

## **Collegium Ramazzini**

The Collegium Ramazzini is an international scientific society that examines critical issues in occupational and environmental medicine with a view towards action to prevent disease and promote health. The Collegium derives its name from Bernardino Ramazzini, the father of occupational medicine, a professor of medicine of the Universities of Modena and Padua in the late 1600s and the early 1700s. The Collegium is comprised of 180 physicians and scientists from 35 countries, each of whom is elected to membership. The Collegium is independent of commercial interests.

### **CONTROL OF BIOCIDES IN THE EUROPEAN UNION**

#### **The Collegium Ramazzini Calls for Action to Protect Human Health**

The European Parliament and the Council are considering the European Commission's draft biocide regulation (COM(2009) 267 final), which is intended to replace the current EU Biocidal Products Directive 1998/8/EC. A unique opportunity therefore exists to enact advanced policies to better control the market placement and use of biocides in order to protect human health and the environment from harmful effects. The new legislation will set the stage for biocide use in Europe for many years to come, and a stronger EU biocide legislation can become an important step toward eliminating biocide hazards worldwide, in accordance with the Rotterdam convention. The strengthened legislation should also include means to promote non-chemical alternative methods of pest control and to support a sustainable, proper use of biocides.

Despite European policies to tackle the risks of biocide use, there is still a huge data gap concerning uses, releases, combination effects and their impacts throughout their whole life cycle. Initial investigations indicate that the use of antimicrobial compounds has increased in concert with a growing frequency of antimicrobial resistance in bacteria. Microbial resistance, due to improper or over use of antimicrobial biocides drives the development of even more toxic antimicrobials, yet the microbes adapt.

About 400 active substances are in active use in thousands of products, at an annual consumption of 400.000 tons. The majority of these products and active substances have yet to be appropriately evaluated for adverse effects.

The considerations are similar to those that the Collegium Ramazzini commented on in its Statement on statement on the control of pesticides in the European Union in 2008. We therefore make the following recommendations:

#### **Biocides Need Stricter Regulation Than the Current Proposal Contains**

A growing body of scientific evidence demonstrates links between exposures to hazardous biocides and potentially serious adverse impacts on human health and the environment. Currently licensed biocides include known and suspected carcinogens, endocrine disruptors, allergens, neurotoxins and reproductive toxicants. Infants, children, pregnant women and the developing foetus are particularly vulnerable to biocides. The Collegium Ramazzini therefore urges the EU to adopt strong legislation to protect public health and the environment against adverse effects of biocides. **Specifically, the Collegium urges the following changes:**

- There is ample evidence to support the need for **stringent** "cut-off" criteria to eliminate the most hazardous biocides from products and the environment, including carcinogenic, mutagenic, or toxic for reproduction (categories 1, 2, & 3 under current Directive 67/548/EEC), developmental neurotoxicity, or immunotoxicity. No substance should be approved if it is considered to be endocrine disrupting, in line with the criteria defined in the pesticides regulation.

The cut-off regime must be complemented by a consistent substitution regime: the comparative assessment must be applied to all biocidal products with candidates for substitution and it must evaluate non-chemical options as alternatives.

- Any derogation or dispensation from the above restrictions should be granted only when there are no effective and safer alternatives to control a serious public health danger in the Member State concerned. The application of such products should be limited to professional, qualified users and linked to risk reduction measures, monitoring and substitution plans.

- The new regulation should ensure that nano biocides – newly marketed compounds which may generate new hazards – are approved only if their safety is well-proven, and clear labeling requirements should be in place.

- The data requirements (Annex II or III, combined with Annex IV) are insufficient to reliably detect the relevant risks as basis for the intended biocide usage restrictions. For developmental neurotoxicity, immunotoxicity, endocrine disruption and the effects of mixtures, no data requirement is indicated, which would of course prevent the regulation of substances showing such effects.

- The EU should support the sustainability of biocidal products: Preventive and non-chemical measures should be the preferred option. Sustainability could also help tackling the problem of antimicrobial resistance, which is spurred by improper and exaggerated use of disinfectants. The legislation should also *restrict biocide use in public areas which are frequented by vulnerable groups or large crowds*.

On behalf of the Collegium Ramazzini Executive Committee