

STATEMENT OF THE AMERICAN CHEMISTRY COUNCIL
BEFORE THE CHARTERED SCIENCE ADVISORY BOARD
ON MAXIMUM CONTAMINANT LEVEL GOALS FOR PERFLUOROOCTANOIC ACID
AND PERFLUOROOCTANE SULFONIC ACID

JULY 18, 2022

GOOD AFTERNOON. I AM STEVE RISOTTO AND I AM A SENIOR DIRECTOR AT THE AMERICAN CHEMISTRY COUNCIL. THANK YOU FOR THE OPPORTUNITY TO PROVIDE BRIEF COMMENTS. ACC SUPPORTS THE DEVELOPMENT OF NATIONAL DRINKING WATER STANDARDS FOR PFOA AND PFOS. WE ARE DEEPLY CONCERNED ABOUT EPA'S DRAFT APPROACH TO DEVELOPING MCL GOALS FOR THESE TWO SUBSTANCES, HOWEVER, AND ABOUT THE AGENCY'S DECISION TO ANNOUNCE THE DRAFT GOALS AS INTERIM LIFETIME HEALTH ADVISORIES PRIOR TO THE COMPLETION OF THE BOARD'S REVIEW.

OUR CONCERNS ARE BASED ON TWO MAIN ISSUES -

- THE DATA FROM THE FAROE ISLANDS ARE NOT AN APPROPRIATE BASIS FOR HUMAN HEALTH RISK ASSESSMENT FOR EITHER PFOA OR PFOS, AND
- IF THE AGENCY'S CONCLUSION IS THAT PFOA IS A "LIKELY" CARCINOGEN, THEN THE MCL GOAL SHOULD BE SET AT ZERO (0) – CONSISTENT WITH EPA'S LONG-STANDING POLICY.

THE EPIDEMIOLOGY DATA DO NOT PROVIDE CLEAR EVIDENCE OF AN ASSOCIATION WITH REDUCED VACCINE RESPONSE IN CHILDREN. THE RESEARCHERS OBSERVED AN ASSOCIATION BETWEEN MATERNAL SERUM CONCENTRATIONS AND ANTIBODIES IN ONLY ONE OF TWO COHORTS OF CHILDREN INVESTIGATED - A COHORT WITH LOWER SERUM CONCENTRATIONS OF THE TWO SUBSTANCES.

MOREOVER, THE EVIDENCE FOR AN INCREASE IN INFECTION RATES AMONG CHILDREN IS CONFLICTING. CONTRARY TO EPA'S ANALYSIS, THE NATIONAL TOXICOLOGY PROGRAM CONCLUDED THAT THERE IS LOW CONFIDENCE THAT EXPOSURE TO EITHER PFOA OR PFOS IS ASSOCIATED WITH AN INCREASED INCIDENCE OF INFECTIOUS DISEASE OR A LOWER ABILITY TO RESPOND TO INFECTIOUS DISEASE.

FINALLY, EPA DID NOT CONDUCT ITS OWN BENCHMARK DOSE ANALYSIS OF THE VACCINE RESPONSE DATA. THE DETAILED OUTPUT FROM THE 2018 MODEL THAT IS THE BASIS OF THE AGENCY'S

CONCLUSIONS HAS NOT BEEN MADE AVAILABLE TO STAKEHOLDERS. THE VALUES SELECTED BY EPA FOR ITS ASSESSMENTS COME FROM THE EARLIER COHORT OF CHILDREN FOR WHICH AN ASSOCIATION WAS NOT STATISTICALLY SIGNIFICANT WHEN APPROPRIATE CONFOUNDING FACTORS WERE CONSIDERED. ALTHOUGH THE MODELERS REPORT EVIDENCE OF A SIGNIFICANT ASSOCIATION AFTER COMBINING THIS COHORT WITH THE LATER GROUP, CONFLICTING FINDINGS BETWEEN THE TWO GROUPS RAISE CONCERN ABOUT THE VALIDITY OF THE JOINT ANALYSIS.

THE PFAS PANEL HAS RECOMMENDED THAT EPA LOOK AT OTHER NON-CANCER HEALTH ENDPOINTS AS PART OF ITS ASSESSMENT — INCLUDING FETAL GROWTH AND SERUM LIPIDS. THE AVAILABLE EPI STUDIES OF REDUCED BIRTH WEIGHT ARE CONFLICTING HOWEVER — WITH TWO OF THE FIVE STUDIES REPORTING NO SIGNIFICANT ASSOCIATION. ALTHOUGH THERE IS SOME EVIDENCE FOR AN ASSOCIATION WITH A MODEST INCREASE IN SERUM LIPIDS IN HUMANS, MOREOVER, THE INCREASE DOES NOT CORRELATE WITH INCREASED CARDIOVASCULAR DISEASE. ACCORDINGLY, THE C8 SCIENCE PANEL FOUND NO EVIDENCE OF A LINK WITH DISEASE.

SIMILARLY, THE STUDY SUGGESTING AN ASSOCIATION BETWEEN RENAL CELL CARCINOMA AND PFOA EXPOSURE IS LIMITED IN SIZE AND DOES NOT SHOW A CLEAR DOSE-RESPONSE IN THE QUARTILE ANALYSIS. ALTHOUGH THE RESEARCHERS REPORTED A POSITIVE TREND WHEN CONSIDERING CONTINUOUS EXPOSURES, THERE IS NEED FOR ADDITIONAL SENSITIVITY ANALYSIS TO EVALUATE THE SIGNIFICANCE OF THE FINDING. THE LACK OF A CLEAR RESPONSE IN OTHER EPI STUDIES AND THE ABSENCE OF SUPPORTING BIOASSAY DATA UNDERMINES THE RELEVANCE OF THE RENAL CELL FINDINGS.

HOWEVER, IF EPA CONCLUDES THAT PFOA IS A “LIKELY” CARCINOGEN UNDER ITS 2005 CANCER GUIDELINES, THE MCL GOAL SHOULD BE SET AT ZERO. THIS IS CONSISTENT WITH THE AGENCY’S PRACTICE FOR OTHER SUBSTANCES CONSIDERED TO BE POSSIBLE CARCINOGENS. WHILE IT HAS BEEN SOME TIME SINCE EPA HAS ESTABLISHED AN MCL GOAL THE AGENCY HAS GIVEN NO INDICATION OF ITS PLAN TO CHANGE THIS APPROACH. THE MCL GOAL IS CONSIDERED AN ASPIRATIONAL ONE. SETTING THE GOAL AT ZERO WILL HELP ALLEVIATE THE COMMUNICATIONS NIGHTMARE THAT THE AGENCY HAS CREATED WITH ITS RECENTLY ANNOUNCED INTERIM HEALTH ADVISORIES — WHILE BEING NO LESS PROTECTIVE.

THANK YOU FOR YOUR ATTENTION.