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NOTE

From: General Secretariat of the Council
To: Delegations

Subject: A more transparent, more effective and safer assessment of chemicals substances
- Information from the French, Italian and Luxembourg delegations

Delegations will find in the Annex an information note from the French, Italian and Luxembourg delegations on the above subject, to be dealt with under "Any other business" at the Council (Environment) meeting on 13 October 2017.

A more transparent, more effective and safer assessment of chemical substances

- Information from the French, Italian and Luxembourg delegations -

The effects on human health and on the environment of certain chemicals can be very significant and have been receiving increasing attention from European citizens. They are increasingly expressing concern.

Achieving the sustainable development goals and implementing Agenda 2030 call for comprehensive action to remove those negative impacts of chemical pollution on human health and the environment.

Recent cases that have been subject to examination procedures at European level underline these concerns. They have raised questions, leading to controversies, about evaluation methods and the robustness of evaluations carried out by the relevant agencies.

To this end, France, Italy and Luxembourg wish to share this view with all the institutions of the European Union and to identify orientations to strengthen the effectiveness of actions and decisions as well as the confidence of citizens.

a) Adopting a clear and comprehensive strategy on chemicals

Taking chemical risks into account in various technical sectoral regulations does not provide an overall view of the risk management as regards health and the environment. It also makes it difficult for citizens to appropriate the stakes and the decisions taken.

Therefore, in line with point 13 of the Council conclusions on protection of human health and the environment through the sound management of chemicals adopted on 19th December 2016, it seems necessary that the Union should develop a strategy for a general reduction of exposure to chemicals, whatever their source, in order to ensure a high level of environmental and human health protection.

This strategy may include the new strategy proposed by the European Commission on 4th July 2017 to reduce the exposure of European citizens to endocrine disruptors through toys, cosmetics and food packaging.

The preparation and adoption of this strategy, involving all the stakeholders and mobilizing all action levers (research, expertise, regulation, awareness-raising, training, etc.) and expected in 2018, will lead to the definition of a cross-sectoral and ambitious harmonized framework.

b) Strengthening confidence in chemicals assessment and authorization mechanisms

It seems essential to strengthen the trust between citizens and decision-makers at European level.

European legislation on chemicals gives full responsibility to the industry for the products they put on the market. In particular, they must finance and make available all the studies necessary to assess the risks associated with the use of their products. It is therefore on the basis of the studies that they provide that health agencies, at European or national level, assess the risks linked to the marketing of products.

This fundamental principle that responsibility lies with the person who places the product on the market must be maintained.

Nevertheless, this system is regularly criticized on two points which undermine the credibility of the European chemicals assessment system in terms of transparency and independence:

- certain data and studies provided by the industry are protected by a data protection regime and are therefore not accessible to the public. Consideration should be given to investigating how to make access to the results of studies (not the full studies) more transparent for some aspects related to the health and environmental impacts of substances and products;

- the agencies (EFSA, ECHA) do not have the possibility to finance scientific studies that are complementary to those provided by the industry, when, in specific cases, contradictory results or controversies cast doubt on the quality of the expertise provided. The results of such independent studies could be made public (as a transparency goal) and could be compared to results provided by petitioners to check for consistency. Such studies may be costly, and **consideration should be given to a mechanism which, exceptionally and for a very limited number of cases, allows the agencies to undertake such studies independently** in order to strengthen the robustness of the system without compromising the principle of industrial responsibility, and to ensure that the agencies are provided with adequate means to allow for this supplementary workload both in terms of budget and human resources.

More research for improving methods for the identification of hazards related to substances should be a priority under the next multiannual programme post Horizon 2020. Public-private partnerships may be sought to give authorities as well as companies more tools to identify appropriate methods. Initiatives of this nature are underway in some countries, especially on endocrine disruptors, and may lead to increased cooperation between Member States.

France, Italy and Luxembourg would therefore be in favour of the Commission initiating a debate in the coming months with the Member States and the different stakeholders on these orientations.