**Environmental Fate**

1. **Sections 11.1.4.3 "Water and water-sediment degradation data (including simulation studies) - Water/sediment studies" (p. 46/47) & 11.2.1 "Summary of data/information on environmental transformation" (p. 47)**

Bayer Task Force disagrees with the normalization of degradation half-life ($DT_{50}$) values derived from simulation studies to a reference temperature of 12°C. Although this was not done by the Member State Competent Authority (MSCA) due to the already long $DT_{50}$ values (>1000 days at a reference temperature of 20°C), this would also not be justified.

In the "Guidance on the Application of the CLP criteria" published by ECHA (2017), it is stated that "Results of aquatic simulation tests may be used directly for classification purposes, when realistic environmental conditions in surface waters are simulated, i.e.: (…) realistic temperature e.g. 5 °C to 25 °C (…)" (page 565, section II.2.3.1 "Aquatic simulation tests"). In addition, no normalization of $DT_{50}$ values to a specific reference temperature for the purpose of comparability is required, since all the data from the simulation tests performed to address the aquatic system were derived at 20°C.

Therefore, BCS strongly recommends to remove the statements dealing with the normalization of $DT_{50}$ values to 12°C from the respective sections.

2. **Section 11.3 "Environmental fate and other relevant information" – "Soil adsorption" (p. 48)**

2.1 <u>Range of $K_{FOC}$ values, calculation of geometric mean $K_{FOC}$ and arithmetic mean 1/n</u>

Bayer Task Force disagrees with the use of sorption data derived from the study performed by [redacted] (2012a; Renewal Assessment report (RAR) Volume 3 CA, B.8, KCA 7.1.3.1.1/04) to calculate an overall geometric mean Freundlich coefficient ($K_{FOC}$) and an overall arithmetic mean Freundlich exponent (1/n) over all studied soils due to several reasons specified below. Consequently, a recalculation would lead to $K_{FOC}$ and 1/n values deviating from those specified in this section. This point was also addressed during the public commenting of the RAR (Volume 3 CA, B.8) of diflufenican.

Several deficiencies in the performance of the study were identified by assessing study details with the use of the quality criteria specified by EFSA (EFSA, 2017). (i) The tested substance concentrations did not cover a range of two orders of magnitude (0.013 - 0.0022 mg/L), (ii) the test item stability could not be proven since no parental mass balance was established and (iii) fitted data of the Freundlich sorption isotherms of four soils did not adequately match the experimental data, expressed by visual assessment and by regression coefficients ($R^2$) <0.975. In addition, the separation of the aqueous and soil phases were only checked visually, which was also noted by the Rapporteur Member State (RMS) in the RAR. Due to the pronounced adsorption affinity of diflufenican to soil particles, this most likely led to the erroneously allocation of diflufenican residues adsorbed to soil particles to the fraction dissolved in the aqueous phase. Hence, this most likely has led to an underestimation of diflufenican adsorption, resulting in lower adsorption endpoints (e.g., $K_{FOC}$, 1/n). In Annex 5 of the applicable OECD test guideline 106 (OECD, 2000) the importance of a sufficient phase separation and minimum required centrifugation conditions are specified. According to Figure 1a and Figure 1b, centrifugation conditions applied in the study by [redacted] (2012a; 2900 rpm for 10 min) were not sufficient to separate the soil from the aqueous phase at a ratio of 2 g soil / 50 mL $CaCl_2$ solution and soil densities of 1.12 to 1.454 g/cm³.

The underestimation of diflufenican adsorption in the study of [redacted] (2012a) can be additionally underlined when performing a t-test, revealing that $K_{FOC}$ values obtained in [redacted] (2012a) are significantly different from those obtained in the remaining studies ($p<0.05$; only the RMS accepted soils were used).

According to the reasons mentioned above, sorption data derived from the study performed by [redacted] (2012a) should be excluded from the overall assessment of sorption behavior of diflufenican and therefore, a recalculation of the overall geometric mean Freundlich adsorption coefficient ($K_{FOC}$) and an overall arithmetic mean Freundlich exponent (1/n) should be performed.

2.2 Proposed pH-dependent adsorption of diflufenican

Bayer Task Force disagrees with the assessment of the Member State Competent Authority (MSCA) that diflufenican exhibits a pH-dependent adsorption to soil due to the reasons specified below. This point was also addressed during the public commenting of the Renewal Assessment Report (RAR; Volume 3 CA, B.8) of diflufenican.

Taking relevant physical-chemical properties of diflufenican into account, no pH-dependent sorption to soil can be expected. Diflufenican exhibits neither a dissociation constant ($pK_a$) nor a pH-dependent water solubility and is also stable to hydrolysis at pH 5, 7 and 9.

In addition, Bayer AG checked pH dependency of diflufenican sorption using the helpful and accepted German InputDecision Tool v3.3 (Bonath et al., 2012). There, different correlations of $K_F$ or $K_{FOC}$ with $pH_{water}$, organic carbon (OC), clay or CEC is checked with a Kendall Test. The outcome is a strong and significant correlation of $K_F$ with OC for diflufenican (tau 0.6, corr. coeff. = 0.823) and a less strong correlation with clay. The correlation of $K_F$ with pH (tau = -0.25, corr. coeff. = -0.59) is much less pronounced and statistically not significantly different from 0 ($p = 0.16$).

It should be noted that for a correlation the same pH base - water or $CaCl_2$ - is needed. Since information on measured pH values in both, $CaCl_2$ solution and water, was not available for all soils investigated in the adsorption/desorption studies, a recalculation from $pH_{CaCl2}$ to $pH_{water}$ or vice versa is needed to assess a potential pH dependency of diflufenican using all available adsorption data. The recalculation from $pH_{CaCl2}$ to $pH_{water}$ or vice versa is described in FOCUS (2014). This recalculation was not done by the MSCA or RMS, respectively, but is strongly recommended. Using back-calculated $pH_{water}$ values, the correlation of $K_F$ with pH is even weaker (p 0.305).

According to the reasons mentioned above, a pH dependent adsorption of diflufenican to soil cannot be justifiably concluded.

**References:**

[redacted] 2012. Input-Decision 3.3 – A simple MS Excel-Tool to select appropriate input parameters for groundwater simulations in the national authorisation process of pesticide products, Federal Environmental Agency (UBA), Germany. URL:
https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwiR7PHqidneAhUhMewKHUwpDlQQFjAAegQICBAC&url=https%3A%2F%2Fwww.bvl.bund.de%2FSharedDocs%2FD

ownloads%2F04_Pflanzenschutzmittel%2FInput_Decision_3.xlsm%3F__blob%3DpublicationFile%26v%3D5&usg=AOvVaw1USbX1IbAPMa5Hy_ZW9XLU. Accessed on November 16th, 2018.

ECHA, 2017. Guidance on the Application of the CLP Criteria. Version 5.0, July 2017. URL: https://echa.europa.eu/documents/10162/23036412/clp_en.pdf. Accessed on November 22nd, 2018.

EFSA, 2017. Outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA Supporting Publication 2017:EN-1326. URL: https://www.google.com/search?q=doi%3A10.2903%2Fsp.efsa.2017.EN-1326&ie=utf-8&oe=utf-8. Accessed on November 16th, 2018.

FOCUS, 2014. Generic Guidance for Tier 1 FOCUS Ground Water Assessments, version 2.2, 66 pp.

OECD, 2000. Guideline 106, OECD Guideline for the Testing of Chemicals, Adsorption/Desorption, January 2000.