



July 3, 2023

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
Washington, DC 20460

**Re: Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA),
(Docket ID: EPA-HQ-OPPT-2020-0465)**

Dear Administrator Regan:

On May 3, 2023, the Environmental Protection Agency (EPA) published a proposed rule titled "Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA)."¹ This letter constitutes the Office of Advocacy's (Advocacy) public comments on the proposed rule.

Advocacy has significant concerns regarding EPA's proposal. Primarily, Advocacy is concerned that the agency's proposal exceeds its statutory authority by prohibiting most commercial and industrial uses of methylene chloride. Furthermore, Advocacy highlights the absence of regulatory flexibilities for the use of methylene chloride by small businesses that do not have feasible alternatives. Additionally, Advocacy is concerned that EPA does not satisfy the statutory requirements to consult and coordinate with other federal agencies to avoid duplicative and overlapping requirements. Lastly, Advocacy strongly recommends that the agency accept additional data after the public comment period, address concerns pertaining to the proposed action level, and establish a de minimis threshold.

¹ 88 Fed. Reg. 28284 (May 3, 2023).

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA). As such, the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),² as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),³ gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.⁴ The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the *Federal Register*, unless the agency certifies that the public interest is not served by doing so.⁵

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."⁶

B. The Proposed Rule

In 2019, EPA finalized a rule addressing unreasonable risk to consumers from methylene chloride use in consumer paint and coating removal by prohibiting manufacturing, processing, and distribution in commerce of methylene chloride for consumer use in paint and coating removal.⁷

On May 3, 2023, EPA published a proposed rule to restrict further the use of methylene chloride under TSCA. Methylene chloride is used as a solvent in a wide range of industrial, commercial and consumer applications, including adhesives and sealants, automotive products, and paint and coating removers. TSCA requires that EPA address any unreasonable risk of injury to health or the environment identified in a TSCA risk evaluation to the extent necessary so that the chemical no longer presents an unreasonable risk. EPA evaluated 53 conditions of use of

² 5 U.S.C. §601 et seq.

³ Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).

⁴ Small Business Jobs Act of 2010 (PL. 111-240) §1601.

⁵ *Id.*

⁶ *Id.*

⁷ *Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a)*, 84 Fed. Reg. 11420 (March 27, 2019).

methylene chloride and determined that 47 conditions of use present an unreasonable risk of injury to health for workers and consumers.

Based on these risk determinations, EPA is proposing to prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for consumer use. EPA is also proposing to prohibit most industrial and commercial uses of methylene chloride.

For the remaining uses, EPA is proposing to require a workplace chemical protection program (WCPP), which would include a requirement to meet an existing chemical exposure limit (ECEL) set by EPA, as well as exposure monitoring and training. EPA proposes an ECEL of 2 ppm (8-hour time-weighted average (TWA)) and a short-term exposure limit (STEL) of 16 ppm (15-minute TWA). The uses allowed under a WCPP would include the following:

- Manufacturing
- Processing as a reactant
- Laboratory use
- Industrial or commercial use in aerospace and military paint and coating removal from safety-critical, corrosion-sensitive components by Federal agencies and their contractors
- Industrial or commercial use as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications, including in the production of specialty batteries for such by Federal agencies and their contractors
- Disposal

The proposal also includes time-limited exemptions for uses of methylene chloride that would otherwise significantly disrupt national security and critical infrastructure.

TSCA requires EPA to provide a primary alternative regulatory action. The alternative includes a WCPP for several additional conditions of use than would be allowed under the proposed regulatory action. It also provides longer compliance timeframes for prohibitions. Additional uses allowed under the primary alternative (but prohibited under the proposal) include the following:

- Industrial and commercial use in finishing products for fabric, textiles, and leather
- Industrial and commercial use as solvent that becomes part of a formulation or mixture
- Industrial and commercial use as a processing aid
- Industrial and commercial use for electrical equipment, appliance, and component manufacturing
- Industrial and commercial use for plastic and rubber products manufacturing
- Industrial and commercial use in cellulose triacetate film production
- Industrial and commercial use for oil and gas drilling, extraction, and support activities
- Industrial and commercial use in paint or coating removal from safety-critical, corrosion-sensitive components of aircraft owned or operated by air carriers or commercial operators

In advance of this proposed rule, EPA convened a small business advocacy review panel under SBREFA to consult with small entity representatives (SERs). The report issued by that panel is available in the docket.⁸

II. Advocacy's Small Business Concerns

Advocacy has several concerns with the rule. First, Advocacy is concerned that the agency's proposal exceeds its statutory authority by prohibiting the use of methylene chloride for most commercial and industrial uses. Second, Advocacy is concerned that the agency did not provide available regulatory flexibilities for the use of methylene chloride for small businesses that do not have feasible alternatives. Third, Advocacy is concerned that EPA does not satisfy the statutory requirement to consult and coordinate with other federal agencies, particularly OSHA, to avoid duplicative and overlapping requirements. Finally, Advocacy recommends the agency accept additional data after the public comment period, address concerns with the proposed action level, and establish a de minimis threshold.

A. Advocacy is concerned that the agency's proposal to ban most commercial and industrial uses of methylene chloride exceeds its statutory authority under TSCA.

According to TSCA, once EPA determines that a chemical substance presents an unreasonable risk of injury to health or the environment, it must apply one or more requirements listed in section 6(a) "*to the extent necessary* so that the chemical substance or mixture no longer presents such risk."⁹ In the proposal, EPA presents the ECEL and STEL values as the benchmarks for determining unreasonable risk. Specifically, EPA asserts that, as a matter of risk management policy, ensuring exposures remain at or below the ECEL will eliminate any unreasonable risk of injury to health.¹⁰ EPA further confirmed that the "ECEL represents the concentration at or below which an adult human, including a member of a potentially exposed or susceptible subpopulation, would be unlikely to suffer adverse effects if exposed for a working lifetime."¹¹

However, EPA proposes to ban most of the industrial and commercial uses of methylene chloride instead of allowing the regulated entities to determine compliance feasibility or demonstrate their ability to comply with the ECEL. For example, EPA cites uncertainty regarding compliance with the ECEL, particularly in comparison to OSHA's permissible exposure limit (PEL) for methylene chloride of 25ppm.¹² It is important to note that TSCA does not specify any level of certainty or compliance capability; it simply requires that the unreasonable risk must be addressed only to the extent necessary. By issuing the ECEL, the EPA

⁸ "Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule Toxic Substances Control Act (TSCA) Section 6(a) Methylene Chloride," October 28, 2021, available at EPA-HQ-OPPT-2020-0465.

⁹ 15 U.S.C. §2605(a). [emphasis added]

¹⁰ 88 Fed. Reg. 28290.

¹¹ *Id.*

¹² *Id.* at 28321.

identifies the threshold at which the unreasonable risk is considered addressed. If a user can comply with the ECEL, as proposed by EPA, there should be no unreasonable risk present. Speculating about compliance capability goes beyond the scope of the statute.

Furthermore, EPA even proposes to ban the use of methylene chloride for businesses using methylene chloride as a processing aid, including those who have demonstrated their ability to comply with the ECEL. During the SBREFA panel, one such business provided process descriptions, diagrams, and monitoring data indicating their ability to meet the proposed ECEL. EPA acknowledged that the information provided to EPA indicated that inhalation exposures were frequently below the ECEL and in some cases below the level of detection.¹³ Despite this evidence, EPA still proposes a ban for this use, although it would allow the use to continue under a WCPP in the primary alternative regulatory action, further confirming that EPA considers the use of methylene chloride as a processing aid to be allowable if the unreasonable risk is addressed.

If a WCPP with an ECEL is indeed protective of health and the environment in certain uses, as EPA claims, then banning those uses that can demonstrate compliance with the ECEL would go beyond the “extent necessary.” If a workplace can document and demonstrate compliance with a WCPP, such a use should be allowed to continue. Imposing regulations on a use that can meet the ECEL exceeds the agency’s statutory authority under TSCA. Therefore, EPA should not propose banning the use of methylene chloride for entities that can demonstrate compliance with the ECEL in the WCPP.

B. Advocacy is concerned that the agency did not provide available regulatory flexibilities for small businesses’ uses of methylene chloride that do not have feasible alternatives.

1. EPA should consider all the required impacts of a proposed prohibition on the use of methylene chloride as mandated by TSCA.

EPA is obligated to consider the reasonably ascertainable economic consequences of the rule, including consideration the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health.¹⁴ However, in the proposed rule, EPA bans the use of methylene chloride for the furniture refinishing industry, which primarily consists of small businesses. EPA acknowledges that alternative products may not be economically viable and/or appropriate (i.e, may cause damage to the wood substrate).¹⁵ This prohibition could have a significant impact on this sector, potentially leading to the closure of an unknown number of the 5,000 potentially affected furniture refinishing firms.¹⁶ The potential

¹³ 88 Fed. Reg. 28314.

¹⁴ 15 U.S.C. §2605(c)2(A)(iv)(I).

¹⁵ 88 Fed. Reg. 28286.

¹⁶ *Id.*

average lost profits could be as much as \$67 million, in the case of a complete sector shutdown.¹⁷ These costs are in addition to the compliance costs estimated for the rule.

Advocacy has similar concerns for the industries using methylene chloride to remove coatings from metal substrates. The impact on these industries is likely to be significant because it will include numerous uses such as: automotive wheel and parts refinishing, agriculture, architectural refurbishing, construction and infrastructure repair, lawn and garden products repair, and HVAC and electrical products repair. According to a small business supplier for these industries, the regulation would affect over 23,000 refurbishing and powder coating businesses, the majority of which are considered small businesses. They would also face negative consequences, potentially leading to business closures.

Small entity representatives have pointed out that EPA's economic analysis does not consider the impact on American manufacturing competitiveness resulting from the prohibition of such uses. In addition, small businesses highlighted that the agency also did not adequately consider the environmental effects. For instance, the proposed ban on the use of methylene chloride in paint and coating removers would result in durable goods that can no longer be recycled or refurbished, leading to their disposal in landfills. This could result in millions of additional cubic yards of landfill space and millions of pounds of wasted metals, woods, and other constructed materials. The replacement of these goods in turn would have an impact on natural resources. EPA did not account for these impacts and related costs in its proposed rule. Advocacy strongly urges the agency to consider the adverse effect on the national economy if many refurbished and recycled parts become unavailable due to the prohibition. EPA should also assess the costs associated with landfill disposal of parts become unavailable due to the prohibition. Finally, the agency must consider the costs related to mining materials, logging lumber, and processing materials and lumber to meet the demand for new parts in larger quantities.

2. EPA should grant a TSCA Section 6(g) exemption for the furniture refinishing and metal power coating removal industries.

According to TSCA Section 6(g), EPA has the authority to provide a time-limited exemption for a specific condition of use if it determines that "condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure."¹⁸ EPA has considered providing such an exemption for the furniture refinishing use of methylene chloride in the proposal, but concluded that it is not necessary because "reasonably available information demonstrates that alternative methods or substitute chemicals are available to some extent..."¹⁹ However, this statement contradicts other instances where EPA acknowledges that there are no economically viable or appropriate or

¹⁷ 88 Fed. Reg. 28286.

¹⁸ 15 U.S.C. §2605(g).

¹⁹ 88 Fed. Reg. 28313.

alternatives available.²⁰ EPA also cites fatalities as a reason to deny an exemption,²¹ despite the fact that there have been no deaths from acute exposures since the ban on consumer use of methylene chloride, in 2019.

Under the proposed Section 6(g) exemptions included in this rule, EPA requires compliance with the WCPP. Based on this approach, EPA denies an exemption for the furniture refinishing industry because of the “likely inability of this sector to comply with a WCPP.”²² If complying with the ECEL included in WCPP adequately addresses the unreasonable risk, then an exemption for continuing a use should not be necessary. An exemption excuses a regulated party from a legal requirement.²³ In granting EPA the authority to provide an exemption for condition of uses that are considered to be a critical or essential use for which no technically and economically feasible safer alternative is available, Congress intended that these entities would not be subject to the legal requirement to address the unreasonable risks (i.e. the ECEL and WCPP). Advocacy believes that EPA can utilize this exemption for furniture refinishing and other similarly situated industries without an available technically and economically feasible safer alternative, taking into consideration the hazard and exposure concerns.

Advocacy also recommends that the agency consider feedback from small entities to determine the most appropriate time limit for the exemption. Furthermore, Advocacy encourages the agency to establish a certification program for the use of methylene chloride by the furniture refinishing industry and by the metal power coating removal industry, along with other measures to address the unreasonable risk associated with the use of methylene chloride. In addition, Advocacy supports any efforts by the agency to ensure that small businesses can maintain access to methylene chloride for industrial and commercial uses, including establishing training, certification, and limited access programs.

3. EPA should establish reasonable transition periods for any uses subject to a ban.

According to TSCA, when the agency is contemplating a prohibition or a substantial restriction on the use of a chemical, it is required to set an appropriate transition period.²⁴ To make this determination, “the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.”²⁵

²⁰ 88 Fed. Reg. 28286.

²¹ *Id.* at 28313.

²² *Id.*

²³ Regulatory Waivers and Exemptions, Recommendation by the Administration and Management Committee, Administration Conference of the United States (ACUS), December 15, 2017, available at [Regulatory Waivers and Exemptions | Administrative Conference of the United States \(acus.gov\)](https://www.acus.gov/regulatory-waivers-and-exemptions) (last visited June 29, 2023).

²⁴ 15 U.S.C. §2605 (c)2(A)(iv)(I).

²⁵ *Id.*

If EPA decides to ban the use of methylene chloride, it should take into account the limited resources available to small entities and establish differing compliance or reporting requirements and timetables. Despite acknowledging the possibility that longer timeframes may be necessary for entities to achieve compliance, EPA proposes rapid compliance timeframes.²⁶ However, the agency does include extended time frames in its primary alternative regulatory action. If the agency has determined that a longer compliance timeline is necessary and practicable, then those timelines should have been proposed in the initial proposal and should be finalized. Advocacy urges the agency to consider feedback from small entities to ensure that the maximum compliance timeframe is provided, allowing for an appropriate transition period.

C. Advocacy is concerned that EPA does not satisfy the statutory requirement to consult and coordinate with OSHA to avoid duplicative and conflicting requirements.

EPA should not have proposed duplicative, overlapping and conflicting regulations by issuing a WCPP, including an ECEL, to cover worker exposures subject to OSHA's jurisdiction. TSCA Section 9 requires EPA to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."²⁷ EPA states that the agency engaged in such coordination with other federal agencies, including OSHA "to identify their respective authorities, jurisdictions, and existing laws with regard to risk evaluation and risk management of methylene chloride."²⁸

Under the RFA, the sixth element of the Initial Regulatory Flexibility Analysis (IRFA) is to identify any duplicative, overlapping, and conflicting federal rules.²⁹ Rules are considered duplicative or overlapping if they are based on the same or similar reasons for the regulation, the same or similar regulatory goals, and if they regulate the same classes of industry. Conflicting rules impose two conflicting regulatory requirements on the same classes of industry. In the IRFA, EPA is required to examine the potential conflicting and duplicative rules that can unnecessarily add cumulative regulatory burdens on small entities without any gain in regulatory benefits.

EPA's proposal is duplicative of OSHA's regulations for methylene chloride because they both aim to protect workers from unsafe exposure to methylene chloride and they apply to the same classes of industry. EPA's proposal conflicts with OSHA's regulations as it imposes different regulatory requirements on the same classes of industry. In addition to proposing a different, much lower, exposure limit from OSHA, EPA is proposing additional requirements for user notification, recordkeeping, periodic monitoring, and respirator selection criteria as part of the

²⁶ 88 Fed. Reg. 28316.

²⁷ 15 U.S.C. §2608(d).

²⁸ 88 Fed. Reg. 28330.

²⁹ 5 U.S.C. §603(b)(5).

WCPP.³⁰ EPA acknowledges that entities currently in compliance with the OSHA standard may have to increase the frequency and scope of their compliance activities, such as through the implementation of engineering controls to reduce exposures to the extent feasible, periodic exposure monitoring frequency, establishment of regulated areas, use of respiratory protection, and notification of monitoring results.³¹

TSCA provides EPA with the discretion to avoid such duplicative, overlapping and conflicting federal requirements. Specifically, under TSCA Section 9, if EPA determines that the identified unreasonable risks for methylene chloride “may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such a law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk.”³² In the proposed rule, EPA does not determine that unreasonable risk from methylene chloride can be addressed by an action taken under a different federal law.³³

Regarding workplace exposures, EPA reasons that an action under TSCA can address occupational unreasonable risk and reach entities that are not subject to OSHA, such as self-employed individuals and public sector workers who are not covered by a State Plan. EPA also expressed concerns about the potentially longer timeframe for updating OSHA’s standards. EPA further adds that regulations issued under TSCA’s authority can prevent a patchwork of regulations among several agencies using multiple laws and differing standards, making it a more efficient and effective means of addressing the unreasonable risk of methylene chloride.³⁴

TSCA should be administered as a gap-filling statute. EPA should focus its intentions on those workers not currently protected under the Occupational Safety and Health Act.³⁵ EPA should not attempt to supplant existing regulatory frameworks. Advocacy believes that EPA should proceed with a rulemaking that covers those entities not subject to OSHA’s regulations and allow OSHA to address the identified unreasonable risks within its jurisdiction.

EPA’s concern about a patchwork of different standards for different entities is ironic because the agency is creating a similar situation by requiring compliance with two federal regulatory frameworks and compliance with different standards. Advocacy believes that under TSCA Section 9, EPA should have consulted with OSHA to address the risk concerns with its standards

³⁰“Initial Regulatory Flexibility Analysis for Methylene Chloride; Regulation of Methylene Chloride under TSCA §6(a) Proposed Rule; RIN 2070-AK70,” U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, [IRFA] at pg. 27 (April, 2023).

³¹ *Id.*

³² 15 U.S.C. §2608(a)(1).

³³ 88 Fed. Reg. 28330.

³⁴ IRFA at 43-44.

³⁵ 29 U.S.C. 651 et seq. (1970).

and worked to support OSHA updating its PEL for methylene chloride instead of creating an additional regulatory framework for the same entities.

D. Advocacy recommends EPA accept additional data after the public comment period deadline, address concerns with the proposed action level and establish a de minimis threshold.

1. Concerns about the limited public comment period.

EPA should consider allowing regulated entities to submit requested data after public comment period has closed. This issue was raised during Advocacy's roundtable discussion on the proposed rule, where a trade organization participant expressed valid concerns about the limited public comment period. Advocacy recognizes the legitimate concerns for the regulated entities to review and respond to rulemaking of a massive scope which will significantly impact most industrial and commercial uses of a widely used chemical. Advocacy understands that EPA declined to extend the comment period but Advocacy urges the agency to remain open to receiving additional feedback from the regulated entities in response to its proposal.

In particular, the proposed rule indicates that in some cases prohibition could be avoided if EPA could identify reasonably available information such as monitoring data or technical information that would indicate with certainty that relevant regulated entities for these conditions of use could sufficiently mitigate identified unreasonable risk by complying with the ECEL and other requirements of the WCPP. However, generating such responsive data and aggregating relevant information may require more than the 60 days provided for public comments. Therefore, Advocacy recommends that the agency develop a line of communication that allows for additional information to be considered by the agency before developing its final rule. By doing so, EPA can ensure that all relevant data and perspectives are thoroughly evaluated, leading to a more comprehensive and effective final rule.

2. Action level is too low and cannot be measured in real time.

The proposed action level set by EPA is too low and cannot be accurately measured in real time. The agency establishes an ECEL action level at half of the 8-hour ECEL, or 1 ppm.³⁶ The ECEL action level would be a definitive cut-off point, relieving certain compliance activities like periodic monitoring.³⁷ EPA assumes that a regulated entity has the necessary means to detect values at this action level, as they are above the detection limit (ranging from 0.2 to 0.4ppm).³⁸ However, small business stakeholders have expressed their disagreement with this assumption. While there may be commercially available methods to detect an exposure at the action level, it is not instantaneous, and the ability to measure it on-site is not currently readily available. Instead, samples must be sent to a laboratory, which can take three or more days to obtain

³⁶ 88 Fed. Reg. 28300.

³⁷ *Id.*

³⁸ *Id.*

results. The small entities also expressed concerns about the likelihood of decreasing lab capacity. In light of this feedback from small entities, Advocacy recommends that the agency consider adjusting the action level. It is crucial to take into account the practical limitations faced by small businesses and ensure that the action level is both feasible and accurately measurable in real-time.

3. EPA should establish a de minimis threshold.

EPA is seeking comments on whether it should consider a de minimis level of methylene chloride in formulations for certain continuing industrial and commercial uses to account for impurities (e.g., 0.1% or 0.5%) when finalizing the prohibitions.³⁹ Advocacy strongly supports the inclusion of a de minimis level of methylene chloride, especially for unintentional presence of methylene chloride, and encourages the agency to consider feedback from the regulated entities on potential appropriate de minimis threshold amounts.

III. Conclusion

Advocacy is concerned that the agency's proposal exceeds its statutory authority by prohibiting a vast majority of the commercial and industrial uses of methylene chloride. Additionally, Advocacy is concerned about the lack of available regulatory flexibilities for the use of methylene chloride by small businesses, particularly in cases where feasible alternatives are not available. Moreover, Advocacy is concerned that EPA does not satisfy the statutory requirement to consult and coordinate with OSHA to avoid duplicative and overlapping requirements. Lastly, Advocacy strongly urges the agency to accept additional data after the public comment period, address concerns with the proposed action level, and establish a de minimis threshold to mitigate unintended consequences.

Advocacy recommends the EPA to reconsider the proposed rule. While it is important to protect public health, it is also important to follow the law and take small business impacts into consideration. Advocacy urges the agency to consider feedback from small businesses on these important issues.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Tayyaba Zeb at (202) 798-7405 or by email at tayyaba.zeb@sba.gov.

Sincerely,

/s/
Major L. Clark, III
Deputy Chief Counsel

³⁹ 88 Fed. Reg. 28333.

Office of Advocacy
U.S. Small Business Administration

/s/

Tayyaba Zeb
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Copy to: Richard L. Revesz, Administrator
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