



ETAD Position on two French Notifications 2004/327/F and 2004/328/F

ETAD is the leading health and environment association representing the organic pigment and dye manufacturers most effected by the proposed NFPL (New French Positive List). We represent 46 companies internationally and have close links with other national organisations representing organic colorant suppliers.

ETAD advocates harmonization of regulations for chemicals in materials intended to come into contact with food in Europe, and other regions of the world.

ETAD is cooperating with the EU Commission and other stakeholders in moving regulatory development for the protection of consumer health and the environment.

ETAD appreciates the effort by the French Authorities to develop further regulations concerning colorants for plastic materials intended to come into contact with food towards a harmonized concept at EU level. However, it is recommended that France should not pre-empt such regulations by adopting national data requirements and a national positive list at a time when regulatory developments at EU level in this area ("Super Regulations") are progressing.

ETAD fully supports the French Authorities' intended goal to ensure a high degree of consumer protection in the food contact area, however we consider that the proposed positive list will not lead to the desired objective.

Impact on Market and Free Trade

Adequate regulations and compliance controls must ensure that all pigment providers are required to perform at the same level, namely, to ensure that French pigment manufacturers or suppliers based in France are not put at a disadvantage owing to these regulatory requirements that may not be as closely followed by outside suppliers.

Exceptions to this may well force pigment user industries to move out of the French market and leaving alternatives of less value to consumers.

ETAD is concerned about undue distortion of free trade by the new requirements coming into force unilaterally irrespective of the accelerating development at EU level to harmonize regulation for plastic materials intended to come into contact with food. The proportionality of the extra cost of testing for colorants that have been on the market for many years or decades without raising concerns, against the value of limited improvements in consumer and environmental protection is questioned. Coordination with the EU regulatory process and its implementation would eliminate the risk of re-assessment by the Scientific Committee of Food (SCF) of colorants having already been evaluated as a prerequisite for their transfer from List B to List A of NFPL.

An authorisation system for regulated chemicals for certain food contact applications is advocated. Thus, free trade and a competitive environment are maintained in a responsible manner, since consumer safety and environmental protection are common, accepted and effective objectives of those existing regulations, irrespective of the risk assessment methodology applied.

Imported articles and plastic materials intended to come into contact with food shall be subject to the same rules. In addition, emphasis must be placed on adequate regulatory controls to ensure that imported articles (plastic items, etc.) are also in compliance with local rules and requirements.

Innovation and protection of CBI

A potential slow down or the eventual disappearance of competitive innovation, that creates value to consumers and society, is an economic downside of NFPL. Single petitioners must absorb the rather high cost of testing for the benefit of numerous other suppliers of chemicals and downstream manufacturers (free riders). Inclusion of cost sharing, the formation of consortia is suggested to facilitate an authorisation system. This would also further enhance a competitive and innovative environment.

Authorisation and positive listing

Positive listing of colorants using the C.I. Generic Name nomenclature as is proposed in the NFPL is not adequate to identify those formulated products which are authorised. The C.I. Generic Name identifies only "the essential colorant" of a product, which may contain additionally other substances which have been added to improve the products application performance. In order to guarantee the desired level of consumer protection any intentionally added component must have a recognised food contact authorisation status.

Such regulations must not only include components of the claimed formulations themselves but must also take into account the effects of by-products and impurities resulting from the manufacturing process of the pigment and/or formulations thereof. A product described simply by its C.I. Generic Name can be manufactured by a number of synthetic routes leading to significant differences in the impurity profile.

In all cases, it is insufficient to apply regulations to chemical moieties and components of formulations themselves. Instead, effective regulations must take into account the processes used to manufacture pigments and formulation components as well as final products (e.g. ink formulations, masterbatches etc.) and articles.

Reporting and testing requirements based on exposure

ETAD supports the continuation of the purity criteria as laid down in Arrêté, November 1986, and further specified by Council Resolution AP (89)1, as being a practical regulatory approach for taking into account manufacturing process dependent variations in the impurity and by-product profile of colorants of technical quality. Inclusion of thermal decomposition requirements, analytical characterization of migration and alignment of the exposure dependant toxicological test package with Directive 2002/72/EC are seen as a complementary step towards science-based risk assessment and regulatory harmonization within the EU. Any data requirements should be based on realistic exposure scenarios.

Conclusion

ETAD concludes that the adoption of this new French draft order will undoubtedly lead to distortion in the market and confusion of the downstream users.

Further ETAD concludes the order will not lead to the desired improvement in consumer safety.

ETAD Recommendation

The commission should require the postponement of adoption of the draft order on the grounds that it is already under consideration as EU level (see new frame work directive and "Super Regulation"). The Association offers its assistance and knowledge of organic colorants to the EU to develop a sound proposal for regulating these products for safe food contact use.