

From: FINK-HOOIJER Florika (ENV)
Sent: samedi 18 décembre 2021 21:17
To: [REDACTED]@eriforum.eu
Cc: [REDACTED] (ENV); [REDACTED] (ENV); [REDACTED] (ENV);
ENV DIRECTOR GENERAL; [REDACTED]@eriforum.eu
Subject: Essentiality Concept + ERIF event invitation

Follow Up Flag: Follow up
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Categories: [REDACTED]

Dear [REDACTED],

thank you for your message. I much enjoyed the exchange with the ad hoc Council members.

In relation to your inquiry, pursuant to the Chemicals Strategy for Sustainability, the Commission is defining criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments.

I take note of your call for advancing on this topic with a view to establishing stronger legal and regulatory certainty. In fact, the Commission has launched a study to support this process and targeted consultations are ongoing. The Commission plans to consult all relevant stakeholders on the development of the concept and the possible policy options in Spring 2022. The Commission intends to present the horizontal criteria on essential uses by the end of 2022 and introduce the concept in the proposal for the REACH revision, as first steps.

I would also like to thank you for the information about the webinar on the "Legal Dimensions of the 'Essentiality' test" organized by the European Innovation and Regulatory Forum. I have forwarded the invitation to register to relevant colleagues as I will unfortunately not be able to join myself due to scheduling issues.

With Season's greetings,
F. Fink-Hooijer

Florika FINK-HOOIJER
Director General



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From: [REDACTED] <[\[REDACTED\]@eriforum.eu](mailto:[REDACTED]@eriforum.eu)>
Sent: Wednesday, December 15, 2021 11:12 AM
To: FINK-HOOIJER Florika (ENV) <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>
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Subject: Essentiality Concept + ERIF event invitation

Dear Director General

Many thanks for your excellent introduction and discussion at the meeting of the Ad Hoc Council yesterday.

I asked a question about how the new “essentiality test” would be defined, which will have to implement to “concept essential use” that arises in the Chemicals Strategy for Sustainability. That concept could have implications for many various sectors.

You mentioned the importance of regulatory predictability for the huge investments that are going to be needed for the Green Transition, which as I said is no longer about ideals, but about survival.

The concern raised by the new “essentiality” criterion is that it is as yet undefined, and therefore causes legal and regulatory uncertainty, not only for innovators but for the functioning of the European economy as a whole.

“Essentiality” has been discussed in the European Innovation and Regulatory Forum (ERIF, www.eriforum.eu) – an independent, not-for-profit think tank promotes Better Regulation for the EU Green Deal. ERIF wrote a note on the rationale and implications raised by “essentiality”, which I include for your information.

I am also seizing the opportunity to share an invitation below to the next webinar organized by ERIF on this topical debate, in which we will address legal considerations on the essential use concept. We would be delighted if you joined the event. Please do not hesitate to share the invitation to interested colleagues in your team.

Best regards,

[REDACTED]

European Innovation and Regulation Forum



**WEBINAR SERIES
THE EUROPEAN REGULATION AND INNOVATION TALKS
A DISCUSSION WITH**

[REDACTED]
Mayer Brown LLP

[REDACTED], EU Law and Policy
Wageningen University

**Novel Regulatory Concepts, Management of Potential
Harms, and Regulatory Predictability:
Legal Dimensions of the 'Essentiality' test**

Wednesday, 19 January 2022, 16h00 – 17h00 CET
Format: Zoom call (dial-in details to be shared upon registration)

Dear Colleague,

Throughout the OECD area, market access for new and existing products, and the technologies they make use of, is principally determined by **tests of safety, normally based on the likelihood of harm** to man or nature. Use of this concept, derived from the 'harm principle', facilitates the effective functioning of markets, creates consumer confidence, and ensures a high-level of regulatory predictability when risk management laws are implemented. Indeed, legislators, officials, and courts have been refined the meaning and application of this concept over more than two hundred years.

Things are however changing. New and additional tests of market access and retention are being proposed by EU policy-makers, most prominently the **concept of 'essential use'**. With the exception of a small number of narrowly focused and well-understood applications, this is a novel and untried regulatory philosophy that poses major challenges, if regulatory failure is to be avoided. Among the most prominent legal challenges are establishing a clear legal basis for its application and defining legally-binding criteria that can be applied by the EU's Administrative State to ensure predictability and proportionality.

I am delighted to invite you to address these and other pressing issues at the next ERIF webinar with [REDACTED] from Mayer Brown LLP and [REDACTED] from Wageningen University. [REDACTED]

[REDACTED] the concept of essential use in the EU legal framework, which we will discuss during the webinar and warmly recommend as background reading – Please see the bibliographical references below.

The webinar will be held on **Wednesday, 19 January 2022 (16h00 CET)**, lasting for approximately 60 minutes. The event and subsequent discussion will be held under The Chatham House Rule.

We will use the Zoom software, but the option will be open to call in by phone as well.

Please do not hesitate to forward this invitation to interested colleagues.

To attend, please register [HERE](#).

Upon registration, you will receive a confirmation email with all the relevant dial-in details.

About our speakers:



ort, J-P. (2021), "[The Concept of Essential Use to Regulate Chemicals: Legal Considerations](#)", in *International Chemical Regulatory and La*

tt, K. and G. van Calster (2021), "[The Concept of Essential Use: A Novel Approach to Regulating Chemicals in the European Union](#)", in *Tra* 59-187.

We look forward to welcoming you again to our ERIF Talks soon.

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