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CONTRIBUTION

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| From: | General Secretariat of the Council |
| To: | Ad hoc Working Party on One Substance One Assessment |
| N° prev. doc.: | WK 6848/2024 |
| N° Cion doc.: | ST 16973/23, 16972/23, 16961/23 + ADD 1 |
| Subject: | OSOA Package: comments from a delegation |

Following the call for comments on the above set out with WK 6848/2024, delegations will find attached comments from AT.

AUSTRIA

Further WRITTEN COMMENTS: ‘One substance, one assessment’ (OSOA) Legislative Package (WK 6525/2024 ADD4)

AT thanks the COM and the BE Presidency for taking into account our previous comments.

Regarding the current status of discussion, in general, AT can support the proposals of the Presidency (WK06525/2024 Add4, “Presidency Flash”). Regarding the “thematic blocks” below, we have the following comments.

3) Involvement of the MS, delegated and implementing acts

AT welcomes further explanation of the COM regarding Art 24 and Art 24 a *new*. (Art 24 deals with delegated acts (Art 290 TFEU) whereas Art 24 a *new* appears to be a mixture between delegated and implementing acts (Art 290 and 291 TFEU).

4) Medicinal products data: scope and structure of the text

AT supports the Presidencies approach (having medicinal products in Annex I and the scope in art 3) for the reasons of clarity.

5) Definitions and scope

AT supports the approach of the BE Presidency and notes positively that adding a new Annex IV, listing environmental sustainability related regulations, is still envisaged.

7) Studies notification and enforcement

AT still sees it beneficial to clarify that chemicals data generated internally in companies for the purpose of quality and process control are excluded from the scope of Art 22. Such data is usually very case specific, sensitive and of limited interest for the public.

The clarification could be done either by adding to Art 22 a new para reading: *Para 1 does not apply to chemicals data generated for the purpose of quality and process* or at least by taking the issue up into a guidance document.
