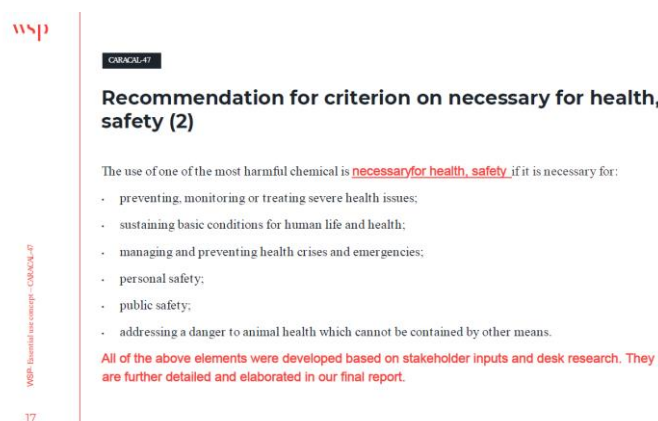


Chemical Strategy for Sustainability AnimalhealthEurope input in the “essential use concept” discussions

AnimalhealthEurope has reviewed the presentation on the “essential use concept” written by WSP and would like to take the opportunity to provide input to the ongoing debate.

AnimalhealthEurope represents manufacturers of animal health products, which include vaccines, veterinary medicines and diagnostics. Our membership covers 90% of the European market for animal health products.

AnimalhealthEurope is pleased to see that animal health has now also been taken into account by the consultant.



However, we are disappointed with the still disproportionately minor consideration given to animal health within this proposal in the context of One Health.

Today in the EU, there is a clear understanding of the interconnectivity between the environment, human and animal health, with the One Health concept gaining political momentum over the past years. In fact, a One Health Directorate was recently created under DG SANTE in the European Commission given the recognised importance. This proposal fails to adequately take into account the One Health impacts.¹

There is a stark lack of balance between the three elements of One Health in the proposal, with a disproportionate weight given to protecting the environment to the detriment of both human and animal health. This demonstrates a disregard both the positive contributions of animal health (e.g. safe and sustainable food, companionship) and the negative impacts on human health if animal health is not adequately protected (e.g. zoonotic disease spread).

Moreover, the mentions of addressing a “danger” to animal health and “cannot be contained by other means” disregard the strong importance that the European Commission and indeed a large majority of EU citizens place on animal welfare.

¹ OHHLEP One Health definition

One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems.

It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent.

The approach mobilizes multiple sectors, disciplines and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change, and contributing to sustainable development.

As the EU Regulation on transmissible animal diseases (Animal Health Law) states:
“...animal health and welfare are linked: better animal health promotes better animal welfare, and vice versa. When disease prevention and control measures are carried out in accordance with this Regulation, their effect on animal welfare, understood in the light of Article 13 of the Treaty on the Functioning of the European Union (TFEU), should be considered in order to spare the animals concerned any avoidable pain, distress or suffering.”

Furthermore, we would like to recall that both human and animal medicines are subject to a very strict legislative framework with safety being a major chapter in any authorisation dossier. This includes consumer safety, user safety, target animal safety, as well as environmental safety. Only medicines that meet all the requirements and demonstrate a positive benefit-risk ratio are authorised to be placed on the market in Europe. This sector-specific legislation is at risk of being overruled by the group assessments proposed in the Chemical Strategy for Sustainability, e.g. for PFAS, designating all substances in that group automatically as “substance of very high concern”, while this is not necessarily the case for those used in medicinal products.

In conclusion, any veterinary medicine approved to restore or protect the health and welfare of animals should be considered as necessary for health and therefore considered an essential use. This classification should include the entire manufacturing process and not only the final medicine. We therefore respectfully request to take this into account when elaborating a final proposal for criteria to define “essential use”.