 24 hours/day, for 5 days in a row and then not at all until another 28 or rather 23 days later, is this enough time for accumulation of the metal to cause an adverse outcome?

Next, the team asked: What is the likelihood these metal(loid)s would be absorbed in the body? Would menstruators experience the effects?

Per the second question, Professor Heiger-Bernays responded: "I suspect that some metals would be absorbed if they were released from the tampons. Metals are poorly absorbed through the skin - the best absorption is through epithelial cells in the GI tract after eating food containing lead - or lead paint chips. So epithelial cells of the vagina are more like those of the GI tract than of the skin, there will likely be more absorption than via skin. Which effects? The most sensitive is on the developing brain - the fetus. And in the case of menstruators, highly unlikely that they are pregnant - right? However, the maternal blood lead levels are critically important for what will happen in the fetus - so we don't want to add more lead or other neurotoxicants to the child-bearing age person."

More research needs to be conducted about the ability of these toxins to move into the vagina, as we're unaware of how effectively this could be absorbed into the bloodstream, especially with the repeated usage that tampons are used for. Since they're a regular option for menstruators with 2-7 days of bleeding (on average)⁶, this is concerning—especially given the epithelial cells of the vagina. Professor Heiger-Bernays stated that "maternal blood levels are critically important for what will happen in the fetus." This emphasizes increased vulnerability in

⁶ Mayo Clinic Staff, "Menstrual Cycle: What's Normal, What's Not," Mayo Clinic, accessed December 13, 2024, https://www.mayoclinic.org/healthy-lifestyle/womens-health/in-depth/menstrual-cycle/art-20047186.

pregnant women and the fetus. Currently, there is no research confirming the effects of toxins in fetuses or the human body from tampons—however, it does not inhibit a person's ability to launch into action. It's already known that lead and arsenic are extremely harmful to human health. By addressing and resolving this hazard, there is a possibility to adopt intervention points and resolve these toxin concerns.

Consultation with Dr. Jenni Shearston

Early in the research progress of the report, the team contacted Dr. Jenni Shearston, who is the author of the "Tampons as a source of exposure to metal(loid)s" study. A list of questions were asked, such as which specific tampon brands were studied, if the study extended to pads, and if Shearston had a theory on how the metals leached into the tampon product.

Shearston responded that she was "unable to disclose" the brands tested, but added that "it's really important is the consistency of our results: we found metals present in all the tampons we tested, regardless of brand." Shearston added that the study did not test pads, focusing their research on tampons as they "hypothesized that potential exposure risk is greater for products that are used inside the vagina and are therefore in greater contact with the vaginal mucosal membrane."

Shearston theorized that the metals could have been absorbed by cotton plants from the soil, fertilizer, or pesticides. Another possibility was that metals could've been deposited on the surface of cotton from air, if the crop was grown near a pollution source like a highway or smelter. If water – containing metals – is used in the manufacturing process, then it could've gotten into the tampon source. The manufacturing process, Shearston said, could've introduced these toxins. Additionally, some metals are parts of lubricants, coloring agents, fragrances, or antimicrobials that may be added to some tampons.

Additionally, Shearston commented that companies could reduce and prevent the risk (depending on how the toxins enter the tampons). More rigorous testing should be implemented. If investigations reveal the metal is from the soil, an option would be to source cotton from geographic areas of the world with lower metal content in the soil.

Despite the research study, Shearston and her team "are not recommending that people change their product use, especially because tampons are an important option for people to manage their menstruation." This is due to the lack of research – which Shearston is currently working on – though Shearston advises "women to remain aware, to keep asking questions about what chemicals are in tampons and other menstrual products, and to demand further research so that we can learn if metals in tampons are impacting people's health."

Conversation with Women's Voices for the Earth

The team reached out to Women's Voices for the Earth (WVE) – a nonprofit advocacy group that drives action toward a future free from the impacts of toxic chemicals. WVE strongly emphasizes that toxic chemicals don't belong in menstrual care products. Among their many research studies, WVE conducted an analysis called "Report: What's in Your Period Product?" analyzing ingredient disclosures on period product labels in New York and across the United States in 2022. The research focused on New York, as its legislature passed "the first law in the country requiring disclosure of all intentionally added ingredients in period products on the label – a law which went into effect in October 2021." WVE period product labels and found compliance with the NY law was not consistent, as language disclosing ingredients was vague; materials were labeled as "fragrance" or "ink." By omitting the chemical name, customers are not fully informed about the product.

In an interview with the team, WVE expressed that it was important for women to be aware of this conducted study. They explained that consumers are unaware that tampons have toxins. This research allows menstruators to ask more questions. If consumers are aware, they can assess and make more informed decisions. Tampons and pads are most commonly used because it's what most menstruators are accustomed to (a sentiment aligned with Dr. Shearston), as it's cultural to use what you've become accustomed to.

The team inquired about the possibility that the chemicals were due to odor control. In a widely read NPR article, the media outlet wrote that "chemicals could get into tampons in a

⁷ Women's Voices for the Earth, "What's in Your Period Product?," accessed December 13, 2024, https://womensvoices.org/report-whats-in-your-period-product/.

⁸ Women's Voices for the Earth, "Menstrual Care Products," accessed December 13, 2024, https://womensvoices.org/menstrual-care-products/.

number of ways, from raw materials like cotton being contaminated by pollutants in the soil and water to manufacturers intentionally adding them as odor control or antimicrobial agents."

WVE stated that "fragrance is purely marketing, [and] there's no need for it." They believe that finding the metalloid source could be tricky due to contamination during the process, but it's immensely important. Additionally, consumer transparency is crucial so customers can make informed decisions that work for their bodies.

Assessment of Tampon Manufacturing Process

The video "Here's How Tampax Tampons Are Made" provides a detailed explanation of the tampon manufacturing process. It begins by introducing the absorbent materials used: cotton and rayon. These fibers are selected for their effectiveness and combined in varying proportions depending on the product type. Some tampons are made entirely of cotton, others entirely of rayon, and some use a blend of the two.

The manufacturing process starts with cleaning and aligning the fibers to create an absorbent sheet. This sheet is then rolled and compressed into a cylindrical core, forming the tampon's absorbent structure. This compression is essential to ensure the tampon's functionality and durability during use.

The tampon applicators are made separately from BPA-free plastic, plant-based plastic or cardboard. Once the tampon core is prepared, it is placed inside the applicator, and a string is attached securely for safe removal.

Quality control is a critical aspect of production. Each tampon undergoes rigorous testing to ensure it meets safety and performance standards. Sterilization ensures the product is hygienic and ready for use. Finally, the tampons are individually wrapped for protection and packaged into boxes for distribution. The process overall demonstrated the complex steps involved with making tampons, and how there are many possibilities as to where the toxins originated from.

The FDA and their Mitigation of Menstrual Products

In an email sent to the FDA regarding the premises of our project, four questions were asked regarding the legislation surrounding tampons, any initiatives created in response to the

recent Shearston et al paper, and the logic behind the classification of tampons as medical devices. To summarize the EPA's response to this initial email, a series of links to existing resources were provided as answers to the questions asked. The email contents did not specifically detail or comment on why tampons are classified as medical devices, but did link a webpage explaining how to market medical devices. After clarification was requested about the specific reasoning behind the medical devices, the FDA clarified that their reasoning was due to the fact that "tampons would likely fall under element C of the definition as they are intended to affect a bodily function." "Element C" listed in the webpage defines a medical device as an object that is "intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o)." In this second response, the FDA ended the email by making it clear that the FDA's Center for Devices and Radiological Health (CDRH) has the authority to "force removal of devices from the market to even fines and/or incarceration for nefarious actors."10

In response to the Shearston et al paper, the FDA said that they were "aware of the recent findings" and had begun a literature review. They also commissioned an internal bench laboratory study to "evaluate metals in tampons." No further information was provided upon request. Thus, the FDA does have the authority to enforce the removal of medical devices, and its current decision not to remove certain tampons from the market is deliberate and meaningful. However, this does not mean that their decision will remain the same, as the findings of the laboratory study or literature review may or may not alter their decision.

⁹ U.S. Food and Drug Administration. "How to Determine if Your Product is a Medical Device." Accessed December 11, 2024.

https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device.

¹⁰ U.S. Food and Drug Administration, "How to Determine If Your Product Is a Medical Device."

Evaluating Cotton as a Source of Metals and Metalloids

Dr. Shearston's study, *Tampons as a Source of Exposure to Metal(loid)s*¹¹, found metals in all the tampons tested, regardless of brand. The research did not say exactly where these metals came from, but it identified several potential sources of contamination. Among the major hypotheses is that cotton, which is used as the main ingredient in tampons, can be a culprit in metal exposure because of its environmental and agricultural conditions.

Dr Shearston suggested that metals would come into cotton products via several pathways:

- *Environmental Factors:* The soil, fertilizer, or pesticide can contain metals. In addition, if the industrial pollution around cotton crops from the highway or the factory leaches metals onto the plant.
- *Water Sources:* Metals in untreated irrigation or manufacturing water might migrate into cotton fabric.
- *Manufacturing Processes*: Metals can be introduced in manufacturing accidentally (through machines) or by accident (via dyes, lubricants).

These hypotheses, along with the information of the manufacturing process for Tampax, guided the investigation into how cotton production and processing might influence the metal content in menstrual products.

To explore the potential role of cotton in metal contamination, the group Barnhardt Manufacturing Co., a prominent cotton supplier, with questions about contamination risks and mitigation strategies. This inquiry aimed to understand how soil, water, and manufacturing practices might influence the metal content in cotton used for menstrual products. Their response provided insights into industry safety standards and the measures taken to address residual metals.

¹¹ Shearston, Jenni, Kristen Upson, Milo Gordon, Vivian Do, Olgica Balac, Khue Nguyen, Beizhan Yan, Marianthi-Anna Kioumourtzoglou, and Kathrin Schilling. "Tampons as a Source of Exposure to Metal(loid)s." Environment International 166 (2024): 107440. Accessed December 9, 2024. https://www.sciencedirect.com/science/article/pii/S0160412024004355.

Barnhardt Manufacturing Co. was contacted using their "Contact Us" form. The inquiries mainly focused on how the production process of cotton could be used to influence the content of metals in menstrual products and how this was prevented from occurring. In particular, the intention was to know if soil metals affect cotton plants and what Barnhardt does to make sure it produces pure cotton.

Stacy Glover, Senior Sales & Business Development Manager, provided a document¹² outlining industry practices, emphasizing rigorous safety and compliance standards in tampon production. It also explained that though heavy metals exist in nature, they're not deliberately placed into menstrual products. Further, the report detailed how trace metals were reduced at the end of the process.

What Barnhardt's declaration did stress was a number of points:

- *Regulatory Conformity and Safety:* Manufacturers comply with local and national safety regulations like the EU General Product Safety Regulation and UK REACH regulations. These structures are safe for the manufacturing of period products, so the consumers trust their usage.
- *Presence of Metals in Nature:* The report admitted that heavy metals are naturally present in soil, water, and air and can be accidentally found in cotton and other material in tampons. But those levels in menstrual products are far less than the safe levels for food and water set by the EU, the UK and the USA.
- *Testing and Disclosure:* To deal with the risk of trace substances, the industry relies on scientifically-based testing procedures such as EDANA Guidelines for Testing Feminine Hygiene Products. Such tests mimic the realistic conditions so that menstrual products are safe, contrasting with more aggressive testing methods like the dissolution of tampons in nitric acid used in academic studies.
- *Abstraction of Residual Metals:* Through the EDANA Stewardship Programme, the industry has minimized residual metals as much as possible. This program maintains trace chemicals in products below recommended levels and aims for transparency in product composition.

https://www.edana.org/about-us/news/statement-on-tampons-as-a-source-of-exposure-to-metalloids

¹² EDANA. "Statement on Tampons as a Source of Exposure to Metal(loid)s." EDANA, July 16, 2024. Accessed December 13, 2024.

- Consumer Safety Guarantee: The statement stated that there was no evidence to connect menstrual products with health risks. Post-market surveillance and research conducted by regulatory authorities also back up the assertion that these products are appropriate for the purposes for which they are intended.

The industry statement provided some direction for thinking about the presence of metals in menstrual products. In the environment, naturally occurring heavy metals may still exist in small amounts, but safety testing and regulation minimise the threat to the public. It emphasized the need for industries to work together to ensure product safety and transparency while answering the public's objections due to independent studies.

Policy Actions

It was also important to look into the current ways in which this issue has been addressed in the past. First and foremost, there was a bill introduced to Congress by Mrs. Carolyn B. Maloney of New York. It is referred to as the "Robin Danielson Feminine Hygiene Product Safety Act of 2019," which was re-introduced to Congress multiple times since its creation but never received significant support or passed. The bill consists of four main sections, but the second and fourth sections demonstrate the scientific findings that the bill is based on, followed by a section detailing how dioxins and other potentially harmful substances in feminine hygiene products must be reinforced, respectively.

The Robin Danielson Act establishes that there is not enough research surrounding the substances in feminine hygiene products. Through the course of their reproductive lives, women may use up to 24,360 tampons. The bill established trace amounts of dioxins have been found in these products, and the EPA and the World Health Organization have both confirmed that dioxins are carcinogenic. Given the frequency in which these products are used, menstruators may be subject to excessive amounts of exposure to these substances throughout their lifetimes. Finally, the bill concedes that the FDA requires tampon manufacturers to monitor dioxin levels in raw materials and finished tampons routinely, but addresses the issue that this information is not

readily available to the public. It suggests that the FDA consider whether to expand its regulation to "include other types of feminine hygiene products and a broader list of contaminants."¹³

The Robin Danielson Act also makes a series of suggestions in the final section of the bill. It calls for the National Institutes of Health (NIH) to conduct more thorough research of the levels of chlorine, dioxins, and synthetic fibers in feminine hygiene products and whether or not they impact the health of the individuals who use these products, as well as the health of the children conceived by these women. Additionally, it calls for manufacturers to submit their data about possible carcinogens in menstrual products to the Commissioner of Food and Drugs. It also firmly defines "feminine hygiene products" as "tampons, pads, liners, cups, sponges, douches, wipes, sprays, and similar products used by women with respect to menstruation or other genital tract secretions." The bill then calls for such data to be submitted to the appropriate federal agencies and released to the public.

It is noteworthy to mention that the language used in the Robert Danielson Act does not protect transgender individuals who menstruate but do not identify as women. Thus, it does not protect all menstruators and may negatively affect the excluded demographic if passed without the appropriate revisions.

The State of New York also passed a law in 2019 that mandated tampon companies to list all of their ingredients on packaging for menstrual products. It defines "ingredients" as anything deliberately included in the composition of the product. It also calls for a fine of 1,000 dollars per package against any violators. While this law is a step in the right direction, it also does not take into account any substances that may have entered the tampon through the cotton farming process, including substances like lead and arsenic. It was for this reason that the team believed it necessary to investigate the cotton farming process.

¹³ Carolyn B. [D-NY-12 Rep. Maloney, "Text - H.R.3865 - 116th Congress (2019-2020): Robin Danielson Feminine Hygiene Product Safety Act of 2019," legislation, July 22, 2019, 2019-07-19, https://www.congress.gov/bill/116th-congress/house-bill/3865/text.

¹⁴ "NY State Senate Bill 2019-S2387B," accessed December 9, 2024, https://www.nysenate.gov/legislation/bills/2019/S2387.

Conclusion

All in all, it was clear to the team that there was a severe lack of information pertaining to menstrual products or their safety to consumers. The lack of answers prevents qualified organizations and experts from finding suitable solutions. Therefore, more studies must be conducted to determine the exact source of the toxins, how harmful they can be to the body, and whether or not other products are at risk. In summary, before any direct action can be taken, there needs to be an increase in research to identify the source and its urgency properly.

Fortunately, there are many ways this issue can still be addressed. For production, the team recommends implementing more detailed testing. This should be done both after sourcing the cotton, and again towards the end of manufacturing, to assure that the product is free of toxins as close to release as possible. However, this cannot be promised without assertive enforcement of federal regulations. The FDA must urge manufacturers to test and improve monitoring to ensure that the companies are complying. Oftentimes, the FDA only "recommends" achieving certain labels, such as biocompatibility, implying that it is only a suggestion and not necessary. To fix this, there must be a direct requirement for testing and a guarantee that there is no amount of toxins in the product. In the event that the FDA is unable to form requirements, companies should be urged to test all throughout the manufacturing process. If the toxins are coming from the water, it can be cleaned prior to use. If the issue is the soil, the cotton can be grown elsewhere or grown with alternative pesticides or fertilizers. Once companies are tested and the toxins are detected, then the Emergency Planning and Right to Know Act can be implemented to further inform the public of these findings, and can penalize companies for failing to comply with regulations.

Additionally, previous acts should be advanced and applied in a federal field. Policies such as the Feminine Hygiene Product Safety Act of 2019 require the National Institutes of Health to improve studies of the health risks of menstrual products. New York became the first state to have a law requiring proper labeling of menstrual products with the Menstrual Disclosure Act. However, while all ingredients are required to be labeled, ingredients are defined as material

¹⁵ Carolyn B. [D-NY-12 Rep. Maloney, "Text - H.R.3865 - 116th Congress (2019-2020): Robin Danielson Feminine Hygiene Product Safety Act of 2019," legislation, July 22, 2019, 2019-07-19, https://www.congress.gov/bill/116th-congress/house-bill/3865/text.

that was "intentionally added." Since Dr. Shearston's study does not confirm whether these toxins were intentionally incorporated, and companies have denied adding them on purpose; the law is not applicable. To properly tackle this issue, the FDA and other companies must recognize the significance of finding toxins in menstrual products, both intentionally and unintentionally. These policies must be passed and modified to study the effects of metals and metalloids found in tampons to ensure there is no risk.

Aside from policies, it is important that consumers are aware of the presence of toxins in menstrual products and make conscious decisions with their knowledge. However, it is impractical to recommend that consumers eliminate tampons as an option entirely. While there are alternatives such as diva cups and discs, the majority of menstruators prefer tampons because of its simplicity and familiarity. Consumers can instead switch to smaller known brands, as the original study only used major tampon brands. Ultimately, it is recommended that consumers make their own informed decision based on their lifestyle and concerns, while also calling for action to be done to further research and solve this issue.

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