

food ingredients after the MOU with AAFCO expires on October 1, 2024, and while FDA evaluates the animal Food Additive Petition and GRAS Notification programs. In addition, this draft guidance describes FDA's enforcement policy for certain ingredients reviewed using the AFIC process.

The Food, Drug, and Cosmetic Act (FD&C Act) gives FDA the authority to regulate substances used in animal food, including substances that are food additives and substances that are GRAS for their intended uses in food.¹

Since 1920, AAFCO has maintained the AAFCO Official Publication (OP), which contains, among other things, a comprehensive list of animal food ingredients, including FDA-approved food additives, substances that are GRAS for one or more intended uses, and animal food ingredient definitions established through the AAFCO Ingredient Definition Request Process. In 2007, FDA entered into an MOU, 225-07-7001, with AAFCO that outlines how FDA would provide its scientific and technical expertise to AAFCO in reviewing requested ingredient definitions requested by industry or AAFCO. This MOU has been renewed and revised several times. The current MOU 225-07-7001 expires in October 2024 and will not be renewed. See <https://www.fda.gov/animal-veterinary/animal-food-feeds/fda-letter-stakeholders-acknowledgment-expiring-fda-aafer-mou>.

Following the expiration of the MOU, FDA plans to evaluate its animal Food Additive Petition and GRAS Notification programs to determine if changes are needed to promote the efficient development and review of new animal food ingredients.

We are issuing this draft guidance to announce the creation of the AFIC process to provide an additional way for engagement with FDA regarding animal food ingredients following the expiration of the MOU with AAFCO and during this interim evaluation period. AFIC will provide a process that will help FDA be aware of new ingredients that are marketed in interstate commerce and any potential safety concerns associated with such ingredients. AFIC will serve to provide a baseline of safety information available about such an ingredient, making it easier to compare developments that might occur during marketing. AFIC also will give FDA an opportunity to discuss any potential safety concerns with the developer,

ideally before the ingredient is marketed.

AFIC also will allow for public awareness of and input on ingredients for which FDA is providing consultation. Our goal is to support innovation in animal food technologies while maintaining as our priority the production of safe animal food.

FDA generally does not intend to initiate enforcement action with respect to the food additive approval requirements of the FD&C Act for an ingredient, or animal food containing such ingredient, if such an ingredient has been reviewed and is the subject of a "consultation complete" letter under the AFIC process, and is used in accordance with the "consultation complete" letter, as long as there continues to be no questions or concerns about the safety of the ingredient.

Elsewhere in this issue of the **Federal Register**, we are publishing a notice of availability for a draft guidance #293, "FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients." This draft guidance communicates FDA's enforcement policy regarding certain ingredients listed in chapter 6 of the 2024 AAFCO OP (or recommended by FDA for inclusion in the AAFCO OP) after the expiration of the Agency's MOU with AAFCO.

Elsewhere in this issue of the **Federal Register**, we also are publishing a notice seeking stakeholder input regarding our current Food Additive Petition and GRAS Notification review processes for animal food ingredients. Additionally, we intend to hold listening sessions and will later provide scheduling information for those listening sessions.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Animal Food Ingredient Consultation (AFIC)." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521), as at this time we believe that fewer than 10 persons will avail themselves of this process in any given year. The draft guidance does refer to previously approved FDA collections of

information. The collections of information in 21 CFR 570 have been approved under 0910-0342; the collections of information in 21 CFR 571 have been approved under 0910-0546.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: August 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award; Infant-Toddler Court Program—National Resource Center

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental award.

SUMMARY: HRSA is providing up to \$1,750,000 in supplemental award funds in federal fiscal year (FY) 2024 to the current recipient of the Infant-Toddler Court Program (ITCP)—National Resource Center (NRC) award, to expand activities to help lead nationwide improvements to child welfare and early childhood systems.

FOR FURTHER INFORMATION CONTACT: Kateryna Zoubak, Early Childhood Systems Analyst, Division of Home Visiting and Early Childhood Systems, Maternal and Child Health Bureau, HRSA, at ezoubak@hrsa.gov or 240-475-8014.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: ZERO TO THREE National Center for Infant, Toddler and Families, Inc.

Amount of Non-Competitive Award(s): One award of up to \$1,750,000.

Project Period: September 30, 2022, to September 29, 2027.

Assistance Listing (CFDA) Number: 93.110.

Award Instrument: Non-competitive supplemental funding to the existing Cooperative Agreement.

Authority: 42 U.S.C. 701(a)(2) (title V, sec. 501(a)(2) of the Social Security Act)

¹ See 21 CFR part 570, subpart E.

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant number	Award recipient name	City, state	Award amount
U2DMC32394	ZERO TO THREE National Center for Infant, Toddler and Families, Inc.	Washington, DC	Up to \$1,750,000.

Justification: The FY 2023 and 2024 appropriations for Maternal and Child Health Block Grant Special Projects of Regional and National Significance increased funding for the ITCP, compared to the FY 2022 enacted level when the most recent new awards were made. A Congressional Report accompanying the Further Consolidated Appropriations Act, 2024 (Pub. L. 118–47) indicated the funding would “continue and expand research-based Infant-Toddler Court Teams to change child welfare practices to improve well-being for infants, toddlers, and their families” (Senate Report 118–84). Consistent with this language, HRSA plans to use this funding to continue work initiated in FY 2023 by the ITCP NRC to expand subawards and technical assistance to ITCP teams and advance reach and impact of the program. Activities included financial and technical support for infant-toddler court sites that previously received funding under announcement number HRSA–18–123, but that do not currently receive HRSA funding under announcement number HRSA–22–073/074.

The planned supplemental award to the ITCP NRC will be used for project activities within the scope of the most recent funding opportunity (HRSA–22–

074), to continue and expand current technical assistance, evaluation and evidence-building activities, and implementation support to local ITCP sites. Supplemental funding for similar activities may be considered in future years, subject to the availability of funding for the activity and satisfactory performance.

Carole Johnson,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award; Early Childhood Developmental Health Systems Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental award.

SUMMARY: HRSA is providing supplemental award funds in federal fiscal year (FY) 2024 to the current recipient of the Early Childhood Developmental Health Systems Program

(ECDHS) cooperative agreement (HRSA–22–091), to support existing activities relating to early childhood developmental health services.

FOR FURTHER INFORMATION CONTACT: Lynlee Tanner Stapleton, Ph.D.; Lead Public Health Analyst, Division of Home Visiting and Early Childhood Systems, Maternal and Child Health Bureau. Telephone: (301) 443–5764; Email: *lstapleton@hrsa.gov*.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: ZERO TO THREE National Center for Infant, Toddler and Families, Inc.

Amount of Non-Competitive Award: One combined award of up to \$1,000,000 (consisting of a \$600,000 supplement and a \$400,000 supplement).

Supplement Project Period: September 30, 2024, to September 29, 2025.

Assistance Listing (CFDA) Numbers: 93.110/93.129.

Award Instrument: Non-competitive supplemental funding to the existing Cooperative Agreement.

Authorities: Social Security Act, section 501(a)(2) (42 U.S.C. 701(a)(2)) supplement part A; and Public Health Service Act section 330(l) (42 U.S.C. 254b(l)) supplement part B.

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant number	Award recipient name	City, state	FY23 supplement award amount
UK2MC46349	Zero to Three National Center for Infant, Toddler, and Families, Inc..	Washington, DC	\$1,000,000

Justification: The Consolidated Appropriations Act, 2023 (Pub. L. 117–328) and the Further Consolidated Appropriations Act, 2024 (Pub. L. 118–47) made available additional funding beyond the original FY 2022 enacted level to “expand placements of early childhood development experts in pediatrician offices with a high percentage of Medicaid and Children’s Health Insurance Program patients” (per Senate Report 118–84). To implement this increase, HRSA funds an additional four Transforming Pediatrics for Early Childhood (TPEC) recipients beyond the original four (for a total of eight) and will continue to provide a supplement

of \$600,000 to the current ECDHS recipient to provide technical assistance to these additional TPEC recipients and support national ECD integration in pediatric care.

The Further Consolidated Appropriations Act, 2024, also provided funding to HRSA’s Bureau of Primary Health Care to support health centers, including “to further integrate early childhood development services and expertise” (as described in Senate Report 118–84). To implement this funding, HRSA will provide an additional supplement of \$400,000 to the ECDHS recipient to continue their current technical assistance support,

which began in FY 2023, to HRSA funded Health Centers expanding their early childhood development services with funds awarded under HRSA–23–028.

Supplemental funding for similar activities may be considered in future years, depending on the availability of funding for the activity and satisfactory performance.

Carole Johnson,
Administrator.

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