



## **SFP comments on Implementing Regulation on a Traceability System for Tobacco Products, Delegated Regulation on Data Storage Contracts and Implementing Decision on Security Features,**

These comments are endorsed by 41 organisations, a full list available at the end of this document and at <https://smokefreepartnership.eu/position-papers-briefings-reports>. We also endorse the submissions of ECL and ASH (UK).

We welcome the opportunity to comment on the draft Implementing Regulation (IR Art 15(11)), Delegated Regulation (DR Art 15(12)), as well as Implementing Decision (ID Art 16(2)). We applaud the Commission for its ability to respect the implementation calendar despite the complexity of the matter and the pressures of vested interests. We also applaud Recitals 5 and 24 of IR Art 15(11) which demonstrate the Commission's efforts to respect and implement the Illicit Trade Protocol (ITP). The ITP has been ratified by the EU and 7 Member States (MS) to date. We recall that the ITP was developed as a response to the fact that the majority of illicit tobacco products are genuine and diverted from the legal supply chain. We must also stress that there is a strong economic incentive for operators to allow legal products to be diverted into illicit channels. The main goal of the traceability system, therefore, must be to control the legal supply chain.

**Independence:** Art 35 of the IR Art 15 (11) and Art 8 of the ID Art 16(2) are based on regular practice within the Commission regarding the definition of independence from commercial interests. However, the tobacco industry should not be treated as any other. As stated in the WHA resolution WHA54.18, *"the tobacco industry has operated for years with the express intention of subverting the role of governments ...in implementing public health policies to combat the tobacco epidemic"*. This is the reason why the drafting of these articles is so crucial, in light of the EU and MS obligations under Art 5.3 WHO FCTC and under Art 8 ITP which requires Member States to effectively control the supply chain, in the letter and spirit of the FCTC and the ITP.

This is even more relevant because independence criteria apply to many aspects of the technical standards for both the tracking and tracing system and security features.

Art 35 of the IR Art 15 (11) concerns the entirety of the traceability system (Recital 24), in particular:

- ID issuers (Recital 5, Art 3.2, 3.7(a))
- anti-tampering devices (Recital 14 and Art 7. 2)
- data repositories (Recital 19 and Art 26.1).

These criteria are applied throughout the contracts with repository providers (Recitals 1, 4, Art 7.2(a), 8, 17.3(b) of the DR Art 15 (12)).

Similar criteria are applied to the provider of at least one authentication element that is part of the security feature (Recital 6 and Arts 3.2 and 8 of the ID Art 16(2)).

## Proposed amendments to the independence criteria

These concern Art 35 of IR Art 15(11) and Art 8 of IR Art 16(2):

- There should be an additional turnover requirement in Article 35(2)(e), of 0% turnover before a contract under the Regulations, and at most 15% after. This would help towards ensuring that third parties that have close ties with the tobacco industry do not manipulate their turnover data in order to fit the criteria.
- No provider shall subcontract any of the authentication elements or other tasks to any party that does not meet the above mentioned definitions of Independence.
- The conflict of interest criteria in Article 35(2)(f) should also cover technical and operational staff in addition to management, and be retrospective for at least two years.

Similar obligations have a precedent with respect to DG SANTE requirements on professional conflicts of interest in Call for tender n° EAHC/2013/Health/10 concerning Multiple Framework Contracts with reopening of competition to support tobacco policies (<http://bit.ly/2fxNg2h>, p.36). Also, we note EMA staff is required to have zero conflicts (<http://bit.ly/2xNOIYZ>).

- We propose that MS establish and review, at least annually, a list of providers of data storage, anti-tampering devices and authentication elements which comply with the independence criteria
- We propose that, should an UI issuer, anti-tampering device provider, data repository or authentication element provider cease to comply with the independence criteria, this would immediately void their contracts

## List of endorsing organisations:

1. EU: CPME: Standing Committee of European Doctors
2. EU: ECL: Association of European Cancer Leagues
3. EU: EHN: European Heart Network
4. EU: ECCO European CanCer Organisation
5. EU: International association of mutual benefit societies
6. EU: INWAT: International Network of Women against Tobacco Europe
7. International: Corporate Accountability International
8. Belgium: Belgian Foundation against Cancer
9. Belgium: Kom Op Tegen Kanker
10. Bosnia and Herzegovina: PROI: Progressive Reinforcement of Organizations and Individuals
11. Bulgaria: Smoke Free Life Coalition Bulgaria
12. Czech Republic: Česko Bez Kouře
13. Finland: Suomen ASH: Finland's Action on Smoking and Health
14. France: CNCT: Comité National Contre Le Tabagisme
15. France: La Ligue contre le cancer
16. Germany: ABNR: Aktionsbündnis Nichtraucher
17. Germany: Unfairtobacco
18. Ireland: ASH Ireland

19. Ireland: [Irish Cancer Society](#)
20. Italy: [SITAB: Società Italiana di Tabaccologia](#)
21. Kosovo: [Kosovo Advocacy and Development Center](#)
22. Lithuania: [NTAKK: Lithuanian National Tobacco and Alcohol Control Coalition](#)
23. Norway: [Norwegian Cancer Society](#)
24. Poland: [MANKO Association](#)
25. Portugal: [CATR: Centro de Apoio, Tratamento e Recuperação](#)
26. Portugal: [ONG Portuguesas pelo Controlo do Tabagismo](#)
27. Romania: [ARPS: Asociatia Romana pentru Promovarea Sanatatii](#)
28. Serbia: [Association „Health Mission“](#)
29. Serbia: [Serbian Society for the Fight Against Cancer](#)
30. Slovenia: [No Excuse Slovenia](#)
31. Slovenia: [Slovenian Coalition for Public Health, Environment and Tobacco Control](#)
32. Spain: [IDEPP: Grupo de I+D en Economía, Políticas Públicas y Salud](#)
33. Spain: [XQNS!](#)
34. Sweden: [Tobaksfakta - Independent Think Tank](#)
35. The Netherlands: [Alliantie Nederland Rookvrij!](#)
36. The Netherlands: [Dutch Cancer Society](#)
37. Turkey: [Turkish National Coalition on Tobacco or Health](#)
38. UK: [ASH \(UK\)](#)
39. UK: [Cancer Research UK](#)
40. UK: [UKCTAS: UK Centre for Tobacco and Alcohol Studies](#)
41. Ukraine: [Life: Regional Advocacy Center](#)