

#### **Contents**

Introduction
The use of risk-based regulation in the context of rapid innovation
The precautionary principle and essential use criteria
Workshop details
Workshop presentations
Risk and precaution
Essential use within the context of risk management
Public perception of essential use
Breakout sessions
Breakout one: risk and precaution
Question one: How could a risk-based approach effectively protect the environment and society from chemicals with insufficient data (or when the science is uncertain)?
Question two: Under what circumstances should precautionary control be applied?
Breakout two: essential use
Question three: How can the concept of essential use adequately deal with uncertain risk, and can it deliver a more effective and efficient approach to risk management of chemical groups?  Why/why not? How could the essential use concept fit into existing regulatory regimes?9
Question four: What are the alternatives to essential use and are they preferable? Why/why not?  Could essential use be used in combination with existing/new approaches?9
Recurring themes in presentations and breakouts
Other suggestions from participants:
References

This document is a report of a science-policy workshop attended by around 60 delegates, bringing natural scientists, social scientists and policymakers together to discuss risk and precaution in chemicals policy and chemicals safety decision-making. This report does not contain any recommendations and it does not represent the views of any of the organising committee or the organisations which they represent. The content of the presentations given at the event is reflected, and the general nature of the discussions that arose is presented, with points raised in the breakout groups gathered as themes at the end of the document. It is the intention that these perspectives can feed into future discussions on the evolution of chemicals policy, particularly in areas where the science is currently uncertain.

#### Introduction

Chemicals policy in the UK today is based mainly on a combination of regulatory regimes and industry selfmanagement and due diligence. To release chemicals and products into the market or into the environment without any knowledge on exposure and hazards is highly risky; we know some chemicals are hazardous to human and environmental health, and not all hazards can be predicted. We also know from the Lancet Commission reports that human health is being adversely affected by poor air quality and pollution.1 With global chemicals production set to double by 2030, pollution must not double.<sup>2</sup> Human health and the environment could be even more severely harmed if the pace of innovation outstrips safety data generation and the implementation of effective chemicals management strategies. Conversely, to ask for a comprehensive traditional exposure assessment and toxicology testing programme covering the many multiple possible effects for hundreds of substances can cost millions of pounds, take many years and be a barrier to innovation.

Regulation is most effective when it is proportionate and drives innovation and diligent practices, to reduce, and ideally minimise, the harms of hazardous chemicals on human health and the environment. As part of the discussions on a UK Chemical Strategy, the government needs to find pragmatic and proportionate ways forward in chemical risk management and decision-making that society can trust to keep them safe and whilst also enabling innovation. The process should incorporate sound scientific evidence as much as possible. Consideration should be given to using new approach methods (NAMs), new concepts, new risk paradigms, and combining natural sciences and social sciences into decision-making. We need innovation in regulatory risk assessment to support innovation in chemicals, whilst maintaining high levels of environmental and human health protection.

# The use of risk-based regulation in the context of rapid innovation

Risk-based regulation acknowledges that while a chemical may be hazardous, the risk it poses can be reduced by controlling exposure to the chemical. This type of regulation requires scientific data to understand both the hazard and exposure of the chemical. In some cases, scientifically based conservative assumptions can be used in modelling. However, actual measured or modelled data is not always available, and the science is not always certain, such that regulatory decisions on whether to authorise or restrict use of a chemical must often be taken with provisos and in the face of significant uncertainty.

The chemicals industry is expected to double globally by 2030.<sup>2</sup> At this rapid pace of innovation and growth and given the current levels of resourcing and

regulatory approaches, the scientific methods used to gather safety and exposure data for substances cannot be expected to keep pace. Recent evidence suggests that the 'planetary boundary' is already being exceeded by chemicals in the environment, i.e., our planet is struggling to cope with the overall anthropogenic chemical burdens in air, land and water and we will start to see more adverse effects in the years ahead.3,4 Additionally, there are chemicals currently in use for which there is insufficient data available to fully evaluate their safety. The Royal Society of Chemistry has developed policy positions for two such areas where the pace of innovation has outstripped the generation of safety evidence, namely poly- and perfluoroalkyl substances (PFAS) and potential endocrine disrupting chemicals (EDCs).5

# The precautionary principle and essential use criteria

The precautionary principle states that neither a lack of information nor scientific certainty should delay action or regulation when there are potential severe and irreversible consequences. This principle underpins why the concept of essential use has been proposed by some as a possible pragmatic risk management solution when faced with potentially large numbers of data-poor chemicals, for which a substance-by-substance approach to regulation can be slow and impractical. The essential use concept involves identifying the applications of chemicals and allowing their use when 'essential' but prohibiting other uses to limit exposure and potential harms. The concept was introduced in the Montreal Protocol, where a substance qualifies as 'essential' only if:

- "1. it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and
- 2. there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health"<sup>6</sup>

The Montreal Protocol was narrow in scope, regulating select ozone depleting substances. If the essential use concept is to be applied to a wide-ranging group of data-poor substances, there are important methodological and practical questions to be further defined, such as

- which applications qualify a substance as 'essential,'
- when the concept should be applied,
- how it compares with other possible approaches to regulation,
- who makes these important decisions.

In the workshop 'When the science is uncertain, what is the role of risk-based approaches and precautionary control in chemicals policy?', around 60 attendees were brought together from academia, industry, NGOs, policy and professional bodies from the UK and EU to share and discuss this question.

The workshop was co-sponsored by the Royal Society of Chemistry (RSC), the Department for Environment, Food and Rural Affairs (Defra) and the Chemicals Industry Association (CIA). We invited the speakers below to set the scene, prior to an afternoon of breakout discussion groups on the practicalities of using risk-based regulation, precautionary control and the essential use concept to regulate chemicals when scientific evidence is uncertain.

#### **Workshop details**

The following persons are thanked for chairing and speaking during the workshop sessions.

#### **Chairs:**

- Professor Ragnar Lofsted (Kings College London)
- Catherine Gunby (Fidra)
- Silvia Segna (Chemicals Industry Assocation)

#### **Introductory Speakers:**

- Stavros Georgiou (Health & Safety Executive)
- Dr Camilla Alexander-White (Royal Society of Chemistry)
- Edward Latter (Defra)

#### Panellists:

- Geoffrey Podger (Kings College London)
- Professor Frederic Bouder (University of Stavanger)
- Professor Nick Pidgeon MBE (Cardiff University)
- Andrew Fasey (Mayer Brown)
- Professor Ian Cousins (Stockholm University)
- Dr Anna Watson (CHEM Trust)
- Dr Silke Gabbert (National Institute for Public Health and the Environment, Netherlands)
- Dallas O'Dell and Woong-Ki Lee (The London School of Economics and Political Sciences)

#### **Workshop presentations**

#### **Risk and precaution**

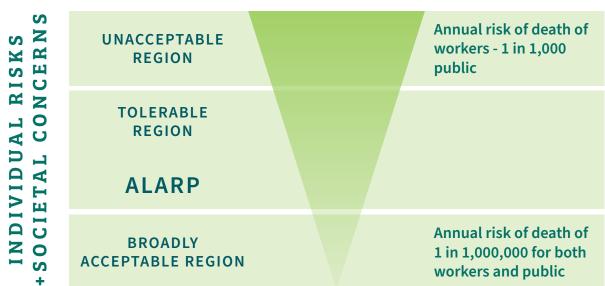
Opening the workshop, **Mr Geoffrey Podger** observed that the role of scientists is to present options to politicians. He warned that in some cases politicians "are very much welcoming of scientific advice, provided it agrees with what they've already decided to do". Therefore, he called for transparency and accountability, proposing that when publishing a decision, politicians also publish the scientific evidence it is based on, or the justification for why it is not based on scientific evidence. He also stressed the importance of defining terms such as 'hazard', 'risk' and 'essential' so that no one party can take advantage of them being unclear.

Mr Podger also voiced concerns around the diminished inclusion of science and evidence in EU decision-making in recent years, particularly as the UK develops its post-Brexit chemicals strategy following EU exit. Due to international trading, pressure will come from industry for new UK regulation to follow EU regulation. Mr Podger suggested that the EU Chemicals Strategy for Sustainability (CSS) will be largely determined by EU politicians, who are driven by their own political agendas, and that there would be opportunities for the UK to have science and risk-based regulation. However, he recognised this would lead to divergence between EU and UK regulatory regimes, which would bring challenges.

Professor Frederic Bouder's presentation explored how to define important terms. Professor Bouder noted that academics and governments usually define 'precaution' in similar terms: as something that is justified when there is a significant threat combined with high levels of scientific uncertainty. In practice however, precaution is applied to different situations across different countries and areas of regulation, some of them not meeting those conditions. Professor Bouder suggested that this disparity is often due to variations in the appreciation of risks and benefits and the levels of threat and uncertainty that are deemed acceptable by decision-makers. Quoting from a seminal paper on risk by Fischoff, Professor Bouder shared factors that affect the acceptability of risk:

"the certainty and severity of the risk; the reversibility of the health effect; the knowledge or familiarity of the risk; whether the risk is voluntarily accepted or involuntarily imposed; whether individuals are compensated for their exposure to the risk; the advantages of the activity; and the risks and advantages for any alternative".

#### TOLERABILITY OF RISK (ToR)



#### Figure 1: Tolerability of Risk diagram

The ToR diagram accounts for the effects of both individual risks and societal concerns on the acceptability and tolerability of risk. ToR is informed by death rates and surveys of the public. ALARP: as low as reasonably practicable. Diagram from Professor Frederic Bouder's presentation.

While the risks associated with certain substances can be defined as acceptable or unacceptable, there are some substances that have risks but are still considered as needed by society. This is where the tolerability of a risk is pertinent. Professor Bouder shared the Tolerability of Risk (ToR) diagram (figure 1), a decision aid for policymakers developed by the Health and Safety Executive (HSE) in Great Britain.<sup>8,9</sup> ToR considers both individual risks and societal concerns and categorises substances as unacceptable, tolerable and acceptable. Measures should be put in place to lower the risks of chemicals in the tolerable region. Professor Bouder suggested that an updated ToR diagram may help make risk communication around chemicals regulations clearer in the future.

The social factors affecting the acceptability of risk are not unique to chemicals regulation. Professor **Nick Pidgeon** shared lessons learnt from other risk areas such as climate change and biosecurity. The amount of communication about a risk has an impact on how the risk is perceived by the public. This was seen during the **social amplification of the 2012 Chalara outbreak**, where Chalara (ash tree dieback) quickly became a top priority for the UK Government after a rise in media coverage increased public awareness of the outbreak. Similarly, whether communication focuses on the costs or benefits of an issue will shape public perceptions.

Narratives, attitudes to risk and the values of the public also play a role in the acceptability of risk. During the **UK's Citizens Assembly on Climate Change**, participants overwhelmingly chose nature-based solutions for carbon removal, even though evidence suggests that nature-based solutions alone may not be sufficient to reach the UK's current carbon removal requirements. Additional social factors affecting the acceptability of risk are the trust the public has in experts and policymakers, and the distributional equity of a risk.

Professor Pidgeon also encouraged policymakers to be aware of the Collingridge dilemma, which is the idea that because of uncertainties risks cannot always be predicted before a technology has been fully developed, but once the technology is in use, it may be too late to avoid the risks. <sup>10</sup> To address the Collingridge dilemma, Professor Pidgeon suggested that initial deployment decisions should wherever possible be reversible, organisations should be flexible, and small-scale trials should be performed before full implementation.

# Essential use within the context of risk management

A commitment to define criteria for the application of the essential use concept was included in the EU's **Chemicals Strategy for Sustainability** (CSS) under the new **EU Green Deal**. The CSS includes 85 actions and 12 proposed amendments to EU REACH and is intended to simplify and strengthen existing EU frameworks. Key actions include applying the essential use concept to phase out the most harmful chemicals, fast-tracking restrictions based on hazard, and emphasising essentiality and sustainability.

Mr Andrew Fasey highlighted stakeholder concerns about the incoming legislation. When essential use was used in the Montreal Protocol, the scope of chemicals was small, but the CSS will apply the concept on a much larger scale. Stakeholders are unsure how the essential use concept will effectively and efficiently regulate a broad range of chemicals. Additionally, Mr Fasey raised concerns that the amount of incoming EU legislation is overwhelming and that it is unclear how the parts will be integrated together and within the existing framework. The terms 'essential' and 'sustainable' have not yet been defined by the CSS. These issues make it difficult for stakeholders to understand how the CSS will affect them.

As deeming a chemical essential requires there to be no safer and economically feasible substitute, alternatives assessments will have to be carried out for many chemicals. These assessments are not simple, and stakeholders are concerned that the EU does not have the resources to carry out these assessments in a way that makes the essential use concept more efficient than existing risk- and hazard-based regulation. Mr Fasey suggested that the essential use concept should be used to make quick decisions about lots of chemicals, then companies can apply for exemptions retrospectively if they believe their use is essential.

Professor Ian Cousins, who has made significant contributions to current discussions in the UK and EU about the essential use concept, stated that risk assessment has failed for per- and poly-fluoroalkyl substances (PFAS). As more evidence has emerged about the hazards of PFAS, the environmental levels considered safe have decreased, but as PFAS are persistent and have already been in use, safe levels have already been exceeded. Professor Cousins also noted that it is impractical to completely ban all PFAS as some of their uses are considered essential in some critical areas of society, e.g. in medical devices and some occupational protective clothing.

Professor Cousins shared aspects to consider when applying the essential use concept. First, the substances for consideration need to be identified and the concept should only be applied to the 'most harmful substances' for which traditional risk assessment approaches may not be appropriate for their safe management. The essential use concept can be made more efficient by regulating chemicals as groups. Second, there are different ways the function of a chemical can be substituted. For example, Bisphenol-A (BPA) in thermal paper receipts can be substituted by a different chemical (chemical function), thermal paper receipts can be created using different materials (end use function), or electronic receipts can be used instead (service function). Third, to be 'essential' substances must be critical for the health and safety of society and have no acceptable substitutes. Professor Cousins shared that more clarity on what defines 'essential' will be available soon when the Wood Report, commissioned by the European Commission to define criteria for essentiality, is published.

**Dr Anna Watson** presented insights from the **UK Chemicals Stakeholder Forum's** working group on essential use. The purpose of the working group was to discuss how the essential use concept has been used in the past and is proposed to be used to regulate hazardous chemicals. The stakeholders viewed the essential use concept as a pragmatic way of reducing pollution and speeding up chemical regulation. They agreed that the application of the essential use concept should require some evidence of harm and prioritise the most hazardous chemicals. Stakeholders also argued that persistence alone also justified the application of the essential use concept. However, the stakeholders also had some concerns. First, not all the uses of chemicals are known and therefore it could be difficult to determine whether a substance is essential. Second, essential uses should improve quality of life, but measuring this impact varies on whether the benefit is individual or societal.

### Public perception of essential use

Note that the following speakers presented results from pilot studies which should not be used to draw conclusions. Results from the main studies, once completed, will help to provide insight into public perceptions of essentiality and risk.

Dr Silke Gabbert presented her work at the Dutch National Institute for Public Health and the Environment. The study surveyed citizens of seven European countries on the essentiality of persistent chemicals. The pilot study has been completed and results from the main study are currently being analysed. Results from the pilot study suggest that perceptions of 'essential' and 'non-essential' differ depending on the country and use of the chemical. Dr Gabbert called for definitions of 'necessary,' 'critical for the functioning of society' and 'acceptable,' as well as inclusions of citizens' perspectives in decision-making.

**Dallas O'Dell** and **Woong-Ki Lee** presented their work on public perceptions of PFAS in the UK. The pilot study consisted of two parts: a needs-based assessment and an economics-based assessment.

The needs-based assessment evaluated perceptions of which products containing PFAS are essential for the critical functioning of society. Products were either functional (products with functional and technical capabilities) or experiential (products that people desire). The pilot results suggest that experiential products were perceived as less essential, needed, and worth consuming than functional products. Additionally, results suggested that PFAS added significantly lower benefit to experiential products compared to functional products.

In the economics-based assessment, participants were informed that the risks of PFAS are uncertain and that because PFAS is persistent the risks could be irreversible. Participants were asked how much of a price increase for everyday products they would be willing to accept in return for a ban of PFAS that would remove health and environmental risks entirely. Pilot results suggested that participants were willing to pay £25 per month on average, although this number was regarded by some as higher than expected and may not be representative of opinions of risk from chemicals more broadly.

#### **Breakout sessions**

To understand how risk assessment and precautionary control could be used to regulate data-poor chemicals, we asked participants to discuss four questions. The key points from these discussions are summarised below.<sup>11</sup>

#### **Breakout one: risk and precaution**

## Question one: How could a risk-based approach effectively protect the environment and society from chemicals with insufficient data (or when the science is uncertain)?

- There are different types of uncertainty depending on what data is available. Therefore, whether a riskbased approach could provide effective protection differs on a case-by-case basis.
- Grouping allows data from representative chemicals to be used via the concept of read-across to efficiently regulate multiple similar chemicals for which data may be insufficient.
- REACH legislation has data requirements to deal with uncertainty. Issues arise from situations that were not considered when the legislation was made, such as mixtures and persistence without proven harm. Lessons must be learnt if there are evidenced cases where risk assessment has failed before.
- When regulating chemicals for which the science is uncertain there are factors to be considered:
- 1. Acceptability
  - The public's appetite for risk should be gauged.
  - The risk to workers differs from risk to the public.
  - The public has delegated authority to regulators to make decisions in their interest.

- 2. Transparency
  - Uncertainty is intrinsic to science.
  - Communication to the public should be done in a way that is understandable (e.g. likelihood of being struck by lightning).
  - Communication to the public should be done by scientists.
  - Policymakers are not required to follow scientific advice but must be transparent when they do not.
  - Transparency from industry makes more data available.
- 3. Flexibility
  - Legislation must be prepared to adapt to new scientific approaches and data.
  - A timescale is needed for review and revisions to regulations.
- 4. Prioritisation
  - A framework is needed for prioritising chemicals for further research.
  - Methods could include modelling, machine learning, toxicokinetics, New Approach Methods (NAMs).

### Question two: Under what circumstances should precautionary control be applied?

- Precaution should be applied in the following circumstances:
- when the science is uncertain in either the hazard assessment or exposure assessment, as defined by independent scientific experts
- when a substance is chemically or functionally related to a group that is known or strongly suspected to be harmful
- when the adverse effect may be irreversible
- when the substance is persistent or bioaccumulative, as a toxic threshold will be reached at some point
- when it is unclear how the chemical will be used, i.e., details of use are not provided and therefore exposure cannot be so easily controlled

- when vulnerable populations come into contact with the substance
- when the substance is produced in amounts over a certain tonnage
- when the substance is used widely or has high environmental motility
- There is currently no regulatory pathway for a substance to move to a lower risk category if further evidence shows it to be less harmful than initially thought. Therefore, if precaution is being used to regulate chemicals, there must be a framework to lift precaution as more data becomes available.

#### Breakout two: essential use

# Question three: How can the concept of essential use adequately deal with uncertain risk, and can it deliver a more effective and efficient approach to risk management of chemical groups? Why/why not? How could the essential use concept fit into existing regulatory regimes?

- The Montreal Protocol is regarded as a successful implementation of the essential use concept. It was effective because it was international, and exemptions were narrow and time restricted. The Montreal Protocol did result in some regrettable substitution as some alternatives turned out to be greenhouse gases that affect climate change.
- It is easier to regulate obviously essential and nonessential substances, but those in the grey area are difficult. Who decides which grey area substances are essential and how can you ensure consistency in this? A form of regulation that encourages business to shift away from all those uses that the business clearly accepts as non-essential (e.g. given cost-effective substitutes) could help narrow the list of substances which will require more effort to regulate effectively.
- Exposure still needs to be considered for substances deemed essential. Non-essential uses should not be penalised if exposure is already well controlled.
- Deeming a substance 'non-essential' incentivises R&D for safer alternatives. Conversely, deeming a substance 'essential' disincentivises R&D for safer alternatives.

- It is important to avoid regrettable substitution.

  Alternative substances must be assessed to ensure they are safer than the original, but this takes time.

  Alternatives may not be entirely safe, but just less harmful than the original.
- Introducing the essential use concept in one jurisdiction risks pushing industry into less regulated countries.
- It is difficult to know what all the uses of a chemical are, and therefore whether the chemical is essential. This would require significant time and effort and it is unclear whether the essential use concept would be more efficient than current methods used in regulation. There would have to be an onus on industry to prove the substance is essential.
- Enforcing the essential use concept would be difficult and require increased NGO monitoring for whistleblowing, especially considering the very large volume of different uses and competing views on whether each use is essential.

# Question four: What are the alternatives to essential use and are they preferable? Why/why not? Could essential use be used in combination with existing/new approaches?

- Cost/risk-benefit analysis is preferable as it acknowledges the trade-offs in a transparent way and helps in understanding issues in an evidence-based manner. The essential use concept can be stricter than cost-benefit analysis as 'essential' and 'beneficial' are not the same.
- Risk assessment can be used but this requires data and knowhow and is regarded as expensive.
- New approach methods (NAMs) could allow data to be gathered more efficiently, allowing risk assessments to be performed. Implementation of NAMs would require regulatory transformation.
- Authorisation under REACH regulation makes the essential use concept redundant.
- It would be useful to be able to test-drive policy before full introduction

# Recurring themes in presentations and breakouts

The following is a summary of the major themes that emerged from the workshop. These are not recommendations, but rather a starting point for further discussions about risk-based decision-making, precautionary control and the essential use concept, and important considerations for their application.

- 1. **Definitions** of relevant terms are needed so that it is clear what effect proposed regulations would have. Key terms include:
  - hazard
  - precaution
  - acceptable
  - uncertain
  - essential
  - sustainable
  - necessary
  - critical for the functioning of society
- 2. Apply the essential use concept as an **efficient means of applying precautionary control** for substances with limited toxicity and/or exposure data.
  - Finding out about the uses and possible substitutes of a chemical is time consuming.
     Instead, an authorisation system could be used for essential uses.
  - Uncertainty should not prevent action if there is some evidence of harm.
  - Regulate chemicals in groups to increase efficiency.
  - Transparency from industry will make regulation using the essential use concept more efficient.
- 3. **Regulation must be dynamic** to allow changes in regulation as more data becomes available, and to avoid regrettable substitution and the Collingridge dilemma.<sup>12</sup>
  - There must be a framework with a timeline to lift or increase precaution as more data becomes available.
  - Well established 'command and control' regulation restricting certain substances could potentially be complemented by a broader regulatory framework to multiply industry good practice and help move the market (e.g. compulsory company auditing or reporting of action to move away from chemicals of concern deemed non-essential by the company).
  - Alternative substances must be tested to make sure they are safer than the original and the outcome of these tests must be acted upon.
  - Reversible decisions, flexible organisations and small-scale trials reduce risk of the Collingridge dilemma.

- 4. Regulation should be based on **frameworks** and evidence.
  - Frameworks are needed to ensure consistent decision-making.
  - Essential use could be one part of a risk assessment framework.
  - A framework is needed for prioritising chemicals for further research.
  - Governments should publish the scientific evidence that regulatory decisions are based on.
  - Industry needs to be transparent about how its hazard data is used through the entire regulatory process, including the development and generation of new data to inform new regulations.
- 5. The **public's perspective** needs to be considered, and governments should **communicate** and be **transparent** to gain public trust.
  - Public consultations and participatory processes provide insight into public perceptions of essentiality and risk to inform regulatory decisions.
  - Regulators need to be aware that perceptions will change in different locations/ different groups and depending on how the issue is presented to them.
  - Frameworks that take acceptability into account (such as the Tolerability of Risk diagram) help to make risk communication clearer.

### Other suggestions from participants:

- Exposure of essential chemicals still needs to be controlled.
- Non-essential uses should not be penalised in situations where exposure is well controlled.
- R&D for safer alternatives to essential chemicals should be incentivised.
- The essential use concept cannot resolve all issues of chemical pollution.
- The transition to a circular economy may change perceptions of what is essential and create new risk management challenges.

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- <sup>10</sup> Collingridge (1980) The Social Control of Technology. St. Martin's Press.
- <sup>11</sup> The views of the participants in the breakout sessions were diverse, and in summarising the discussions it is possible that not everyone's view is represented in the write up. This section does not represent the views of RSC or the other members of the organising committee.
- <sup>12</sup> The Collingridge dilemma is the idea that because of uncertainties, risks cannot always be predicted before a technology has been fully developed, but once the technology is in use, it may be too late to avoid the risks.

### **Acknowledgements**

#### Special thanks to the workshop organising committee:

Edward Latter and Gershwinder Rai (Defra)

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