Chemicals policy and regulation update

Index

1. Update on REACH issues

1.1 Consultations

- Proposed restriction of calcium cyanamide as a fertiliser - **deadline for comments 25 March 2020.**
- Applications for authorisation covering 30 uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and 4-nonylphenol, branched and linear, ethoxylated. Deadline for comments closed on 8 January 2020.
- Proposed occupational exposure limits (OELs) for lead and its compounds and diisocyanates had a deadline of 16 December 2019.
- Call for evidence on a restriction on lead in ammunition and fishing tackle had a deadline of 16 December 2019. ECHA published a Q&A document based on the questions received during an online information session
- Proposed restriction for skin sensitisers in textiles and leather articles had a deadline of 19 December 2019.

1.2 Restriction

- RAC adopted its opinion supporting proposal to restrict siloxanes (D4, D5, D6). SEAC agreed on its draft opinion and a consultation on the SEAC draft opinion planned for 18 December 2019.
- SEAC adopted opinion in support of the proposal to restrict the uses of N,N-dimethylformamide (DMF)
- SEAC adopted its opinion in support of the proposed restriction of polycyclic-aromatic hydrocarbons (PAHs) content in granules and mulches used as infill material in synthetic turf pitches and in loose forms on playgrounds and in sports applications.
- ECHA plan to submit a restriction dossier on lead chromates on the new postponed date of 17 January 2020.
- France have submitted an intention to restrict certain substances in disposable nappies (including e.g., PAHs, formaldehyde, dioxins, furans) Proposed submission date is 9 October 2020.

1.3 Evaluation

ECHA have published substance evaluation conclusions for:

- 2-methylpropan-2-ol -
- 2-[methyl[(nonafluorobutyl) sulpho-nyl]amino]ethyl acrylate
- Phenol, dodecyl-, branched
- Quaternary ammonium compounds, di-C16-18-alkyldimethyl, chlorides
- Ethyl methacrylate

- Methyl vinyl ether
- Ethylene carbonate
- M-phenylenediamine

ECHA proposes 74 substances for evaluation under the Community rolling action plan for 2020-2022. Registrants are recommend to coordinate actions with their co-registrants and contact the relevant evaluating competent authority.

1.4 Authorisation

- ECHA recommends 18 substances of very high concern (SVHCs) for REACH Authorisation List. Further information on the proposed substances.
- RAC and SEAC have adopted opinions on authorisation applications for uses of the following substances:
  - chromium trioxide - by group of German companies
  - 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (Triton X-100) - by Ortho-Clinical Diagnostics
- The Commission has granted authorisations for uses of the following substances.
  - sodium dichromate to ZF Luftfahrttechnik GmbH
  - chromium trioxide to ZF Luftfahrttechnik GmbH and Wesco Aircraft EMEA Limited
  - sodium chromate to Aviall Services Inc. and Wesco Aircraft EMEA Limited
  - potassium dichromate to Wesco Aircraft EMEA, LTD
- The Enforcement Forum's next major enforcement project will focus on provisions related to REACH authorisation.

1.5 Reports, Guidance & Updates

- ECHA recommends that companies familiarise themselves with the new REACH requirements for nanomaterials. From 1 January 2020, companies must provide more information on nanomaterials on the EU market. See also the ECHA webinar recording and guidance documents
- ECHA are supporting the Commission in the identification and proposal of new persistent organic pollutants (POPs) by developing risk profiles for the substances methoxychlor and Dechlorane Plus®
- ECHA updated its recommendations on mutagenicity testing. See the recommendations under the 'Toxicological properties' section.
- ECHA has published a list of over 21 000 REACH registered substances mapped in its 'chemical universe'.
- A study commissioned by the EU nanomaterials observatory (EUON) has found that the current framework for characterising and identifying next generation nanomaterials is able to address the majority of them.

- The Commission proposes to improve compliance of chemical registration dossiers by amending the compliance check target of dossiers from 5% to 20%.
- The Commission have clarified that certain provisions relating to registration for phase-in substances will still apply until 31 December 2019.
- Results of a Forum pilot project show that companies need to improve their communication of hazardous substances in products. Further details of the project.

1.6 Workshops/Webinars

- ECHA workshop on workability and quality of SDSs
- Webinar on the 'GreenScreen' tool to compare chemical hazards and identify safer alternatives
- What's new in IUCLID 6.4.
- 'Improving the quality of your REACH registration dossier – what authorities are planning and how you can prepare'
- World Health Organisation (WHO) webinar on 'Implementing EU chemicals legislation - lessons learnt'
- ECHA plans to extend the completeness check to the chemical safety report from April 2020; a webinar is planned for 29 January 2020.
- ECHA and Petrochemicals Europe will hold a workshop in March 2020 to discuss the recently published guideline on 1-methyl-2-pyrrolidone (NMP).

2. International Chemicals: Multilateral Environmental Agreements (MEAs)

2.1 Stockholm Convention – Persistent Organic Pollutants

Amendments to Annexes A and B of the Stockholm Convention
On 3 December 2019, the Stockholm Convention Depository communicated to all Parties the adoption of the following amendments to the Convention, as agreed at the Conference of the Parties to the Convention in April 2019:

- Amendment to the listing of perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) in Annex B, removing some previously acceptable purposes and adding some further time-limited exemptions.
- Amendment to Annex A listing dicofol without specific exemptions.
- Amendment to Annex A listing perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, with specific exemptions for the production and use of PFOA, its salts and PFOA-related compounds.

These amendments are expected to come into force in the EU around December 2020.

The Stockholm Convention's Scientific Committee (POPRC) met on 1-4 October 2019. The key decisions adopted at the meeting were:

- A recommendation that Perfluorohrexane sulfonic acid (PFHxS), its salts and PFHxS related compounds should be listed in Annex A to the Convention without specific exemptions;
- To establish an intersessional working group to further review the Norwegian proposal to list the flame retardant, Dechlorane Plus under the Convention and to prepare a draft risk profile;
- To establish an intersessional working group to further review the EU's proposal to list the pesticide, Methoxychlor in Annex A to the Convention and to prepare a draft risk profile;
- To establish intersessional working groups to review information related to specific exemptions for decabromodiphenyl ether (decaBDE) and short-chain chlorinated paraffins (SCCPs).

Any party still needing to use these substances for any of the specified uses stated in the exemptions need to inform the secretariat of the Stockholm Convention.

More information on October's meeting can be found in the POPRC's Draft Report.

The UK's National Implementation Plan (NIP) is due to be updated by December 2020 to reflect amendments to the Stockholm Convention adopted at the 8th Conference of the Parties in 2017. Defra will consult stakeholders on the prospective updates this year.

A Waste Electrical and Electronic equipment (WEEE) sampling project to assess the POPs brominated flame retardant content of plastic is due to report next month. This project, funded by the WEEE compliance fund and managed by the Industry Council for Electronic Equipment Recycling (ICER), aims to identify the plastic waste that exceed the threshold for treatment as POPs waste to inform possible management and disposal solutions.

2.2 Rotterdam Convention – Prior Informed Consent

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade is a multilateral treaty to promote shared responsibilities in relation to importation of hazardous chemicals.

The fifteenth meeting of the Chemical Review Committee, the scientific body to the Rotterdam Convention, was held on 8-10 October 2019.

Defra will also be starting a process of considering priorities for the Rotterdam Convention for the next Conference of the Parties in 2021. Any potential proposals from the UK will be shared with the CSF in due course.

2.3 Minamata Convention - Mercury

Summary of the Third Meeting of the Conference of the Parties to the Minamata Convention on Mercury: 25-29 November 2019

The third meeting of the Conference of the Parties (COP3) to the Minamata Convention on Mercury focused on measures to support the smooth functioning of the Minamata Convention Secretariat as well as substantive and technical issues aimed at fostering action to address mercury production and use around the world.

We are positive about the progress made on some of the institutional agenda items, including the decisions taken on Secretariat services and the operationalization of the Implementation and Compliance Committee. However, a compromise at the end of the COP which reduced the scope of a decision on effectiveness evaluation and delayed decisions on keys aspects of effectiveness evaluation to the next COP in 2021 will have a direct bearing on the programme of work for the coming biennium and make it harder to track progress and hold parties to account on their Convention obligations. This left many Parties, the Commission and EU Member States believing that the COP had missed an important opportunity.

In addition to the decisions on the sharing of secretariat services between the Secretariat of the Minamata Convention and the Secretariat of the Basel, Rotterdam and Stockholm (BRS) Conventions and on the Implementation and Compliance Committee (ICC), discussions on operational and technical issues resulted in decisions on Customs codes.

On the operational side, the COP set in motion the process to review Annex A on products and Annex B on processes, assess ways to enhance the Specific International Programme, and provide guidance on national reporting. On the technical side, parties approved guidance on contaminated sites, furthered work on releases and waste thresholds, and set in motion a process to assess the possibility of more aggressive action on dental amalgam. The COP also discussed issues relating to emissions of mercury resulting from the open burning of waste.

A Brief History of the Minamata Convention

The objective of the Minamata Convention is to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds.

As a naturally occurring element, mercury can be released into the air and water through the weathering of rock containing mercury ore or through human activities such as industrial processes, mining, deforestation, waste incineration, and burning fossil fuels.

Mercury can also be released from mercury-containing products, including dental amalgam, electrical appliances, laboratory and medical instruments, batteries, antiseptic and antibacterial creams, and skin-lightening creams. Mercury exposure can affect foetal neurological development and has been linked to lowered fertility, brain and nerve damage, and heart disease in adults who have high levels of mercury in their blood.

The Minamata Convention on Mercury was adopted on 10 October 2013. The Convention entered into force on 16 August 2017 and 115 countries are currently parties to the Convention.

3. International Chemicals: Voluntary international initiatives

3.1 Strategic Approach to International Chemicals Management (SAICM)

SAICM complements the multilateral environmental agreements for chemicals and waste i.e. the Basel, Stockholm, Rotterdam and Minamata Conventions. This voluntary framework aims to improve chemicals and waste management globally and negotiations are currently ongoing in relation to the post 2020 framework which will conclude in October 2020.

In October 2019 the UK attended the third meeting of the intersessional process in Bangkok. Discussions were focused on the elements of the beyond-2020 framework, in particular:

- Objectives, targets and indicators
- Governance
- Financial considerations
- Mechanisms to support implementation (specifically issues of concern and the Science-Policy Interface)

Progress was made with regards to the targets: participants agreed a set of principles which should be applied to the draft targets (including making them SMART and communicable). The results of the UK indicators workshop were widely used to inform discussions. It was also decided that a technical expert group will be established to take work on targets and indicators forward.

Discussions on the governance of the post 2020 framework culminated in participants agreeing on the functions of a beyond-2020 conference, along with the roles of the bureau and the secretariat. However, progress was slower on mechanisms to support implementation (e.g. the Science-Policy Interface) and on financial matters.

The next meeting of the intersessional process (IP3) is due to be held in Bucharest, Romania, 23rd-27th of March 2020. **Ahead of this we are keen to explore ways for UK industry and NGO stakeholders to contribute and engage with the post 2020 framework on chemicals and waste.** Following IP3, the SAICM Secretariat has issued a call for contributions on how to enhance engagement, **and we would welcome input on this from CSF members.**

We are devoting an agenda item on the 15th January to discussion of this and will be circulating material for your consideration ahead of the meeting.

Further info: Strategic Approach to International Chemicals Management (SAICM)

4. The OECD's Environment, Health and Safety (EHS) Programme

The EHS programme deals with the safe use of chemicals, nanomaterials, pesticides, biocides, and products of modern biotechnology. It also addresses related areas of concern and interest, such as chemical accidents and Pollutant Release and Transfer Registers (PRTRs). It aims to protect health and the environment, while avoiding duplication of effort, ensuring that efficiencies are made and barriers to trade avoided.

Defra continues to have oversight of the EHS programme through attendance at the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology which last met in June 2019.

For OECD updates - Sign up to MyOECD and subscribe to Chemical Safety News.

4.1 Nanomaterials

A UK delegation of Defra, PHE, EA, HSE and academics attended a meeting of the Working Party on Manufactured Nanomaterials (WPMN) to discuss priorities for its programme of work for 2021-24. This included a focus on how issues surrounding advanced materials can be addressed in the context of chemicals management. It was very much a thought starter which provided useful context and insights into the challenges posed by advanced materials and will be discussed further at the annual WPMN meeting in June 2020.

4.2 Aligning chemicals and waste legislation: case studies

With input from the Chemical Stakeholders Forum, Defra produced and submitted a case study on *the interaction of the EU POPs Regulation requirements with the requirements of waste legislation for managing electronics and electrical waste*. Defra will present this at the upcoming OECD Expert Workshop on the Misalignment of Chemicals and Waste Management Policy on 3rd February 2020.

Here, the Chemicals Committee and the Working Party on Resource Productivity and Waste (WPRPW) are working together to collect case studies of policy misalignment at the chemical/waste interface. These aim to foster a discussion on real-world policy misalignment at the chemicals/waste interface in order to discuss and identify potential, or already applied, solutions. A summary of the workshop, along with the case studies, will be published. We are grateful for the contributions of the CSF so far.

5. Broader policy issues

5.1 The Chemicals Strategy

In the 25 Year Environment Plan, the government committed to publishing a Chemicals Strategy. The Chemical Strategy will set out our ambitious approach towards ensuring the safe management of chemicals, our priorities for action, and details of how we will achieve our goals. We are collaborating with other government departments to develop the Strategy.

We will be publishing a call for evidence in spring 2020 and will be looking to consult on a draft Strategy before publishing the final version in 2022.

At this early stage in the Strategy's development, **no issues related to chemicals are being treated as out of scope** and our thorough programme of engagement will help shape our ambitious vision. Initial conversations with stakeholders, including UKCSF members and academics, focused on understanding the issues and priority areas for the Strategy. The Call for Evidence, scientific evidence reviews, and stakeholder engagement activities will further inform our thinking on the Strategy.

5.2 Net zero and COP26

The UK has set a target that will require us to bring all greenhouse gas emissions to net zero by 2050.

The UK will host COP26 in Glasgow this year, in partnership with Italy. It will be the UN's 26th climate change conference and bring together over 30,000 delegates from around the world, including climate experts, business leaders and citizens to agree ambitious action to tackle climate change. This follows the PM's commitment at the G7 Summit to ensure that the COP26 Summit addresses both climate change and biodiversity as two sides of the same coin.

6. Update from Devolved Administrations

6.1 England – Clean Air Strategy

The Clean Air Strategy, published in early 2019, sets out how we will tackle all sources of air pollution. We have legally-binding targets to reduce emissions of five of the most damaging air pollutants (fine particulate matter, ammonia, nitrogen oxides, sulphur dioxide, non-methane volatile organic compounds) by 2020 and 2030. In the past, the priority was to tackle the biggest individual sources of pollution. As these major sources of emissions have decreased, the relative contribution of smaller and more diffuse sources of air pollution, like smaller industrial sites, product use, open fires in homes and spreading manure on farms, has increased. That requires new action.

In the industrial sector, we will work with the chemical sector to uphold our commitments to maintain continuous improvement in relation to industrial emissions, including ensuring there is a clear process for determining future UK Best Available Techniques for industrial emissions. We are currently reviewing the evidence base for industrial emissions of the 5 pollutants listed above to identify the most challenging industry sectors and pollutants. This will underpin future policy decisions and direction regarding further action needed from all Industrial sectors to meet the National Emission Ceilings Directive ceilings. As this picture emerges we will be able to indicate where more specific action may be needed from the chemical sector, likely in early 2020.

6.2 Wales – Clean Air Plan

On 10 December 2019, the Welsh government launched a public consultation on a draft Clean Air Plan for Wales. It contains a chapter on indoor air quality, which notes that the UK's exit from the European Union may result in the need for a separate UK regime for the regulation of chemicals ('UK REACH'), where policies are made and decisions taken domestically rather than at an EU level.

It goes on to state that in such a scenario, the Welsh government will play an active role in the new regime's governance, to ensure that it upholds a high level of protection for human health and the environment, including regulating articles and products containing chemicals that contribute to poor indoor air quality.

Question 9 in the consultation asks "Are there aspects of indoor air pollution, which you would like Welsh government to address? You may wish to consider what the Welsh government's top priorities should be for regulating chemicals in articles and products, which may contribute to poor indoor air quality." **The public consultation closes on 10 March 2020.**

6.3 Scotland – Forum

As mentioned in previous UKCSF policy updates, the Scottish government is seeking to set a similar forum to improve its understanding of issues affecting relevant stakeholders. This will be linked to the UKCSF.

Anyone interested in participating in such a forum is encouraged to email a note of interest to jason.sharp@gov.scot and louise.cameron@gov.scot.

7. Chemical-product-waste interface subgroup

The group has met once since the last CSF meeting. It discussed work that Defra is taking forward work to map the legislation that affects the chemicals/waste interface and work to support traceability through the supply chain by gaining a better understanding of the information needs of reprocessing facilities.

7.1 Background

The group includes representatives from:

- Chartered Institute of Wastes Management
- Chemicals Industries Association
- Environmental Services Association
- Resource Association
- Make UK
- Tech UK
- Defra
- Environment Agency
- Royal Society of Chemistry

7.2 Aim of group and key issues

The agreed aim of the group, and key issues to tackle are as follows:
To ensure that products are managed in a way that recognises the dual needs to optimise both protection of human health and the environment and maximise resource efficiency. This involves dealing with the legacy of chemicals which contaminate waste streams and putting in place systems that prevent future problems.

These issues are evident in the following ways:

i. **Current EU rules on waste and hazardous chemicals are not well aligned and this affects the uptake of secondary raw materials**. E.g. Waste may contain substances that are no longer allowed in new products, limiting its recyclability and resulting in a waste of potentially useful resources.
ii. **The presence of chemicals may prevent recycling**, make it difficult to sort wastes or reduce the quality and value of secondary raw materials.
iii. **The presence of chemicals may make remanufacture of products difficult**.
iv. **Recyclers/waste managers are often not aware of the presence of regulated chemicals in the waste they receive** as the information is not readily available, particularly pertinent with the rise of online purchasing of goods from overseas. This can lead to inappropriate management.
v. **Limitations in available technology (and/or capacity) may prevent the environmentally sound management of wastes containing chemicals**, as well as limiting opportunities to realise the value of these wastes.

8. Wessex Water project

This project is an innovative catchment approach taken forward by Wessex Water under the Chemicals Investigation Programme (managed by UK Water Industry Research on behalf of the Environment Agency, SEPA and water companies), which is part of the national environment programme undertaken by water companies over 2020-2025.

It brings together a range of different stakeholders to reduce the amount of pharmaceuticals that make their way into the water environment with benefits for public health, patient health, the environment and the future budgets of Wessex Water and the NHS. Whilst, pharmaceuticals are not specifically covered at the UKCSF, this approach to addressing chemicals at source may be of wider interest.

Collaborative public health project

Wessex Water
YTL GROUP

Concern about the environmental and health impacts of pharmaceuticals is growing and the use of medicines by people continues to increase. There are three potential sources of pharmaceuticals in the environment: patient use, improper disposal and point sources from the production of medicines.

Background

Pharmaceuticals have been detected in the natural environment across the world and concern is increasing about their impact on both human and environmental health. Human pharmaceuticals can enter the environment from patient use, improper disposal and as point sources from production. The main pathway for pharmaceuticals and metabolites to enter the aquatic environment is from treated sewage effluent.

Pharmaceuticals in treated sewage effluent are not currently regulated in the UK. But, the water industry in England and Wales has prioritised 20 pharmaceutical compounds for further investigation, including those on the 'watch list'. The watch list details priority substances of concern across Europe.

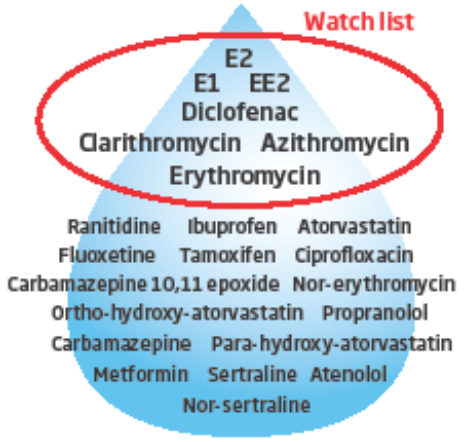
Concerns

Global research into the impact of pharmaceuticals in the environment has demonstrated the potential for pharmaceuticals to impair reproduction in fish and been linked to changes in animal behaviour. For example, research suggests that metformin, which is prescribed for type 2 diabetes, acts as an endocrine disruptor at environmentally relevant concentrations and may be a cause of intersex in fish (where male reproductive tissues show evidence of feminisation). However, it is unclear how increasing levels of these substances may impact our rivers and lakes and there is limited understanding of the impacts at a local level.

Wessex Water is therefore keen to understand more about the impact of pharmaceuticals on the aquatic environment and potential sustainable options for reducing levels. Data on reduction of pharmaceuticals by conventional sewage treatment technologies shows that removal rates are variable and highly complex, energy intensive treatment process would be needed to remove these compounds. Wessex Water has estimated that it would cost c.£2.2bn to reduce pharmaceuticals in sewage treatment works discharges by c.80% at sites serving a population equivalent greater than 10,000.

Priorities

The pharmaceuticals prioritised by the water industry for investigation include those associated with mental wellbeing and long-term health conditions such as cardio-vascular disease and type 2 diabetes, which can often largely be prevented with a healthy lifestyle.



The King's Fund has estimated that it costs the NHS between **£10.6** and **£11.4 billion** per year to treat the chronic diseases associated with obesity, inactivity, smoking and alcohol misuse.

Worldwide, the International Diabetes Federation estimates that the number of adults with diabetes will rise from 1 in 11 to 1 in 10 by 2040.

Wildlife Trusts Avon · Bath & North East Somerset Council · TimeBankPlus · Bath City Farm growing together · DHI help turn lives around · University of Bath

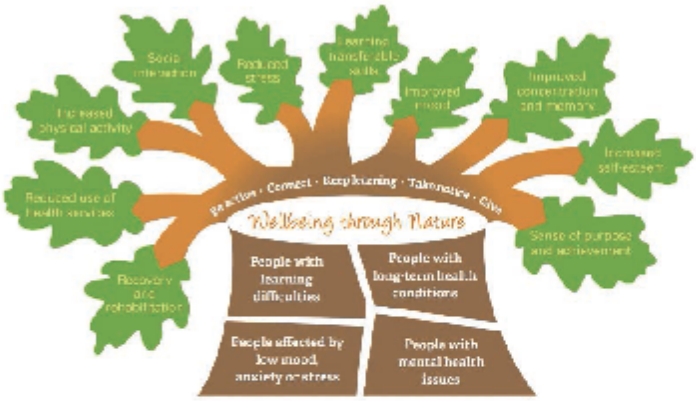
Control at source

Wessex Water is leading a project in Bath and North East Somerset to investigate sustainable options for reducing the amount of pharmaceuticals in the environment. The project is a collaboration between seven key partners providing a combination of funding, resources and support in kind, namely Wessex Water, Bath and North East Somerset Council, Developing Health and Independence, the University of Bath, Avon Wildlife Trust, Bath City Farm and Time Bank Plus.

The project is focusing on two interventions: the use of social prescribing and the disposal of unused medicines.

Medicines waste

It is estimated that unused or partly used prescription medicines cost the NHS in the UK £300 million every year. Improper disposal is estimated to account for around 10% of human medicinal products entering the environment. Unused medicines may be flushed down the toilet or poured away instead of being returned to pharmacies for safe disposal. The project is evaluating options for encouraging correct disposal of unused medicines such as a medicines amnesty.



Social prescribing

This is a way of linking patients in primary care with sources of support in the community. This could include environmental and nature based activities or groups focused on providing social inclusion and support networks. In addition to increasing wellbeing and reducing demand on health care services, social prescribing could also impact on the prescription, consumption and disposal of medicines.

Overall, the project is considering the environmental, economic and social impacts of the interventions such as prescription rates, patient health and wellbeing and the cost of services. The intention is that this can influence primary care options moving forward to enable a healthier environment and community.

The social prescribing model

For more information

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look at our website: wessexwater.co.uk

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