

EFFA Statement on the Presence of Nicotine in Vanilla Beans

To the best of our knowledge nicotine is not used as a pesticide in vanilla cultivation and is no longer allowed (neither in the EU nor in major vanilla producing countries). Therefore, we strongly question whether, from a regulatory point of view the actual Nicotine findings in Vanilla actually do fall under Regulation (EC) 396/2005¹ and whether the pesticide MRLs are in principle applicable at all.

INTRODUCTION

Nicotine is well known as a key component in tobacco. Less known is that this alkaloid is also naturally occurring in other plants. Most prominent examples of commonly consumed vegetables are those belonging to the family of *Solanaceae* (e.g. potato, tomato, eggplant). For a vast range of edible plants its natural presence is under discussion (e.g., tea, mushrooms and various herbs and spices including vanilla) however there is so far no robust scientific evidence and, in most cases, even only limited analytical data regarding nicotine contents at trace levels.

REGULATORY CONTEXT

Nicotine was formerly used as an insecticide but is no longer approved for use in the EU since 2009². However, it is still regulated as a pesticide in the EU.

According to the latest Regulation (EU) 2024/451 amending Annex III to Regulation (EC) 396/2005 the current maximum residue limit (MRL) for nicotine used as a pesticide in vanilla beans is back at the "old/original" value of 0.3 mg/kg. The safety of this threshold was supported by an EFSA opinion of 2011³ and confirmed again in October 2023 by a targeted risk assessment regarding nicotine in spices⁴.

In 2023, with Commission Regulation (EU) 2023/1536 the MRL had been reduced to 0.05 mg/kg to reflect the lower limit of determination without being aware of the consequences.

INDUSTRY UNDERSTANDING

To the best of our knowledge nicotine is not used as a pesticide in Vanilla cultivation in major producing countries.

However, analytical industry data (collected over a period of several years) indicate that vanilla beans as marketed frequently show levels in nicotine significantly higher than 0.05 mg/kg.

¹ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005on maximum residue levels of pesticides in or on food and feed of plant and animal origin

² Decision 2009/9/EG of December 8th on the non-inclusion of nicotine in Annex I of Directive 91/414/EEC and the revocation of authorization for plant protection products containing the active substance.

³ Setting of temporary MRLs for nicotine in tea, herbal infusions, spices, rose hips and fresh herbs, EFSA opinion, 2011

⁴ EFSA Journal 2023;21(10):8372

It should be noted that the current MRL is a temporary one and will be reviewed by the EU-Commission based on new information regarding the nature of the nicotine occurrence, that should be submitted by 22 February 2030 [see note on nicotine in the regulation⁵]

Therefore, the investigations – e.g., by EFFA members – that have been initiated are still ongoing to identify potential routes for contaminations (e.g., direct contamination by smokers but also environmental routes), as well as endogenous occurrence in Vanilla plants.

A few years ago, similar investigations were carried out (by an organic certifying body). They were not able to identify a source of external contamination.

Given that, to the best of our knowledge, nicotine is not used as a pesticide and its use is no longer allowed (not in the EU and also not in major vanilla producing countries), we strongly question whether from a regulatory point of view the actual Nicotine findings in Vanilla really do fall under Regulation (EC) 396/2005 and whether the pesticide MRLs are in principle applicable at all.

In line with the applicable ALARA (as low as reasonably achievable) principle, EFFA members are trying to identify and reduce or even eliminate any potential source of contamination. Besides that, it is deemed necessary to pursue the possibility of an endogenous occurrence.

About EFFA

EFFA, the European Flavour Association, is a non-profit trade association representing European national associations and companies in the flavour industry based in Brussels. Our membership consists of 12 national associations and 11 company members. In total, EFFA is representing over 300 companies in Europe, ranging from smaller SMEs to stock market listed companies.

EFFA's main objectives are to promote and support a consistent European-wide strategy for flavour issues and to elaborate dossiers, for evaluation by the EU Institutions – Evaluation Committees, to stimulate, coordinate and monitor best practice in regulatory, safety, technical and scientific issues, between members of the flavour sector and related industries through standards, guidelines, and codes of practice. EFFA is registered in the Transparency Register under the following number: 7102243339711.

EFFA Secretariat

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⁵ Scientific evidence is not conclusive to demonstrate that nicotine occurs naturally in the concerned crop and to elucidate its mechanism of formation. When re-viewing the MRL, the Commission will take into account the information, if it is submitted by 22 February 2030, or, if that information is not submitted by that date, the lack of it