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## Rektor

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## Yttrande över förslag på rättsakter inom ramen för initiativet ”Ett ämne, en bedömning”

Stockholms universitet har av Regeringskansliet (Klimat- och näringslivsdepartementet) anmodats att inkomma med synpunkter på förslag till rättsakter inom ramen för initiativet ”Ett ämne, en bedömning”.

Universitetet har inga synpunkter på de två förslagen som handlar om fördelning av uppgifter mellan myndigheterna på EU-nivå. När det gäller förslaget som handlar om en gemensam dataplattform (common data platform) är universitetets huvudsakliga synpunkt att transparensen ska öka för att möjliggöra att data som genereras inom det regulatoriska systemet ska kunna användas för akademisk forskning och för andra intressenter som vill granska industrins data och riskbedömningar, samt i förlängningen myndigheternas beslut.

Stockholms universitet kommenterar i det följande skäl, s.k. ”recitals”, och inte artiklar i lagförslaget.

### Recital 2

Data on chemicals can also be produced by non-industry actors, typically by academic research. Calling the the new data platform a “one-stop-shop” indicates that other information sources are not needed. In contrast, we need a development where also academic data are included in the regulatory data base on a regular/automated basis. Ideally via an automatic IT-based route; All studies with regulatory relevance should carry a digital “book-mark” (including chemical CAS or EC number) that connects the scientific publication to the regulatory data platform. Only if this is fully implemented can the platform be a one-stop-shop for data.

The purpose of ensuring transparency in the data is not necessarily to make the general public more aware or more trusting in the system. A more important purpose is to enable third-party scrutiny of the data, and the decision motivations that refer to them, to ensure an objective and scientifically robust regulatory process. This can in turn contribute to increasing the public’s trust in the workings of the system.

Predictability is also not ensured by a database. There is much more to it.

**Proposed amendment:**

*“Moreover, the Regulation aims to provide a comprehensive source for chemicals data and information in the Union publicly accessible. Compiling data from all sources will increase the transparency of regulatory processes on chemicals and enabling third-party scrutiny of data used for regulatory purposes can contribute to the robustness of scientific decision-making.”*

**Recital 4**

Since the data will also be publicly available this should be mentioned here.

**Proposed amendment:**

*“This Regulation aims to increase data availability on chemicals by requiring the relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks. Full public access to the data will also enable third-party scrutiny that can contribute to ensuring the scientific robustness of the system and to policy development.”*

**Recital 6**

The aim of this effort is not primarily to build trust in the system but to ensure that decisions are made based on a complete data set. This database cannot be the single point of reference unless all (relevant) academic research is systematically included therein.

Accessibility of data should include the possibility to download information into common tools for systematic data analysis including Office applications such as Microsoft Excel.

Just compiling the data does not make risk assessments (automatically) more coherent. It merely increases the likelihood that the assessments take the same data into account. Non-industry studies should also be systematically included in this database to ensure completeness.

**Proposed amendment:**

*“This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of incoherencies in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a main point*

*of reference and as a broadened and shared evidence base to enable the efficient delivery of data to support coherent hazard and risk assessments of chemicals across various Union acts on chemicals. Data from independent research should also be included to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.”*

#### **Recital 7**

Non-industry scientists should also be allowed to contribute data to this common platform.

#### **Proposed amendment:**

*“The common data platform should contain chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission in compliance with their reporting obligations. The common data platform should also include chemicals data and information generated as part of Union, national or international programmes or research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies. Data can also be submitted from other sources such as academic research funded by the EU or national research funding bodies.”*

#### **Recital 12**

The overarching principle must be full transparency and public accessibility. Through the democratic processes (legislation and decision procedures) the public allows products on the market, but to ensure/increase the protection of human health and the environment, the data underlying this agreement, i.e. the market approval/registration, must also be made available to the public.

#### **Proposed amendment:**

*“To ensure a high level of protection of the environment and human health, the main principle is full transparency and public accessibility of the data. But, in order to respond to the needs of the digital economy, it is necessary to lay down a harmonised framework to specify any exemptions from this overarching transparency principle. The Authorities that are entrusted with regulatory tasks related to the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies. The data should also be accessible to research performed to ensure a high level of protection of human health and the environment, including for instance research aiming at the identification of emerging risks, or science evaluating the workings of the regulatory system or aiming at providing science-based input to policy development.”*

### Recital 19

This is very good and important.

### Recital 20

If the aim is to actually bring together “all relevant chemicals data” then also academic research data must be included. As this is not happening right now it is more accurate to refer to “all regulatory data”.

#### Proposed amendment:

*“In order to bring together **all relevant regulatory data on chemicals** and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work (‘EU-OSHA’), the ECHA, the European Environment Agency (‘EEA’), the EFSA, and the EMA (‘the Agencies’), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform’s structure, and respect rules on standard formats and controlled vocabularies where available.”*

### Recital 21

This suggests that academic research data could be included in the data platform if requested by the COM and added via the agencies. A simpler and more automated procedure would be preferable. For efficiency reasons, all the relevant scientific data produced with EU funds must be put to regulatory use.

### Recital 23

The requirement to make data available and on the common platform should not be limited to human biomonitoring data, and “environmental sustainability data”.

#### Proposed amendment:

*“To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the ‘as open as possible, as closed as necessary’ principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA **and any exposure, safety or sustainability data on chemicals or materials** they collect or generate to the ECHA.”*

**Recital 28**

This is very good and important. If possible, the time to full implementation should be shortened.

**Recital 32**

If possible, it would be helpful to clarify the meaning of “dissuasive”. In general, penalties are rarely enforced and when enforced they are normally less than “dissuasive”.

**Recital 38**

The data should be searchable and possible to down-load in batches to enable third-party analyses and evaluations including scientific research. The format should be compatible with Office applications such as MS Excel.

Detta beslut är fattat av rektor, professor Astrid Söderbergh Widding, i närvaro av prorektor, professor Clas Hättestrand, och universitetsdirektör Åsa Borin. Studeranderepresentanter har informerats och haft tillfälle att yttra sig. Övrig närvarande har varit Henrik Lindell Kennberg, Ledningssekretariatet (protokollförare). Ärendet har beretts av Områdesnämnden för naturvetenskap. Föredragande i ärendet har varit utbildningsledare Rikard Skårfors.