The International Fragrance Association

IFRA white paper on selected criteria for supporting biodegradability statements pertaining to fragrance ingredients along the supply chain

1. Introduction

For chemical substances that are used in applications where recovery is not possible (i.e., consumer products disposed down the drain), biodegradability becomes an attractive end-of-life option for mitigating environmental exposures and the risk of long-term impacts. Whereas biodegradation is a measurable biological process, biodegradability is considered a substance property that describes its potential for complete biodegradation under specified conditions.

For organic chemicals, standardized screening tests such as the OECD TG 301/310 ready biodegradability test and OECD TG 302 inherent biodegradability test series are used to screen their biodegradability potential for aquatic hazard classification and risk assessment purposes. Relevant terms that are coined by these standards include, “readily biodegradable”, which indicates rapid biodegradation under stringent test conditions, and “inherently biodegradable”, under more favorable conditions (e.g., higher test inoculum concentration). Meeting the pass criteria levels suggests that the chemical tested will ultimately biodegrade in the environment. According to the guideline, inherent biodegradability may be further subdivided into, “inherent, primary biodegradability” depending on the extent of biodegradation observed. However, unlike the OECD TG 301/310 which specifies a 28-day test duration, the OECD TG 302 does not define a test duration. Adding to the complexity, the OECD TG 301/310 can be used to conclude on inherent biodegradability if certain conditions are met.

Today, the use of biodegradation data from the OECD test methods has expanded beyond hazard classification and risk assessment; biodegradability claims have become a focal point for the marketing of consumer products. However, the lack of clarity of the standard test methods (e.g., undefined test duration of OECD TG 302) and rapid expansion of this area has led to a mosaic of approaches and different conclusions on biodegradability for similar substances. Observed differences in approaches include, for example, the application of predictive models, interpretation of guideline criteria, test duration, inclusion of primary (i.e., partial) biodegradation and consideration of products formed.

In response, the IFRA Environmental Task Force (ETF) formed a working group (WG) with environmental experts from the Fragrance Industry to determine scientifically sound criteria and approaches for the purpose of supporting biodegradability statements pertaining to fragrance ingredients. The overall aim of this document is to provide answers to questions we regularly receive from downstream users who feel there is an absence of guidance around the use of the term biodegradability.

In consultation with the IFRA Executive Technical Committee, this document presents the criteria and approaches IFRA experts consider to pass the scientific robustness test and as such are appropriate for supporting biodegradability statements pertaining to fragrance ingredients. It is important to note that the information contained in this document is complementary to what regulatory frameworks define or specifically request and is not a substitute thereto. Further, the criteria put forth through this effort, though recommended, are to be used on a strictly voluntary basis.

Lastly, this document provides criteria and wording around biodegradability related statements in communication between fragrance houses and customers in the supply chain. The information is not intended to be directly used as a basis for consumer-facing biodegradability claims. IFRA Members are advised to recommend to their customers to seek independent legal advice for those claims. In no way shall IFRA be held liable should a consumer-facing biodegradability claim be adopted on the basis of this document.

2. Selected criteria and approaches

Using the state of the art of the science and accumulated industry experience performing biodegradation studies, the IFRA ETF working group elaborated the following recommendations for the purpose of biodegradability statements pertaining to the fragrance ingredients contained in consumer products.

Biodegradability should be assessed on measured data that indicates **ultimate biodegradation** (i.e., complete biodegradation of the substance to CO_2, water and microbial biomass). Other processes such as primary biodegradation (i.e., biotransformation of the parent compound to intermediates or stable products), and abiotic processes (e.g., hydrolysis, photolysis, etc.) are considered insufficient in terms of supporting biodegradability statement pertaining to fragrance ingredients, as they result in only partial degradation of the substance.
Two main subcategories of biodegradability are recognized, **Readily Biodegradable** and **Inherent, Ultimately Biodegradable** and support the general statement "Biodegradable".
Standard methods commonly used for regulatory purposes to conclude on biodegradability endpoint include **screening test methods**: OECD 301/310 (and equivalent) and OECD 302 (and equivalent). For the classification of Ready Biodegradability: - ≥ 60% biodegradation in the OECD 301B, C, D, F and 310 within 28 days or - ≥ 70% biodegradation in the OECD 301A and E, or comparable method, within 28 days. The 10- or 14-day window (i.e., for the OECD 301D) must be met, unless justification for waiving can be provided. No window is applied to the OECD 301C, according to the guideline. For the classification of Inherent, Ultimate Biodegradability: - When the pass level criterion is fulfilled in an OECD 301/310 but the 10- or 14-day window criterion is not or - When the results of an OECD 301/310 or comparable method after 28 days indicate that the pass level criterion is almost fulfilled (i.e., 58% ThO2/ThCO2 or 68% DOC) or - ≥ 60% in the OECD 301B, C, D, F and 310 within 60 days or - ≥ 70% in the OECD 302 and 301A and E or comparable method, within 60 days.)
OECD simulation tests (e.g., OECD 309) are designed to demonstrate degradation under relevant environmental conditions. However, such studies are very complex and only a few have ever been performed on fragrance ingredients. Due to the difficulties related to the interpretation of **high-tier simulation studies,** each case would have to be reviewed by WG before being used for biodegradability statements pertaining to fragrance ingredients intended for supply-chain customers.

Read-across using measured data from structural analogue is a scientifically sound approach, so long as it does not supersede existing measured data. Further, established procedures should be consulted for identifying a structural analogue such as the EFEO/IFRA Guidelines on the Environmental Assessment of Natural Complex Substances (NCS)[1] or the ECHA Read-Across Assessment Framework[2].

Modeling software, though useful for estimating biodegradation potential in other applications (i.e., environmental exposure estimates, hazard screening, R&D, etc.) are not sufficient and should not be used to support biodegradability statement pertaining to fragrance ingredients.

However, for NCS only, exceptions need to be made due to the large number of constituents that lack measured data and are difficult to isolate for testing purposes (see section below on specific guidance for NCS).

NCS can in principle be claimed readily or inherently ultimately biodegradable if the whole NCS is tested to be biodegradable or if ≥ 80% (w/w) of the constituents have data indicating that they are ready and/or inherently biodegradable (Figure 1). In the latter case, when applying the constituent approach, if the NCS has a mix of measured data indicating ready and inherently biodegradable, conservatively, the conclusion should be inherently biodegradable. this is the approach we developed using the reverse logic applied to the following language stemming from section A9.4.3.1 of the Global Harmonized System (GHS, Rev. 9, 2021): "When not-rapidly-degradable components constitute a significant part of the complex substance (e.g. more than 20%, or for a hazardous component, an even lower content), the substance should be regarded as not rapidly degradable". Thus, applying the reverse logic to that statement, the WG concluded that a threshold of ≥80% (w/w) biodegradable constituents should be used as a benchmark when it comes to determining whether NCS can be stated to be biodegradable.

While measured data is preferred to fill the data gap of each naturally occurring constituent, and since some of the many constituents lack measured data, in addition to read-across as explained above, modeling software may be used, but the approach should be well documented, and the constituent should be within the applicability domain of the model. Also, to increase robustness of this approach, at least two modeling software that predict readily biodegradation should be used and their predictions should agree. Provided the conditions of the model are not violated (e.g., its domain of applicability), any two or more of the following models may be used: 1. CATALOGIC; 2. VEGA; and 3. EPIsuite/BIOWIN 1, 2, 5 or 6. Models that predict inherent biodegradation and models that predict half-life for complete ultimate or primary biodegradation (e.g., BIOWIN 3 and 4) should not to be used. Established procedures should be consulted such as the EFEO/IFRA Guidelines on the Environmental Assessment of Natural Complex Substances[1].

Fragrances are formulated mixtures containing many different fragrance ingredients and are not tested for biodegradability. Instead, their biodegradability is assessed based on data on the individual fragrance ingredients by summing the percentage (by weight) of ingredients that are biodegradable. An example is provided in Table 1. Similarly, finished consumer products should not be tested for biodegradability, and their biodegradability should be assessed by summing the percentages (by weight) of ingredients that are biodegradable.

[1] https://ifrafragrance.org/docs/default-source/guidelines/23702_gd_2016_05_27_efeo_ifra_guidelines_on_the_environmental_assessment_of_natural_complex_substances_(ncs).pdf?sfvrsn=65a814d1_0

[2] https://echa.europa.eu/documents/10162/13628/raaf_en.pdf/614e5d61-891d-4154-8a47-87efebd1851a

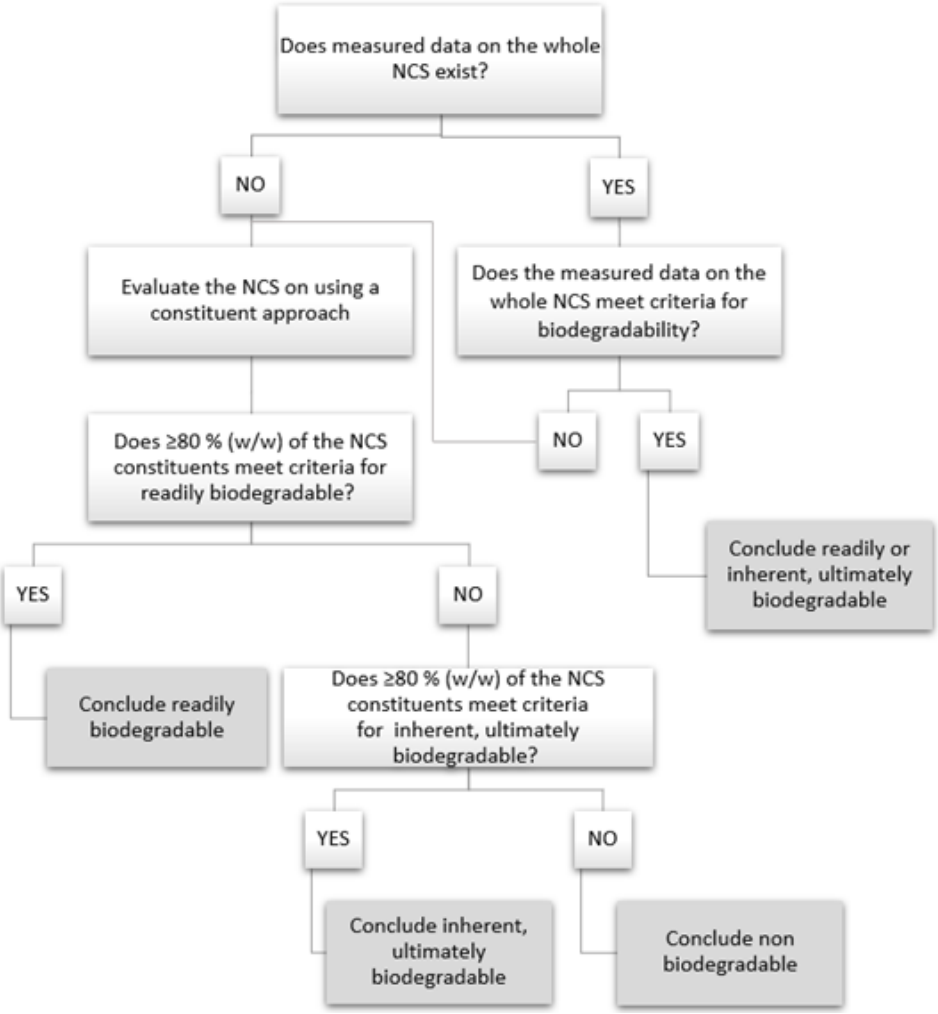

Figure 1. *Proposed decision tree for evaluating NCS*

Table 1. *Example on how to assess the biodegradability of a hypothetical fragrance formula*

	Ingredient	Biodegradable (Yes/No)	Fraction (w/w) of formula	Weighted % Biodegradable
	A	Yes	0.15	15
	B	Yes	0.33	33
	C	Yes	0.07	7
	D	No	0.28	0
	E	Yes	0.17	17
Total		/	**1**	**72**

Conclusion on the biodegradability of the hypothetical fragrance formula: 72% by weight of the ingredients of the fragrance are biodegradable.

V1: Published on 22 June 2023

V2: Published on 30 January 2024 – Amendment: addition of a statement about fragrances and finished consumer products and Table 1