NEWSLETTER JULY-AUGUST 2019

Melamine *'possibly carcinogenic'* to humans, says IARC

Carcinogenic in lab animals but inadequate evidence in humans. Melamine is a "possibly carcinogenic to humans" (group 2B), despite "inadequate evidence", according to an International Agency for Research on Cancer (IARC) monograph. An IARC working group found sufficient evidence for the substance's carcinogenicity in experimental animals but not enough for a definitive decision in humans, mirroring findings by the World Health Organization (WHO). Melamine is mainly used to make laminates, plastics, coatings, adhesives and tableware. Important new applications are under development in the field of fire retardants for polymeric materials, especially polyurethane foams.

Food exposure

The monograph says that the general population is most likely to be exposed by ingesting it in food. The chemical has been shown to migrate into food from tableware and food packaging. In Europe, the current specific migration limit is 2.5 milligrams per kilogram (mg/kg) of food. Meanwhile, the WHO has established a tolerable daily intake (TDI) of 0.2 mg/kg body weight.

In industrial settings, it is often used together with formaldehyde. The IARC working group was not able to identify any occupational cohorts exposed to melamine but not formaldehyde.

Melamine is not metabolised by mammalian tissue but can be by bacteria in the human gut, reports IARC, after reviewing available literature. There is strong evidence that it induces chronic inflammation in the urinary tract in humans. Germany has proposed a harmonized classification for carcinogenicity, which has been on Echa's registry of classification and labeling (CLH) intentions since 2017.

IARC's volume of monographs (119) on the evaluation of carcinogenic risks to humans covers five high-production-volumes (HPV) chemicals, all of which have previously been described as "not classifiable" for their carcinogenicity to humans.These are: melamine, furfuryl alcohol, pyridine, tetrahydrofuran and vinylidene chloride. It also covers 1-tert-butoxypropan-2-ol and β-myrcene. The agency reports that all seven chemicals are possibly carcinogenic to humans (Group 2B), with inadequate evidence in humans but sufficient in experimental animals.The monograph volume is entitled **Some chemicals that cause tumours of the urinary tract in rodents.**

CANDIDATE LIST: ECHA adds four substances to REACH candidate list

The candidate list contains substances that may have serious effects on human health or the environment. Certain legal obligations can ensue from listing. They are also known as substances of very high concern and are candidates for eventual inclusion in the authorization list. It is usually updated twice a year. Six chemicals were added in January. ECHA has recently added four new substances to the REACH candidate list of SVHCs. Their addition follows decisions taken either by the agency's Member State Committee (MSC) or the European Commission and brings the number of SVHCs on the list to **201**. The new chemicals and their properties are:

tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP) – endocrine disruptor for the environment;

2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof) – equivalent level of concern having probable serious effects to human health and the environment;

4-tert-butylphenol – endocrine disruptor for the environment

2-methoxyethyl acetate – reprotoxicant

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Chemical uses

Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP) is primarily used as an antioxidant to stabilize polymers.France proposed its inclusion on the candidate list and the MSC adopted the decision at its June meeting. The MSC also chose to add 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof) to the list. The substance is used as a processing aid in the production of fluorinated polymers.

4-tert-butylphenol is employed in coating products, polymers, adhesives, sealants and for the synthesis of other substances. The Commission notified its intention to add the chemical in February and identified the substance as SVHC in its implementing decision of 5 July. Germany initially proposed its inclusion to the candidate list in March 2016.

Earlier this year Sweden put forward 2-methoxyethyl acetate as a candidate. The substance is not registered under REACH and its uses are unknown.

ECHA ACTIVITIES and POLICIES

ECHA to screen all substance dossiers above 100 tons/year by 2023

ECHA has revealed a plan to evaluate all REACH dossiers for chemicals registered over 100 tons/year by the end of 2023. The initiative is one of numerous measures in the ECHA-European Commission joint action plan to address non-compliant registration dossiers. It sets 15 action points, most of which are to be delivered between mid-year and the end of 2020.

In April 2019, ECHA announced it would screen all registration dossiers by 2027 for substances in the tonnage band **1-100 tons/year**. The chemicals covered by the action plan are those **16.500 fully registered** ones in 66,000 dossiers as of end-2018. The agency will check the compliance of at least 30% of substances, making sure this check is done for all substances where more information is needed. These include those with hazardous properties or where more data needs to be generated to conclude a potential risk. Similar substances will be assessed in groups to gain efficiency and ensure that proposals for further regulatory action are consistent.

For high tonnage substances, the agency will conclude by the end of 2020 whether they are a priority for risk management, for data generation or currently of low priority for further action.

Between 35 and 40% of substances registered above 100 tons and a lower share of 20% for substances registered in the 10-100 and 1-10 tonnage bands are expected to be a priority for data generation. This directly corresponds to the 20% of registration dossiers in each tonnage band that are projected to be checked for compliance by 2027. Last month the agency said it would hike the percentage of dossier compliance checks from 5% to 20%.

Industry collaboration

By the end of the year, ECHA will inform any company submitting relevant new information during a restriction, SVHC identification, an authorization or a harmonized classification process and which has not

preceded such submission with the corresponding update of the registration dossier, regarding its updated obligations according to REACH Article 22. Before 2020, the Agency declared it will have established "transparent and inclusive" working arrangements with major industry associations. The aim is to help commit to develop action plans for the "proactive and continual" improvement of dossiers.

Clarity

The action plan says a common and clear interpretation of legal provisions is key in helping industry grasp what information must be submitted, reduce discussions and support the efficient implementation of REACH. By the end of 2019 the Commission will assess the need, and if necessary make a proposal, to:

- amend REACH Annexes VI to X to provide greater clarity to information requirements; and
- amend Annex XI to ensure adaptations to standard information requirements are properly justified.

Further, the EU executive will assess the need for a possible implementing regulation that would "efficiently put into effect" the REACH evaluation decision-making process.

Enforcement

The agency has also committed to preparing enforcement measures in Member States to address breaches of dossier evaluation decisions by year-end. This will include an assessment of the extent to which enforcement authorities in different states address non-compliance with ECHA's decisions by banning substances on the market. By the end of 2020, the Commission will assess the effectiveness of these enforcement measures, including the information submitted by member states in their Article 127 report.

By the middle of next year, ECHA's Enforcement Forum will have established the template to test annual reporting to ECHA's secretariat, including a summary of all enforcement actions taken by each Member State. The first such report should be made available by mid 2021. ECHA's secretariat will propose to the Forum that such annual reporting be made permanent.

ENDOCRINE DISRUPTING CHEMICALS (EDC), Public Consultation by EU

The European Commission opened a public consultation, running until July 10, 2019 on its Roadmap on the review of EU rules, a "Fitness Check on Endocrine Disruptors."

Specific rules on Endocrine Disruptors (EDs) already exist under various EU legislative frameworks such as the REACH Regulation, Biocides, Plant Protection Products (PPPs), Water, and Medical Devices. On the other hand, legally established scientific criteria on EDs currently only exist under two of those regimes: Biocides (Commission Delegated Regulation (EU 2017/2100) and Plant Protection Products (Commission Regulation (EU) 2018/605). As recognized by the Commission, the existing EU measures "*have been developed at different points in time*" and at times with "*different specific objectives*," which "*has resulted in different approaches for managing endocrine disruptors, depending on the sector being regulated*." This risk of divergence of regulatory approaches towards the same substance under different regimes (for instance chemicals subject to the REACH Regulation that are used as co-formulants in biocidal products) has been highlighted in the past.

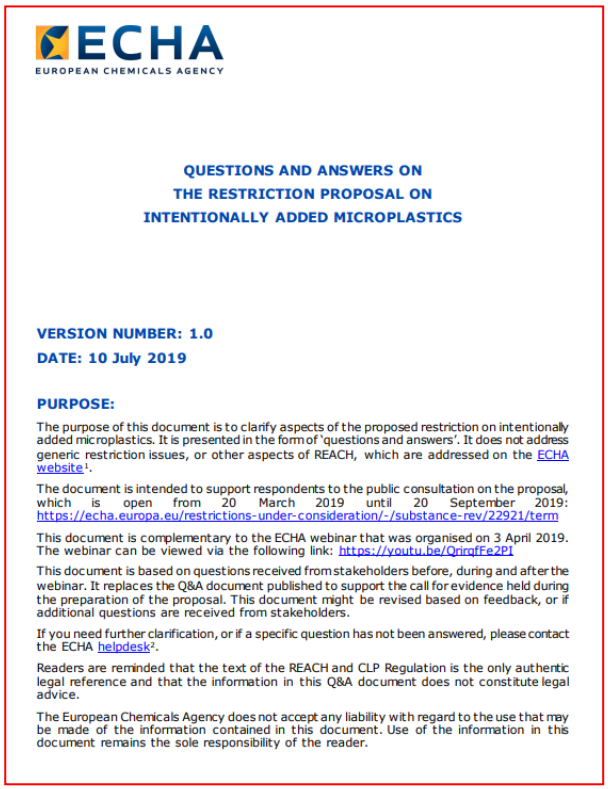
The Commission will, in its Fitness Check, assess whether these are fit for purpose **i.e.** protect human health and the environment through the overall reduction of exposure to EDs. The outcome of the review of existing EU chemicals legislation will "*feed into the reflection on whether legislative changes are necessary*." In particular, the Commission desires to focus on:

- The **coherence of the various EU chemical regimes** to identify "inconsistencies" between these pieces of legislation. This includes particular attention to legislation which does currently not have specific provisions on EDs, such as toys, cosmetics and food contact materials - an indication that the Commission is addressing its mind to the question whether these legislations should equally feature ED specific rules.
- Whether the **"same criteria" for EDs should be introduced horizontally**, across the different EU chemicals regimes, for legal certainty and to ensure a consistent approach to the same substance under the different regimes.
- Examining the **different regulatory consequences** for substances having ED properties under the different legal regimes, varying from general safety provisions to ED specific bans and restrictions.

In view of the potential impacts, affected companies and interested stakeholders should consider submitting comments on the Roadmap by July 10, 2019, especially as it is the Roadmap that "sets the scene" for the entire Fitness Check on the appropriateness of the existing rules on EDs. Aside from technical considerations, inherent to EDs, the involvement of legal counsel in the preparation of the comments might be helpful to potentially strengthen their impact and effectiveness.
After the public consultation, next steps in the Commission's Fitness Check will include a more comprehensive data gathering exercise (including a general three-month public consultation and targeted consultations of key stakeholders and authorities) as well as the organization of the first, annual forum on EDs (tentatively scheduled for October this year). The Commission also plans to launch a web portal on ED substances in 2019.
The completion of the Fitness Check, which would include the detailed analysis, conclusions and recommendations of the aspects outlined in the Roadmap, is foreseen for Q2 of 2020.

MICROPLASTICS

Q&A Document released



ECHA
EUROPEAN CHEMICALS AGENCY

QUESTIONS AND ANSWERS ON THE RESTRICTION PROPOSAL ON INTENTIONALLY ADDED MICROPLASTICS

VERSION NUMBER: 1.0
DATE: 10 July 2019

PURPOSE:

The purpose of this document is to clarify aspects of the proposed restriction on intentionally added microplastics. It is presented in the form of 'questions and answers'. It does not address generic restriction issues, or other aspects of REACH, which are addressed on the ECHA website[1].

The document is intended to support respondents to the public consultation on the proposal, which is open from 20 March 2019 until 20 September 2019: https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22921/term

This document is complementary to the ECHA webinar that was organised on 3 April 2019. The webinar can be viewed via the following link: https://youtu.be/QrirqfFe2PI

This document is based on questions received from stakeholders before, during and after the webinar. It replaces the Q&A document published to support the call for evidence held during the preparation of the proposal. This document might be revised based on feedback, or if additional questions are received from stakeholders.

If you need further clarification, or if a specific question has not been answered, please contact the ECHA helpdesk[2].

Readers are reminded that the text of the REACH and CLP Regulation is the only authentic legal reference and that the information in this Q&A document does not constitute legal advice.

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EUON (European Union Observatory for Nanomaterials). LAST NEWS

Two years since its launch, the EUON has carried out a mid-term review to evaluate how it has met its objective of giving reliable information on the markets and safety aspects of nanomaterials in the EU. The findings show that the EUON is adding value to the EU debate on nanomaterials but more frequent and up-to-date information could strengthen it further.

The EUON aims to increase the transparency of information available to the public on the safety and markets of nanomaterials in the EU. A key aim of the observatory is to create a one-stop shop for information, where EU citizens and stakeholders including NGOs, industry, and regulators can all easily find accessible and relevant safety information on nanomaterials on the EU market. The European Commission funds the EUON and the European Chemicals Agency (ECHA) is responsible for hosting and maintaining it.

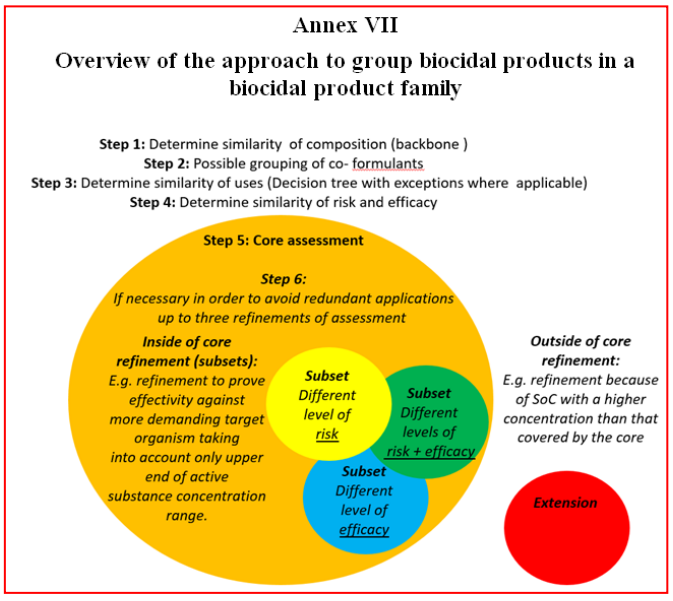
The European Union Observatory for Nanomaterials (EUON) commissioned a study to capture the views of its various audiences. The evaluation considered the benefit of the EUON for its stakeholders, its potential shortfalls and success factors. For the most part, the findings show that the EUON has achieved its objective of acting as a reliable source of information. There is, however, a need for more frequent and up-to-date information on the safety of nanomaterials.

The study found that stakeholders with a lower level of prior technical knowledge appear to derive more benefits from the information in terms of learning something useful that benefits them or their work. Those with higher levels of prior technical knowledge tended to use the website more to keep up to date on relevant developments. The study found that the EUON could do more to promote its content intended for consumers.

The results of this review will serve as input to the EUON's work program for the coming years.

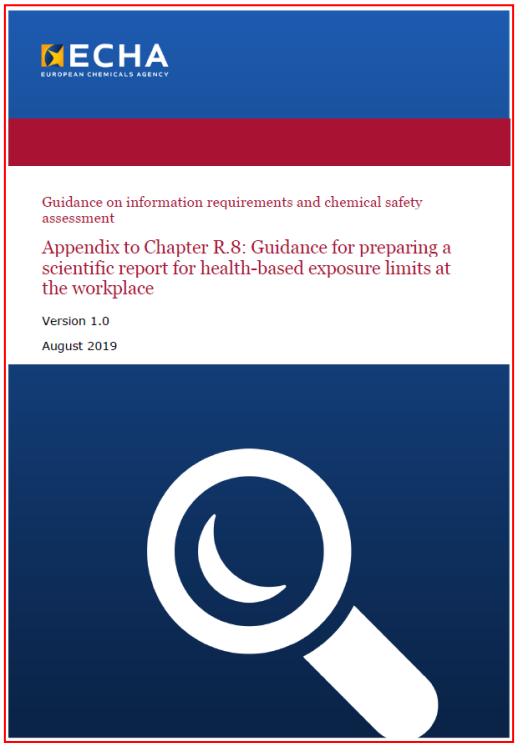
BIOCIDES

A new version of the Note for Guidance implementing the concept of biocidal product family has been discussed during the 84th Competent Authority (CA) meeting. July 19, 2019 document. The document is still a draft version as it has to be completed. It surely helps stakeholders to apply criteria to build up a common approach to biocidal product families. Annex VII drafted a summary figure to group biocidal products in a biocidal product family.



OCCUPATIONAL EXPOSURE LIMITS: New ECHA Guidance

ECHA has published guidance for preparing a scientific report for health-based exposure limits and occupational exposure limits (OELs) in the workplace. It aligns the methodologies in REACH and occupational health and safety legislation, to establish safe levels of exposure to chemicals in the workplace. The document takes the findings of the ECHA/RAC – SCOEL joint task force into account. This is a follow-up of the REACH review, improving the interface between REACH and occupational health and safety legislation. As of 2019, ECHA has started providing recommendations for occupational exposure limits that protect workers exposed to hazardous chemicals



Occupational Exposure Limits (OELs)

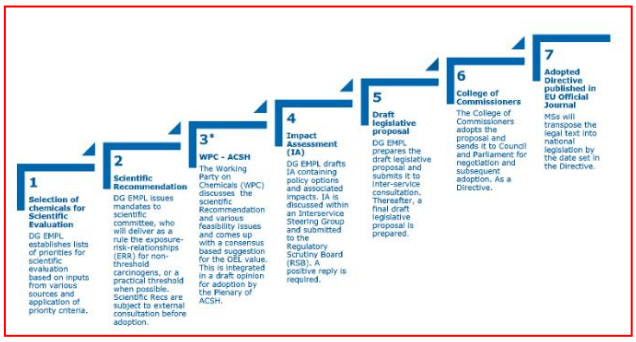
The European Commission seeks advice from independent scientific committees on the assessment of priority chemicals, in order to support proposed actions to adopt new or revised Occupational Exposure Limits (OELs) under Directive 2004/37/EC and Directive 98/24/EC. European Chemicals Agency, through its Committee for Risk Assessment (RAC), supports the European Commission's Directorate-General for Employment, Social Affairs and Inclusion (DG EMPL) by providing scientific opinions on OELs. RAC has recently taken over responsibility for work previously carried out by DG Employment's Scientific Committee on Occupational Exposure Limits (SCOEL).

OELs are a measure for minimizing worker exposure to hazardous substances in the workplace. Such limits are set taking into account the available information (including the most recent data) on the hazards of a substance, particularly with respect to carcinogenicity, mutagenicity and toxicity to reproduction, and on the acute effects of exposure.

OELs are mainly intended to prevent workers from inhaling chemicals as vapors, mists or dusts. However, RAC may also provide recommendations for a skin notation indicating that dermal protection is needed. Other notations are also possible, for example: sensitization or noise. Additionally, RAC may recommend Biological Limit Values (BLV, bio-monitoring exposure levels) or Biological Guidance Values (BGV, bio-monitoring background levels).

OEL process

OELs are established following a process involving a series of steps. The process for the substances being considered for binding OELs under the Carcinogens and Mutagens Directive (2004/37/EC) or the Chemical Agents Directive (98/24/EC), is the ordinary legislative procedure which is shown in the diagram below. Once agreed, these are binding OELs. Substances being considered under the Chemical Agents Directive (98/24/EC) for indicative OELs go through a lighter legislative procedure and a decision is taken by the European Commission. Once agreed, these are indicative OELs.
In addition, for certain policy initiatives the Commission will consult the social partners at EU level in accordance with the social policy provisions of the Treaty on the Functioning of the EU.



COSMETICS: Ukraine moves closer to animal testing ban for cosmetics

The Ukrainian Ministry of Health is hoping to bring the country's laws on animal testing for cosmetics into line with European Union legislation, while also restricting many more ingredients than are currently used.
Currently, Ukraine bans only around 400 substances for use in cosmetics but coming into line with EU regulation will increase this to **1.383**.
In order to decrease problems for manufacturers the legislation will allow for an 18-month transition period and once completed, should allow Ukraine to market its products across the EU more easily.
"The new standards are a guarantee of quality and safety," said a statement issued by the Ministry.
"The idea that something is 'high quality because it's from Europe' will lose its relevance, because the requirements for cosmetics in our country and the EU will be the same." The list of prohibited ingredients will be three times bigger, said the Ministry, and the testing of cosmetics on animals will also be banned.
"Companies that already have the capacity to apply the new standards will easily transition to new conditions," it said. "For others, a transition period of 18 months is foreseen.
"This will allow the adoption of new methodologies and streamline processes without financial risks for companies and unfair competition." The new technical regulation for cosmetic products is one of the steps taken by Ukraine to fulfill the conditions of the Ukraine–European Union Association Agreement laid out between the two countries in 2014.
This commits Ukraine to gradually conform to EU technical and consumer standards in return for political and financial support, access to research and preferential access to EU markets. Ukraine aims to become a full EU member by around 2025.

Public consultations on applications for authorization

ECHA is looking for comments on 27 applications for authorization covering 39 uses of:

Chromium trioxide (EC 215-607-8, CAS 1333-82-0) used in the manufacture of electrolytic chromium/chromium oxide coated steel (ECCS);

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and 4-Nonylphenol, branched and linear, ethoxylated (EC-, CAS-) used in the production of various medical devices (e.g. **in vitro** diagnostic kits) and medicinal products (e.g. active pharmaceutical ingredients); used in the production of chromatography resins for the biopharmaceutical industry, food and beverage sector, and academia;

Pitch, coal tar, high-temp. (EC 266-028-2, CAS 65996-93-2) **and Anthracene oil** (EC 292-602-7, CAS 90640-80-5) used in the manufacture of formulations mixtures for various industrial uses; and

Pitch, coal tar, high-temp. (EC 266-028-2, CAS 65996-93-2) used as a binder in the manufacture of clay targets.

More information about the uses that authorization is applied for, including the description of the function of the substance, exposure scenarios, possible alternatives identified by the applicants, together with socio-economic information, is available on our website. The deadline for comments is **9 October 2019**.

Public consultation on harmonised classification and labelling

ECHA is looking for comments on harmonized classification and labeling proposals for:

2,2-bis(acryloyloxymethyl)butyl acrylate trimethylolpropane triacrylate (EC 239-701-3, CAS 15625-89-5);

Benzophenone (EC 204-337-6, CAS 119-61-9);

Fluopicolide (EC 607-285-6, CAS 239110-15-7);

4,4'-oxydi(benzenesulphonohydrazide) (EC 201-286-1, CAS 80-51-3); and

Toluene-4-sulphonohydrazide (EC 216-407-3, CAS 1576-35-8).

The deadline for comments is **11 October 2019**.

EFSA Guidance on bees and pesticides: work plan published

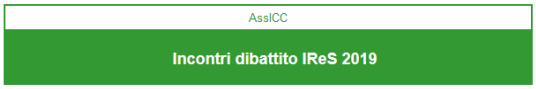
EFSA has outlined how it plans to review its guidance on the risk assessment of **pesticides and bees** in the EU. Stakeholders and pesticide experts from Member States will be consulted regularly throughout the process. The first consultation begins later this month, when stakeholders and Member State representatives will be asked for their views on the current guidance document. Stakeholder feedback will be provided by a consultation group, comprising representatives of EFSA's different stakeholder communities, that has been set up to support the revision of the guidance. Member States will be consulted through EFSA's existing Pesticides Steering Network. Gathering views on the existing guidance, published in 2013, is an important first step in EFSA's review as highlighted in the mandate received from the European Commission. When the feedback has been gathered and analysed, EFSA's scientific working group will begin its review. A full public consultation and workshop will take place when the document has been drafted.

CHEMSAFE attendance 2019-2020

Helsinki (FI), September 8-11
EUROTOX 2019, Exhibition booth + two poster presentations, four people

Milano (Italy),
Exhibition booth, two persons,
Oral presentation by A. Conto " The toxicological evaluation on active pharmaceutical ingredients (API), scientific approaches and safety targets"

Dublin (Ireland),
Partner/attendance, Oral presentation by A. Conto "Microplastics: a new challenge for environmental protection"



11 ottobre – ore 9.00 – 13.00, Two persons, workshop
"Regolamento biocidi EU 528/212: dall'approvazione del principio attivo all'autorizzazione del prodotto biocida. Come affrontare le criticità tecniche e finanziarie per le PMI"

Bruxelles (Belgium), attendante, two persons

Frankfurt Am Main (Germany)
Oral presentation by A. Conto, "Environmental impact of active pharmaceutical ingredients (API) and their ED properties

Sao Paulo (Brazil), exhibition booth with three persons

End of the newsletter