DIN SPEC 10133:2014-09 (E)

Toxicological assessment of additives for tobacco products - A guidance

Contents

Page

Foreword 3

1 Background and objective of this document 4

2 Overview of current legal requirements, agreements and proposals 5

3 Discussion of approaches to the toxicological examination and evaluation of additives to tobacco products 9
3.1 Purpose 9
3.2 Basic considerations 9
3.2.1 General 9
3.2.2 Test matrix 10
3.2.3 Smoke generation 11
3.2.4 Substrates 11
3.2.5 Reference parameters for test doses 13
3.2.6 Scope of testing 13
3.2.7 In vivo versus in vitro testing 14
3.2.8 Positive controls 14
3.2.9 Discriminatory power of test systems 14
3.3 Toxicological data for the unburnt additive 15
3.4 Toxicological testing of the additive after combustion 15
3.4.1 Chemical analytical processes 15
3.4.2 Biological test systems 17
3.5 Interpretation and evaluation of toxicological data 24

4 Conclusions and recommendations 25
4.1 General 25
4.2 Toxicological data for the additive as a neat single substance 25
4.3 Pyrolysis of the additive as a neat single substance 25
4.4 Chemical and toxicological effects of additives on cigarette mainstream smoke 25
4.5 Assessment of test results 27

Annex A (informative) Examples of databases supplying authorized and peer-reviewed toxicological data 31

Bibliography 34